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PharmGenEd™: Bridging the Gap Between Science & Practice

Train-the-Trainer Session

for Cardiology II: Clopidogrel and Beta Blockers

Thursday, September 23, 2010

UNIVERSITY of CALIFORNIA, SAN DIEGO
SKAGGS SCHOOL of PHARMACY and PHARMACEUTICAL SCIENCES

Disclaimer

This presentation was supported by Grant Number IU38GD000070 from Centers for Disease Control and Prevention (CDC). Its contents are solely the responsibility of the authors and do not necessarily represent the official views of CDC.

The content is not intended to be a substitute for professional medical advice, diagnosis, or treatment. Patients should seek the advice of their physicians, pharmacists, or other qualified health providers with any questions they may have regarding a medical condition or a medication.

Train-the-Trainer Agenda

1. Introduction
   - Objective of PharmGenEd™ program
   - Shared curriculum and format
   - Introduction of author
2. Review of educational content for selected therapeutic area
3. Future webinar dates
   - Program implementation
   - Other therapeutic areas
4. Contact information
5. Survey instruments
   - Post training survey for trainers
6. Question & Answer (Q & A) session

Overall Objective of PharmGenEd™ Program

- The "Pharmacogenomics Education Program: Bridging the Gap between Science and Practice" (PharmGenEd™) is an evidence-based pharmacogenomics education program designed for pharmacists and physicians, pharmacy and medical students, and other healthcare professionals.
- The overall objective of the PharmGenEd™ program is to increase awareness about current knowledge of the validity and utility of pharmacogenomic tests and the potential implications of benefits and harms from use of the tests.

Shared Curriculum

- Educational Materials (each 1 hour)
  - Asthma
  - Cardiology I (warfarin & statins)
  - Cardiology II (clopidogrel & beta blockers)
  - Concepts and clinical applications
  - Economic issues
  - Oncology I (solid tumors)
  - Oncology II (hematologic malignancies)
  - Psychiatry I (depression)
  - Psychiatry II (antipsychotics)
- Future webinar dates for these sessions will be provided later

Therapeutic Area Discussion

- Format
  - Patient case
  - Gene/Allele of interest
  - Functional effect
  - Population prevalence
  - Clinical relevance (dosing/selection, efficacy, and toxicity)
  - Genomic test and testing recommendation
  - Patient case summary

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Learning Objectives

- Upon completion of this program, participants will be able to:
  - Identify specific drug therapies used in which pharmacogenomic testing can be applied in the clinical setting
  - Summarize evidence-based recommendations for pharmacogenomic testing
  - Using patient case scenarios, formulate a plan for pharmacogenomics testing based upon available scientific evidence

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Outline

- Clopidogrel pharmacogenomics
  - *CYP2C19* genotype description
  - *CYP2C19* gene associations with clopidogrel response
  - Clinical applications
- Beta-blocker pharmacogenomics
  - *ADRB1* and *ADRB2* genotype descriptions
  - Genetic association with beta-blocker response
  - Clinical applications

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Clopidogrel Pharmacogenomics

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Patient Case 1

- JM is a 55-year old Caucasian male with hypertension and dyslipidemia who suffers a non-ST-elevation myocardial infarction
- He undergoes percutaneous coronary intervention (PCI) with placement of 2 drug-eluting stents
  - Weight: 80 kg
  - Allergies: NKDA
  - Genotype: *CYP2C19**2/*2

Momary et al 2010

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Patient Case 1 (continued)

- He started clopidogrel 300mg loading dose, followed by 75mg maintenance dose
- Question: Based on JM's genotype, is it appropriate to start clopidogrel? If not, what is the alternative therapy?

