Evaluation of Inpatient Warfarin Management in a Community Hospital

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The speaker has no conflicts of interest to disclose

St. John's Hospital

- Located in Springfield, IL
- 450 bed hospital
  - Women and Children Center
  - Prairie Heart Diagnostic Center
  - Level 1 Trauma Center
- Teaching hospital
  - Southern Illinois University School of Medicine
  - Southern Illinois University Edwardsville School of Pharmacy
  - St. John's Hospital School of Nursing

Does your institution have an anticoagulation service?

Joint Commission[1]
National Patient Safety Goal

- NPSG 03.05.01 - "Reduce the likelihood of patient harm associated with the use of anticoagulation therapy."
  - Recommend establishing an anticoagulation program
    - Proper dosing
    - Appropriate laboratory monitoring
    - Management of food and drug interactions
    - Patient Education with face-to-face interaction

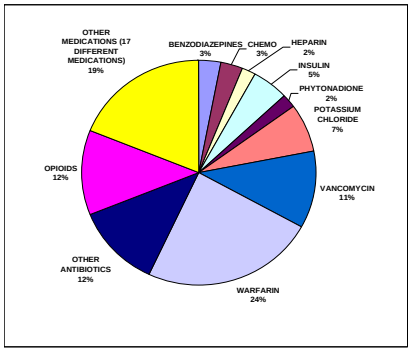
The Warfarin Order Set

- Approved order-set for initiation and maintenance of anticoagulation therapy
  - Require baseline and daily labs
    - Monitor for bleeding
  - Require doses to be written everyday
  - Guidelines for adjusted warfarin dosing based on INR
  - Patient/Caregiver education by nursing
  - Discharge instructions for INR monitoring

Adverse Drug Events

- Web based adverse drug event reporting
  - Increased rate of events over the past quarters
    - Increase in event reporting
      - Paper reporting to electronic reporting
- Number 1 adverse drug event (ADE) reported to the Pharmacy & Therapeutics committee is warfarin complications

2010 Adverse Drug Events



Barriers to the Warfarin Order Set

- Drug Utilization Evaluation (DUE)
  - January - July 2010 - order sets used only 6% overall
  - July - December 2010 - decreased to 3%
- Implement automatic order sets

Primary Goals

1. Evaluate Pharmacist knowledge of warfarin management
   - Warfarin education and competency
2. Evaluate warfarin management
   - Time to therapeutic INR
   - Days of supratherapeutic INR
   - Frequency of bleeding, DVT, PE events
   - Patient education documentation

Methods

Pharmacist Education

- Staff Meeting
- 10 question pre-test
  - Mechanism of action
  - Drug/food interactions
  - Case vignettes
- Re-administration of 10 question pre-test

Example #1

Test Question

- Why is overlapping heparin and warfarin therapy (i.e. "bridge therapy") necessary?
  a. Warfarin has a long half-life
  b. Enoxaparin has a long-half life
  c. LMWH and unfactionated heparin are synergistic with warfarin
  d. Protein C and S

Example #2

Test Question

- Which of the following will interact with warfarin and decrease the INR?
  a. Amiodarone
  b. Allopurinol
  c. Rifampin
  d. Fluconazole

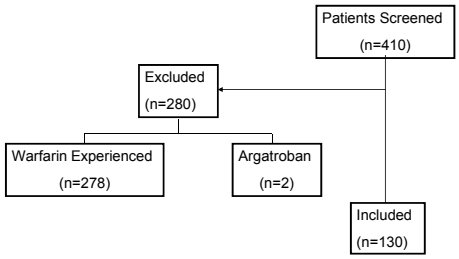
Pharmacist Education

- Scores (n = 26)
  - Pre-test average score = 59.6%
  - Post-test average score = 91.9%

Evaluation of Warfarin Management

- 2 month retrospective review
  - January - February 2010
- Inclusion Criteria
  - Warfarin naïve patients
  - Patients >18 years of age
- Exclusion Criteria
  - INR >1.3
  - Concomitant argatroban therapy
  - Warfarin usage prior to admission