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Clopidogrel Pharmacogenomics: Clinical Relevance

- Clopidogrel background
  - Thienopyridine that inhibits the P2Y12 receptor
  - Improves outcomes in acute coronary syndromes and percutaneous coronary intervention (Yusuf et al 2001, Patrono et al 2008).
  - Reduces risk for stent thrombosis (Steinhubl et al 2002).
  - Approximately 25% of patients are non-responders to clopidogrel (Combescure et al 2010).
  - Variability is largely attributed to differences in clopidogrel pharmacokinetics

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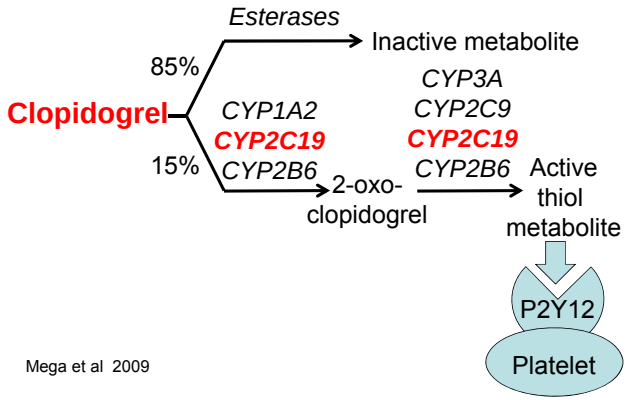
Clopidogrel Pharmacogenomics: Clinical Relevance



Mega et al 2009

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Clopidogrel Pharmacogenomics

- At least 25 *CYP2C19* polymorphic variants have been identified
- Gene/Alleles: *CYP2C19**1, *2, *3, *4, *5, *17
- Functional Effect:

Allele	Nucleotide Change	Type of Variant	CYP2C19 Function
*1	N/A	N//A	Normal function
*2	681G>A	Splicing defect	Loss of function
*3	636G>A	Stop codon	Loss of function
*4	1A>G	Exon SNP	Loss of function
*5	1297C>T	Exon SNP	Loss of function
*17	-808C>T	Promoter SNP	Gain of function

Momary 2010

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Clopidogrel Pharmacogenomics

- Functional Effect (Cont):
  - *CYP2C19* alleles confer the following phenotypes:

CYP2C19 alleles	Phenotype
2 loss-of-function alleles	**PM** - Poor Metabolizer
1 loss-of-function allele	**IM** - Intermediate Metabolizer
No variant allele	**EM** - Extensive Metabolizer
One or two *17 allele(s)	**UM** - Ultrarapid Metabolizer

Furuta et al 2007, Sim et al 2006

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Clopidogrel Pharmacogenomics

- Population Prevalence
  - Genotype / phenotype prevalence

Race	*2, *3, *4, *5 homozygotes (PMs)	*2, *3, *4, *5 heterozygotes (IMs)	*17 carriers (UMs)
Caucasian	2%	25%	40%
African American	4%	30%	45%
Asian	14%	50%	<5%

Momary et al 2010, Sibbing et al 2010, http://www.ncbi.nlm.nih.gov/snp

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Clopidogrel Pharmacogenomics: Clinical Relevance

- Dosing/Selection
  - CYP2C19 PMs and IMs may need higher clopidogrel doses than EMs or alternative therapy.
  - CYP2C19 UMs may require lower clopidogrel doses than EMs.
- Efficacy
  - Meta-analysis of 9684 patients with ACS examined for risk for major adverse cardiovascular events (MACE) with loss-of-function alleles (Mega et al 2009).

Groups	Risk ratio (95% CI) for MACE
PMs vs EMs	1.8 (1.2-2.7)
IMs vs EMs	1.5 (1.1-2.1)
PMs or IMs vs EMs	1.6 (1.3-2.0)

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Clopidogrel Pharmacogenomics: Clinical Relevance

- Efficacy (Cont.)
  - Meta-analysis of 5772 patients examined risk for stent thrombosis with loss-of-function alleles (Mega et al 2009)

Groups	Risk ratio (95% CI) for stent thrombosis
PMs vs EMs	4.8 (2.0-11.4)
IMs vs EMs	2.5 (1.6-4.0)
PMs or IMs vs EMs	2.8 (1.8-4.3)

  - Recent trial showed no reduced clopidogrel efficacy with a *2 or *3 allele and improved efficacy with the *17 allele, but was largely limited to patients with ACS or atrial fibrillation who were managed medically (Pare et al 2009).