Results



Methods

Data Collection

- Initial warfarin dose
- Number of days to therapeutic INR
- Number of days of supratherapeutic INR
- Vitamin K administered
- Bleeding/DVT/PE event
- Patient education documented
- 30 day re-admission

Baseline Characteristics

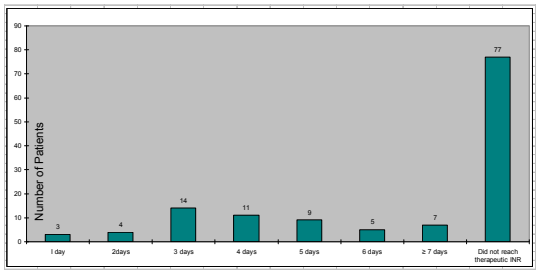
- Number of charts reviewed – 410
- Number of charts included – 130
- Patient characteristics
  - 54% male, 46% female
  - Average age 66.2 years old
  - Average LOS was 11.1 days

Demographics

Indication	Warfarin Naïve Patients (n=130)
Afib/Aflutter	38 (29%)
TKA	21 (16.1%)
DVT	17 (13%)
PE	15 (11.5%)
AVR	13 (10.7%)
Total Hip Arthroplasty	10 (7.6%)
MVR	5 (3.8%)
Other	11 (8.3%)

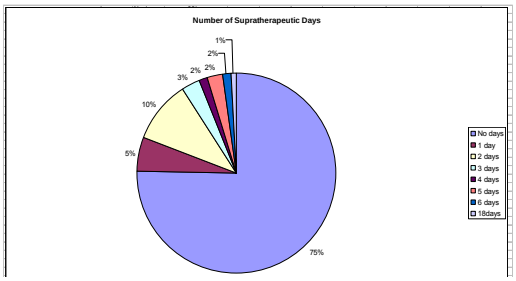
Results

Time to Therapeutic INR



Time (days)

Days of Supratherapeutic INR



* Supratherapeutic INR defined as > 3

Vitamin K Administration

Dose	Route	Frequency
10 mg	PO	X2 at 10:00 and 18:00
10 mg	PO	X2 at 10:00 and 18:00
20mg	Subcutaneously	Once
2 mg	IM	Once
10mg 10mg	IVP IVPB	Day 1 Day 2: x2 doses Q4H
3 mg	Subcutaneously	Once
5mg	IVP	X 2
10mg 10mg	Subcutaneously Subcutaneously	Day1 Day2
2mg 1.25mg	IVP PO	Once Once
2.5 mg	IVP	Once
5mg	PO	Once

Documentation of Patient Education

- According to the documentation
  - 44.6% of patients educated
  - 55.4% of patients not educated

Adverse Drug Events

Bleeding/DVT/PE

- Bleeding = 10%
  - Post-op anemia
  - Decrease in Hgb
- DVT, PE and Stroke
  - None reported

Secondary Endpoints

- No education and 30 day re-admission
  - Chi Squared test
  - P-value = 0.51
- Loading doses >5 mg and Vit K administration
  - Chi Squared test
  - P-value = 0.78

Conclusions

- Most patients didn't reach therapeutic INR while inpatient
- Vitamin K doses, routes, and frequencies were inconsistent
- Patient education is lacking
- Adverse drug events were low
- Pharmacist knowledge improved due to competency

Grant Application

- Pharmacist-driven anticoagulation service
- 0.5 FTE in the first year
- Goals
  - Increase patient safety
  - Decrease LOS[2]
  - Decrease cost[2]
  - Enhance NPSG compliance[1]
  - Increase patient education

References

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Questions?

Thank You!

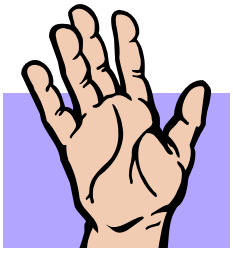
The influence of education and experience in minimizing pharmacist insecurity during a code blue

Kelly Kampschmidt, PharmD

Disclosures

- Dr. Kampschmidt and other investigators have no actual or potential conflicts of interest in relation to this presentation

Audience Participation



Background

- Sudden cardiac arrest
  - Leading cause of death among adults over the age of 40[1]
  - 10% of events occur in people less than 40 years of age[1]
  - 36.1% of events occur in hospital[2]
- Early treatment with CPR, defibrillation, and ACLS are most effective[1]

History

- 1960's
  - Chest compressions first performed[3]
- 1970
  - First report of pharmacists attending codes[3]
- 2007
  - 74% of respondents required pharmacist to attend codes[3]
  - 68% of respondents required pharmacy residents to attend codes[3]
  - 13% of respondents required technicians to attend codes[3]

Pharmacist Role

- Presence of a pharmacist on the resuscitation team was associated with increased compliance with ACLS guidelines[4]
- Most common errors[4]
  - Incorrect drug dose
  - Incorrect defibrillation energy
  - Delay in intervention
  - Omission of indicated treatment
  - Deviation from treatment guidelines

Study Objectives

- Primary objective
  - To determine if comfort at a code is due to knowledge or due to experience
- Secondary objective
  - Comparing comfort level at code blue based on
    - ACLS certification
    - Years working hospital pharmacy

Methods

- Survey tool used to assess baseline comfort and knowledge
- Pharmacist geared education was formulated and delivered to participating pharmacists
- Same survey tool used to assess changes in comfort and knowledge
- Project was approved by the institutional review board

Methods - Survey

- Demographic Information
  - Years working hospital pharmacy
  - ACLS
  - Interest in participating in medical emergencies
    - 4 point scale
      - 1 = very disinterested and 4 = very interested
- Comfort level assessment
  - Are you comfortable attending a code?
  - Are you comfortable performing specific tasks during a code?
    - 4 point scale
      - 1= very uncomfortable and 4= very comfortable

Methods - Survey

- Knowledge Assessment
  - 9 questions
  - Based on the 2010 ACLS guidelines

Inclusion/Exclusion Criteria

- Inclusion Criteria
  - All pharmacists employed by Norton Healthcare working at an adult facility
- Exclusion Criteria
  - Pharmacy administration

Data Analysis

- Primary Objective
  - Influence of Code Experience
    - Baseline surveys
    - Grouped by experience
      - Experience defined as
        - » Attending at least 4 codes in the last 18 months
        - OR
        - » Attending codes continuously in the preceding 5 years
      - Inexperienced did not meet above criteria
    - T-Tests
  - Influence of Pharmacist Geared Education
    - Matched pre and post surveys
    - T-Tests

Data Analysis

- Secondary Objective
  - Influence of ACLS
    - Baseline Surveys
    - T-Tests
  - Influence of Years Working in Hospital Pharmacy
    - Baseline Surveys
    - Correlation

Results – Effect of Code Experience

- Total of 38 out of 60 eligible subjects completed one survey
- 63% response rate

	Inexperience (n= 11)	Experience (n= 27)	P-value
Years licensed pharmacist	17.6	11.7	0.14
Years working hospital pharmacy	14.8	11.8	0.134
BLS certification	54.5% (6/11)	44.4% (12/27)	0.651
ACLS certification	18% (2/11)	33.3% (9/27)	0.331

Results – Effect of Code Experience

How comfortable are you…	Inexperience	Experience	P-value
Attending a code	2.11	3.17	0.0017
Asking what needs to be done	2.09	3.18	0.019
Calculating doses of resuscitation meds	2.45	3.14	0.183
Drawing up resuscitation meds	2.54	3.1	0.057
Anticipating medications that may be ordered	2.18	3.11	0.0248
Performing necessary dilutions	2.3	3.05	0.0715
Accessing the medication tray	2.11	3	0.0004
Labeling medications	2.12	3	0.0035
Communicating with the code recorder	2.14	2.93	0.0005
Providing drug information	2.16	2.92	0.075