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Clopidogrel Pharmacogenomics: Clinical Relevance

- Toxicity
  - *17 allele associated with an increased risk for bleeding with clopidogrel in patients with coronary artery stent placement (Sibbing et al 2010).
    - Risk highest with *17/*17 genotype
    - Risk ~4-fold higher with *17/*17 genotype compared to the wild-type genotype
  - No association between *17 allele and stent thrombosis

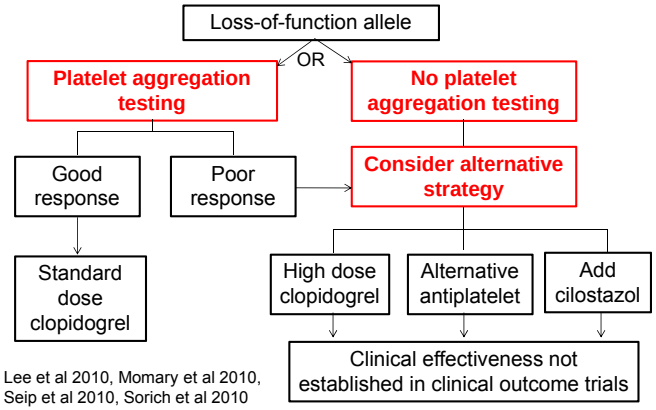
Clopidogrel Pharmacogenomics

- Genetic Testing
  - FDA-approved AmpliChip CYP450 test available
  - Commercial diagnostic companies also offer testing
  - Positive testing for loss-of-function allele confers:
    - Reduced CYP2C19-mediated conversion of clopidogrel to its active metabolite (Mega et al 2009).
    - Less inhibition of platelet aggregation with clopidogrel (Mega et al 2009).
  - Positive testing for *17 allele confers:
    - Greater platelet response to clopidogrel (Sibbing et al 2010).

Clopidogrel Pharmacogenomics: Clinical Relevance

- Pharmacogenomic Test Recommendations
  - Boxed warning in prescribing information (Plavix Prescribing Information. Revised March 2010).
    - Warns of reduced effectiveness in CYP2C19 PMs.
    - States that genetic testing is available.
    - Advises consideration of alternative treatment strategies in PMs.
    - Does not recommend specific strategies for PMs or include recommendations for IMs or UMs.
  - Testing is not mandated.

Clopidogrel Pharmacogenomics: Clinical Relevance



Lee et al 2010, Momary et al 2010, Seip et al 2010, Sorich et al 2010

Clopidogrel Pharmacogenomics: Clinical Relevance

- Alternative Strategy: Substitute Prasugrel
  - Provides greater protection against cardiovascular events, but increases bleeding risk compared to clopidogrel (Wiviott et al 2007).
  - Like clopidogrel, undergoes biotransformation to an active metabolite:

  - Efficacy is not affected by *CYP2C19* genotype (Mega et al 2009).

Clopidogrel Pharmacogenomics: Clinical Relevance

- Alternative Strategy: Add Cilostazol
  - Phosphodiesterase III inhibitor with antiproliferative effects
  - Clopidogrel + aspirin + cilostazol prevents restenosis and target vessel revascularization after stent placement compared to clopidogrel + aspirin but leads to increased bleeding risk (Lee et al 2010).
  - Not specifically studied in patients with *CYP2C19* variant alleles.
  - Most data with triple antiplatelet therapy are in Asians, who have a greater prevalence of the *CYP2C19* loss-of-function alleles.

Clopidogrel Pharmacogenomics: Summary

- Genetic polymorphisms in *CYP2C19* have been associated with inter-individual variability antiplatelet response, clinical outcomes, and bleeding risk with clopidogrel.
- Clopidogrel labeling now contains a boxed warning regarding reduced effectiveness in *CYP2C19* PMs.
- Optimal strategies for *CYP2C19* PMs, IMs or Ums, based on *CYP2C19* genotype, have not yet been established.

Case 1 Summary

- JM has the *CYP2C19* genotype associated with the poor metabolizer (PM) phenotype.
- Clopidogrel is less protective against adverse cardiovascular events and stent thrombosis in PMs.
- Possible Treatment options
  - Substitute another antiplatelet drug (e.g. prasugrel) for clopidogrel.
  - Use a higher dose of clopidogrel (e.g. 150 mg /day)
  - Add cilastazol.
- JM should be monitored closely for bleeding.