Results – Effect of Code Experience

- While not significant, experienced group had fewer years working and a higher percentage with ACLS certification
- Experienced group was more comfortable attending codes
- Experienced group was more comfortable performing specific tasks during a code
  - Asking what needed to be done
  - Anticipating medications that may be ordered
  - Accessing the medication tray
  - Labeling medications
  - Communicating with code recorder

Results – Effect of Pharmacist Education

- Response rate 35%
- 21 Total Matched Respondents
  - 14 Experienced group
  - 7 Inexperienced group
- ACLS certification – 6 respondents
- Years working hospital pharmacy
  - Average 14 years
  - Range 1-42 years
- 1 respondent never attended a code

Results – Effect of Pharmacist Education

- Pre-Test Average: 78.7%
- Post-Test Average: 95.2%
- Specific Areas of Increase
  - First medication used for Vtach/Vfib
    - Pre-Test: 14.5%
    - Post-Test: 85.7%
  - Max dose of atropine
    - Pre-Test: 71.4%
    - Post-Test: 95.2%
  - Drug of choice for treatment of bradycardia
    - Pre-Test: 85%
    - Post-Test: 95.2%

Results – Effect of Pharmacist Education

How comfortable are you…	Pre (n=21)	Post(n=21)	P-value
Attending a code	2.9	2.8	0.213
Asking what needs to be done	2.57	3	0.0125
Calculating doses of resuscitation meds	2.9	3	0.164
Drawing up resuscitation meds	3	3.23	0.0106
Anticipating medications that may be ordered	2.8	2.85	0.332
Performing necessary dilutions	2.95	3.19	0.0282
Accessing the medication tray	3.45	3.47	0.3855
Labeling medications	3.33	3.47	0.1334
Communicating with the code recorder	3.33	3.47	0.1334
Providing drug information	2.85	3	0.1134

Results – Effect of Pharmacist Education

- Comfort level attending codes did not change significantly after participation in pharmacist specific education
- Overall knowledge of code medications increased (78% to 95%)
- Pharmacists were more comfortable performing certain tasks during a code
  - Asking what needed to be done
  - Drawing up medications
  - Performing necessary dilutions

Results – Effect of ACLS

	ACLS (n=11)	No ACLS (n=27)	P-Value
Years licensed pharmacist	7.63	16.27	0.036
Years working hospital pharmacy	7.27	13.69	0.076
Comfortable attending a code?	2.72	2.88	0.63

- Knowledge Assessment
  - ACLS: 83.6%
  - No ACLS: 77.7%

Results – Effect of Years Working

- Average number of years working hospital pharmacy = 12.73 years
- Correlation between years working and comfort at codes = 0.3
- More years working in a hospital does not equate to increased comfort attending codes

Limitations

- Survey tool not validated
- Pharmacists not given dedicated time to complete education
- Response rate low for follow-up survey
- Several practice sites
- Low number of participants may influence study validity
- ACLS guidelines changed during design of study

Conclusions

- Pharmacists with experience attending codes are more comfortable attending codes
- Pharmacist specific code education increases comfort of certain tasks performed during a code
- ACLS certification did not prove to increase comfort level attending codes
- Experience attending codes seems to be a more important factor in reducing pharmacist's insecurities while attending codes

What does this mean?

- To decrease insecurity in attending a code, a pharmacist needs to gain experience attending codes
- New pharmacist orientation should include
  - Hands on experience attending codes
  - Pharmacist specific education about codes as a supplement to experience
- Pharmacists are a vital part of the code team and maximizing comfort in code situations will optimize their contribution

Assessment

Which of the following roles is a pharmacist best qualified to perform during a code?

A. Preparation of medications
B. Perform chest compressions
C. Provide support to family
D. Prepare patient for intubation

Assessment

Which of the following is the best way to minimize pharmacists insecurity while attending codes?