Momary et al 2010

Beta Blocker Pharmacogenomics

Patient Case

- CP is a 57-year old non-Hispanic Caucasian man with HTN diagnosed 3 months ago who comes to your clinic for follow up.
  - PMH: hyperlipidemia
  - CP has changed his lifestyle (diet, exercise etc)
  - Vitals: BP 150/87, HR 86
  - Current medications: simvastatin 20 mg po daily
  - **Genotypes: *ADRB1* Ser49Ser/Arg389Arg**

Question: Is CP a good candidate for beta blocker therapy?

Beta Blockers: Background

- A widely used drug class
- Antagonize β receptor
- Common Indications
  - Hypertension (HTN)
  - Heart failure (HF)
  - Post acute coronary syndrome (ACS)
- 30-60% of HTN patients treated with a beta blocker fail to achieve adequate blood pressure control

Materson et al 1993, Veterans Administration Cooperative Study Group on Antihypertensive Agents 1982

Beta Blockers: *ADRB1*

- **Gene/Alleles:** *ADRB1*
  - Non-synonymous polymorphisms in *ADRB1*
  - Ser49Gly (serine to glycine change at position 49)
  - Gly389Arg (glycine to arginine change at position 389)
- **Functional Effect:**
  - Gly49 allele has a lower number of β1 receptor after exposure to an agonist
  - Ser49 allele may improve β-blocker response
  - Arg389 allele has higher β1activity and may improve β-blocker response

Mason et al 1999, Rathz et al 2002

Beta Blockers: *ADRB1*

- **Population prevalence (%):**

Allele	Caucasians	African Americans	Asians
Gly49	23-29	40-48	26
Arg389	88-94	79-85	91-96

http://www.ncbi.nlm.nih.gov/snp

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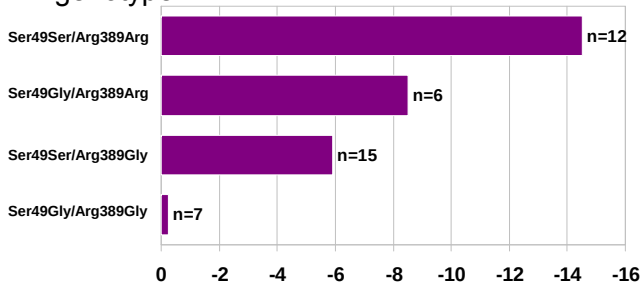
Beta Blockers: *ADRB1*

- **Clinical Relevance: Efficacy**
- Hypertension: Change in DBP by ADBR1 genotype



Adapted from (Johnson et al 2003)
Liu et al 2006

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Beta Blockers: *ADRB1*

- **Clinical Relevance: Efficacy**
- Hypertension and coronary artery disease
  - The INVEST trial compared cardiovascular outcomes in HTN patients with CAD who received either atenolol-based or verapamil-based treatments.
  - In a genetic substudy, Ser49Arg389 haplotype increases mortality risk in the study population
  - However, the risk was not statistically significant in patients who received atenolol-based treatment while it was significant in patient who received verapamil-based treatment.

Pepine et al. 2003, Pacanowski et al. 2008

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Beta Blockers: *ADRB1*

- **Clinical Relevance: Efficacy**
- Heart failure
  - Patients with the Arg389Arg genotype tolerated metoprolol initiation better than those who carried a Gly389 allele.
  - Patients with the Arg389Arg genotype had a greater increase in left ventricular ejection fraction with metoprolol
  - Bucindolol reduced the incidence of death and hospitalization in patients with the Arg389Arg genotype while placebo did not.

Terra et al 2005, Liggett et al 2006, Terra et al 2005

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Beta Blockers: *ADRB1*

- **Clinical Relevance: Toxicity**
  - No literature related to pharmacogenomics impacting drug toxicity
- **Clinical Relevance: Selection/Dosing**
  - No literature related to pharmacogenomics impacting drug selection/dosing
  - Beta blockers may be a better choice to reduce BP for Caucasians and Asians than for African Americans

Beitelshees et al 2006

Beta Blockers: *ADRB1*

- **Pharmacogenomic Testing and Test Recommendations**
  - FDA-cleared *ADBR1* genetic test unavailable
  - The FDA and health professional organizations do not recommend for or against beta blocker genetic testing