A. ACLS certification
B. Hospital work experience
C. Participating in codes
D. No way to prepare for codes

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1. Sudden Cardiac Arrest: A Health Care Crisis. Sudden Cardiac Arrest Foundation Web Site: http://www.sca-aware.org. Published 2010. Accessed August 19, 2010.
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The influence of education and experience in minimizing pharmacist insecurity during a code blue

Kelly Kampschmidt, PharmD
9/17/11

The Effect of Colestipol on Glycemic Control in Patients with Type 2 Diabetes Mellitus

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- The study investigators have no actual or potential conflicts of interest to disclose in relation to this presentation

Objectives

- Discuss the current literature supporting the use of bile acid sequestrants for added glycemic control in patients with type 2 diabetes mellitus
- Identify whether colestipol demonstrates similar blood glucose lowering effects as colesevelam in patients with type 2 diabetes mellitus

Outline

- Summarize the epidemiology/complications of diabetes and the importance of optimal glycemic control
- Discuss the role of bile acid sequestrants as adjunctive therapy in patients with type 2 diabetes
- Introduce the study rationale, purpose, and methods
- Review study results
- Discuss limitations and conclusions

Type 2 Diabetes Mellitus

- Type 2 diabetes is the most common form of diabetes in the United States, ~90% of all cases
- As of 2007, 23.6 million individuals or 7.8% of the U.S. population had a diagnosis of diabetes

ADA Position Statement. Diabetes Care. 2010; 33: s62-s69.
Cowie CC, et al. Diabetes Care. 2006; 29(6):1263-1268.

Type 2 Diabetes Mellitus

- Complications:
  - Blindness
  - Kidney damage
  - Heart disease
  - Lower-limb amputations

ADA Position Statement. Diabetes Care. 2010; 33: s62-s69.
Cowie CC, et al. Diabetes Care. 2006; 29(6):1263-1268

Type 2 Diabetes Mellitus

- Optimal control of blood glucose and LDL (low-density lipoprotein cholesterol) can delay or prevent complications
- For every percentage point drop in gHbA1c (glycosylated hemoglobin A1c), the risk of microvascular complications is reduced by 40%
- Improved control of LDL can reduce cardiovascular complications by 20-50%

ADA Position Statement. Diabetes Care. 2010; 33: s62-s69.
Cowie CC, et al. Diabetes Care. 2006; 29(6):1263-1268

Type 2 Diabetes Mellitus

- Goals of treatment
  - gHbA1c < 7%
  - Fasting plasma glucose (FPG): 70-130 mg/dL
  - Post-prandial glucose (PPG): <180 mg/dL
  - Blood Pressure < 130/80 mmHg
  - LDL goal < 100 mg/dL
  - Lifestyle modifications

ADA Position Statement. Diabetes Care. 2010; 33: s62-s69.

Type 2 Diabetes Mellitus

- Current oral treatment options
  - Sulfonylureas
  - Biguanides
  - Alpha-glucosidase inhibitors
  - Thiazolidinediones
  - Meglitinides
  - Dipeptidyl peptidase-4 inhibitors
  - Dopamine agonists
  - Bile acid sequestrants (adjunct)
    - Colesevelam (FDA approved)

Bile Acid Sequestrants

- To date, both colesevelam hydrochloride (Welchol®) and cholestyramine (Questran®, Prevalite®) have demonstrated gHbA1c and blood glucose lowering effects
- Colesevelam FDA-approved indications:
  - Adjunct to diet and exercise to reduce elevated LDL in adults with primary hyperlipidemia
  - Adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus

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Bile Acid Sequestrants

- Mechanism of Action (MOA)
  - Bind bile acids in the intestine
  - Prevent reabsorption and ↑ bile acid fecal excretion
  - Stimulates conversion of cholesterol → bile acids
    - ↑ LDL clearance
- Proposed MOA for glycemic control
  - ↓ glucose absorption in GI tract
  - Deactivation of FXR

Brinton EA. Diabetes Obes Metab. 2008;10(11):1004-11.
Staels B. Postgrad Med. 2009;121 (3): 25-30.

GLOWS Trial
(Glucose-LOwering effect of Welchol Study)

- Study design
  - Prospective, randomized, double-blind, placebo-controlled, parallel-group, multicentered trial
- Objective
  - Evaluate effect of colesevelam on glycemic control in subjects with type 2 diabetes mellitus

Zieve FJ, et al. Clin Ther. 2007;29(1):74-83.

GLOWS TRIAL

- Methods - randomization x 12 wks
  - 31 pts → Colesevelam 3.75g/day
  - 34 pts → placebo
  - Continue preexisting antihyperglycemic regimen
- Primary efficacy end point
  - Change in gHbA1c
- Secondary endpoints
  - Fructosamine levels, FPG, PPG
  - Lipid parameters

Zieve FJ, et al. Clin Ther. 2007;29(1):74-83.

- Results:

Parameter	Colesevelam	Placebo
gHbA1c (overall)	**- 0.3% (p=0.007)**	**+ 0.2%**
gHbA1c ≥ 8% (at baseline)	**- 0.7% (p=0.002)**	**+ 0.2%**
Fasting plasma glucose	**- 5.1 mg/dL (p=0.118)**	**+ 2.1 mg/dL**
Post-prandial glucose	**- 17.8 mg/dL (p=0.026)**	**+ 2.7 mg/dL**
LDL	**- 9.6 mg/dL (p=0.007)**	**+ 2.1 mg/dL**
Fructosamine levels	**- 10.9 µmol/L (p=0.011)**	**+ 11.7 µmol/L**

Zieve FJ, et al. Clin Ther. 2007;29(1):74-83.

GLOWS TRIAL

- Conclusion:
  - Colesevelam may be a well-tolerated agent for improving both glycemic & LDL control in type 2 diabetics
- Average gHbA1c reduction
  - 0.3 to 0.7%
- Average LDL reduction
  - 9.6 mg/dL

Zieve FJ, et al. Clin Ther. 2007;29(1):74-83.

CHOLESTYRAMINE STUDY

- Study design
  - Randomized, double-blind, crossover
  - Department of Veterans Affairs
- Objective
  - Assess clinical efficacy & tolerability of cholestyramine therapy in pts with dyslipidemia and type 2 diabetes mellitus

Garg A, Grundy SM. Ann Intern Med. 1994;121(6):416-22.

CHOLESTYRAMINE STUDY

- Methods
  - 21 pts included
    - Baseline assessed
      - Basic metabolic panel, liver function tests (LFTs), gHbA1c, Fasting lipid panel (FLP)
    - Cholestyramine vs placebo
      - 8g po BID x 6 wks (powder packet)
      - Follow-up every 2 weeks
        - Basic metabolic panel, LFTs, gHbA1c, FLP
    - Reassess baseline labs

Garg A, Grundy SM. Ann Intern Med. 1994;121(6):416-22.

CHOLESTYRAMINE STUDY

- Results
  - ↓ LDL 28% (p<0.001) and ↑ Triglycerides (TG) 13.5% (p=0.02) as compared to placebo
  - ↓ mean plasma glucose 13% as compared to placebo (p=0.003)
  - ↓ gHbA1c 0.5% (p= 0.17) as compared to placebo
  - ↑ Alkaline phosphatase (ALP) as compared to placebo (mean values, 78 IU/L vs. 86 IU/L; p=0.02)

Garg A, Grundy SM. Ann Intern Med. 1994;121(6):416-22.

CHOLESTYRAMINE STUDY

- Conclusions:
  - In male patients with type 2 diabetes and elevated LDL cholesterol and normal triglyceride levels, cholestyramine effectively reduced LDL levels and may also improve glycemic control.

COLESTIPOL (COLESTID®)

- FDA indication
  - Adjunctive therapy to diet for the reduction of elevated serum total and LDL in patients with primary hypercholesterolemia
- Dosage
  - 2 to 16 grams/day given once or in divided doses

Micromedex® Healthcare Series Intranet. Thomson Reuters (Healthcare) Inc. Version 5.1.