Beta Blockers: *ADRB2*

- **Gene/Alleles:** *ADRB2*
  - 2 common non-synonymous polymorphisms
  - Arg16Gly - Gln27Glu
- **Functional Effect**
  - Arg16Gly: conflicting data
  - Glu27 has a greater agonist-mediated receptor down-regulation

Green et al 1994

Beta Blockers: *ADRB2*

- **Population prevalence (%):**

Allele	Caucasians	African Americans	Asians
Gly16	84-90	76	74
Glu27	44	34	17

http://www.ncbi.nlm.nih.gov/snp

Shin et al 2007

Beta Blockers: *ADRB2*

- **Clinical Relevance: Efficacy**
- Acute coronary syndrome (ACS)
- In a prospective cohort of 735 patients
  - The Gln27Gln genotype had a higher mortality rate than Glu27 carriers
  - The Arg16Arg/Gln27Gln genotype had the highest mortality rate

Lanfear et al 2005

Beta Blockers: *ADRB2*

- **Clinical Relevance: Toxicity**
  - No literature related to pharmacogenomics impacting drug toxicity was found
- **Clinical Relevance: Selection/Dosing**
  - No literature related to pharmacogenomics impacting drug selection/dosing was found

Beta Blockers: *ADRB2*

- **Pharmacogenomic Testing and Test Recommendations**
  - FDA-cleared *ADBR2* genetic test unavailable
  - The FDA and health professional organizations do not recommend for or against beta blocker genetic testing

Patient Case Summary

- CP has the following genotype of *ADRB1 Ser49Ser/Arg389Arg*.
  - This genotype has been associated with a better blood pressure response to a beta blocker.
  - CP does not have a contraindication to a beta blocker therapy.
  - CP is a good candidate for beta blocker therapy.
- The *ADRB2* polymorphisms have not been consistently associated with BP responses to a beta blocker.

Beta Blockers: Summary

- *ADRB1* polymorphisms may influence efficacy of a beta blocker in hypertension and heart failure.
  - Their roles in toxicity and dosing/selection of a beta blocker is currently unclear
- *ADRB2* polymorphisms may influence efficacy of a beta blocker in post-acute coronary syndrome.
  - Their roles in toxicity and dosing/selection of a beta blocker is currently unclear

Beta Blockers: Summary

- Beta blocker pharmacogenetic testing for *ADRB1* and *ADRB2* are currently unavailable for clinical application.

Acknowledgements

- **Author**
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The program is 100% funded by the CDC
(*Grant Number IU38GD000070*)

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END OF CONTENT SECTION

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  - Ashley To, BA

The program is 100% funded by the CDC
(*Grant Number IU38GD000070*)

Future Webinar Dates
(all times are PST)

- **Oncology II: Hematologic Malignancies**
  - Tuesday, Aug. 10, 2010 10am-12pm – COMPLETED
- **Concepts and Clinical Applications**
  - Wednesday, August 11, 2010 – COMPLETED
- **Psychiatry II: Antipsychotics**
  - Tuesday, Aug. 24, 2010 10am – 12pm – COMPLETED
- **Oncology I: Solid Tumors**
  - Thursday, Aug. 26, 2010 10 am – 12 pm – COMPLETED
- **Cardiology I: Warfarin and Statins**
  - Tuesday, Sept. 21, 2010 10 am –12 pm – COMPLETED
- **Cardiology II: Clopidogrel and Beta Blockers**
  - Thursday, Sept. 23, 2010 10 am – 12 pm
- **Economic Issues**
  - Tuesday, Oct. 12, 2010 9:30 am – 11:30 am

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Future Webinar Dates
(all times are PST)

- **Psychiatry I: Depression**
  - Thursday, Oct. 21, 2010 10 am – 12 pm
- **Asthma**
  - TBD
- **PharmGenEd™ Program Implementation**
  - Thursday, Aug. 12, 2010: 10 am – 12 pm – COMPLETED
  - Thursday, Sept. 9, 2010: 10 am – 12 pm – COMPLETED
- Please register at www.pharmacogenomics.ucsd.edu to download materials prior to the scheduled webinar

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Survey Instruments: Evaluation

- Faculty trainers will complete a Post-Training Survey
  - Evaluate knowledge, attitudes, and self-efficacy
- All survey materials will be mailed after completion of all webinars in October 2010

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Question and Answer Session

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