COLESTIPOL (COLESTID®)

- Administration
  - Patients should take other drugs at least one hour before or four hours after colestipol to minimize possible interference with their absorption
- Adverse Effects
  - Constipation, abdominal discomfort, bloating, flatulence, indigestion, heartburn, diarrhea, nausea, vomiting

COLESTIPOL (COLESTID®)

- Monitoring
  - Fasting lipid panel
  - Liver function tests
  - Triglycerides (contraindicated if >400)
- Therapeutic Effect
  - LDL: ↓15-30%
  - HDL (high-density lipoprotein cholesterol): ↑3-5%
  - TG: No effect or ↑

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RATIONALE/PURPOSE

- To date, only two of the three available bile acid sequestrants, colesevelam and cholestyramine, have been evaluated for their glucose lowering effects in patients with type 2 diabetes
- The purpose of this study is to evaluate the effect of colestipol in patients with type 2 diabetes mellitus in a veteran population

METHODS

- Institutional Review Board and VA Research and Development Committee approved
- Retrospective, electronic chart review of patients with an ICD-9 code diagnosis of type 2 diabetes mellitus and an active prescription for colestipol
  - Between January 1, 2005 and June 15, 2010

METHODS

- Inclusion Criteria
  - Age 18 years and older
  - Diagnosis of type 2 diabetes during the study period
  - Active prescription for colestipol at any time during the study period

METHODS

- Exclusion Criteria
  - Not received treatment with colestipol for a minimum of 12 weeks
  - Changes in their antihyperglycemic medications within the 3 month period before or after the initiation of colestipol
  - Lack of a documented gHbA1c within the 6 months prior to/or following the initiation of colestipol

OUTCOMES

- Primary Endpoint
  - A change in gHbA1c from baseline to follow-up after the initiation of colestipol
- Secondary Endpoints
  - Percent change in lipid parameters: LDL, TG, HDL
  - Percentage of patients experiencing an increase in LFTs
  - Documentation of appropriate counseling
  - Occurrence of adverse events related to colestipol

DATA COLLECTION

- Demographic information
  - Age
  - Gender
  - Race
- Baseline information
  - Within the six months prior to the initiation of colestipol therapy
    - gHbA1c
    - Lipid parameters (LDL, TG, HDL)
    - LFTs

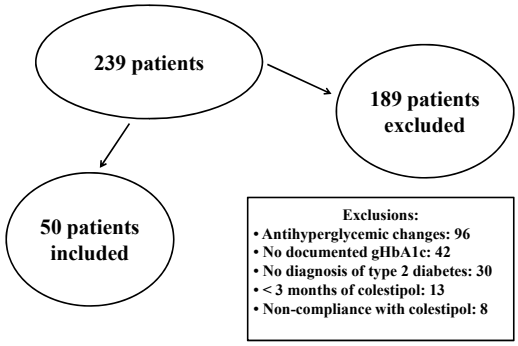
DATA COLLECTION

- After initiation of colestipol
  - gHbA1c (after at least 3 months)
  - LDL, HDL, and TG (after at least 4 weeks)
  - LFTs
  - Any subsequent laboratory values following dose titration of colestipol for up to six months

DATA COLLECTION

- Colestipol information
  - Initial dose
  - Maximum tolerated dose
  - Adverse Effects
  - Medication compliance
- Concomitant antihyperglycemic/lipid-lowering medications
  - Dose when colestipol was started
  - Dosage changes since colestipol was started

PATIENT ENROLLMENT



STATISTICS

- Paired t-test/Wilcoxon signed rank sum test
  - Change in gHbA1c
  - Change in lipid parameters
  - LFTs
  - Counseling
  - Adverse effects
  - Dose dependent changes in gHbA1c

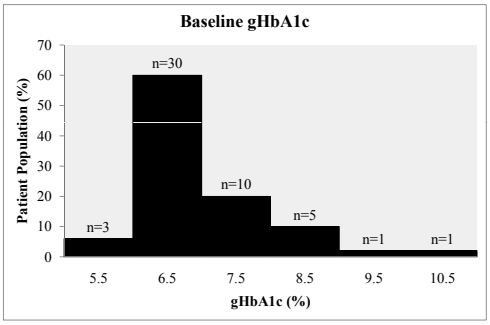
RESULTS

- Demographics; N=50

Gender		Age	Maximum Dose
Male	Female	Mean ± SD	Mean ± SD
50 (100%)	0 (0%)	70.9±8.1 years	4.5±1.6 gm per day

Race	African American	Caucasian	Pacific Islander	Unknown
	26 (52%)	15 (30%)	2 (4%)	7 (14%)

RESULTS



RESULTS

- Primary Endpoint

Parameter	Baseline	Final	Change	P-value
Average overall gHbA1c (%)	6.9%	6.7%	-0.24%	<0.0001
gHbA1c< 7%	6.5%	6.3%	-0.16%	0.001
gHbA1c 7 – 8%	7.4%	7.1%	-0.34%	0.01
gHbA1c > 8%	9.0%	8.5%	-0.56%	0.31

Additionally, there was no statistically significant difference in change in gHbA1c between the 3 baseline categories (p-value= 0.38)

RESULTS

Colestipol Dose	Average Δ gHbA1c	# of patients	P-value
1 gm BID	-0.2%	7	0.15
2 gm BID	-0.2%	32	0.01
3 gm BID	-0.3%	5	0.25
4 gm BID	-0.3%	6	0.06

Additionally, there was no statistically significant difference in change in gHbA1c between the 4 dosage categories (p-value= 0.60)

Results; Secondary Endpoints

- Lipid Parameters

Parameter	Baseline	Final	% Change	P-value
LDL (mg/dL)	**130.8**	**112.3**	**-13.4**	**<0.0001**
HDL (mg/dL)	**40.5**	**40.4**	**+0.6**	**0.89**
TG (mg/dL)	**153.8**	**170.4**	**+18.9**	**0.26**

Results; Secondary Endpoints

- LFTs remained stable; 8 of 50 patients (16%) had persistently elevated LFTs (2/2 alcohol use or hepatitis)
- Education regarding the proper administration of colestipol was documented in 13 out of 50 patients (26%)
- GI-related adverse events were reported by 2 of 50 patients (4%) following dose titration of colestipol

Conclusions

- Therapy with colestipol for additional LDL lowering in patients with type 2 diabetes resulted in an average overall gHbA1c reduction of ~0.24% (p-value<0.0001)
  - This is slightly lower than the reduction observed with other agents of the class
    - Colesevelam: average 0.3 to 0.7% reduction
    - Cholestyramine: average 0.5% reduction
- However, in patients with baseline gHbA1c >8%, the average reduction was 0.5%

Conclusions

- Lipid lowering effects:
  - LDL lowering of ~13% (p-value<0.0001) was observed. Slightly lower than the previously documented effect of 15 to 30% reduction.
  - HDL relatively unchanged. Inconsistent with previously documented effect of 3 to 5% increase.
  - An overall increase in TG of ~19% was noted. Previously documented effects note either no change or elevation in TG.

Limitations

- Retrospective design
- Lack of documentation/follow-up
- Lack of outside medical records
- Lack of patient reporting
- Concomitant medications not all inclusive
- Small sample size
- Diet & exercise

Discussion/Future Directions

- Providers may consider the use of colestipol in patients with type 2 diabetes who need additional LDL lowering despite optimal doses of statins or intolerability of other agents
- Larger, prospective studies with a longer observation period are needed to fully evaluate the effect of colestipol on glycemic control

STUDY QUESTION #1

Which of the following bile acid sequestrants is FDA indicated for adjunct treatment of type 2 diabetes mellitus?

A) Cholestyramine
B) Colesevelam
C) Colestipol
D) a and c

STUDY QUESTION #2

What is the main counseling point(s) for patients when initiating colestipol?

A) Common side effects of colestipol include constipation, abdominal cramps, and nausea
B) Take other medications 1 hour before or 4 hours after colestipol
C) Colestipol must be taken on an empty stomach
D) a and b

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THE EFFECT OF COLESTIPOL ON GLYCEMIC CONTROL IN PATIENTS WITH TYPE 2 DIABETES MELLITUS

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