Diltiazem versus verapamil for the prevention of arterial spasm during transradial access for coronary procedures: a non-inferiority trial

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Disclosures
- IRB Status: Approved
- Funding: None
- Co-investigators:
  - Stacy Emmett, B.S.Pharm, BCCCP
  - William Knopf, MD
  - JoEllen Maurer, B.S.Pharm, MHA
- I have no relevant financial relationships with the manufacturers of any commercial products and/or provider of commercial services discussed in this CME activity
- This program DOES include a discussion of off-label treatment options not approved by the FDA for use in the United States
  - Neither diltiazem or verapamil are approved by the FDA to prevent or treat radial artery spasm during coronary procedures

Learning Objectives
- Describe the reasons for using non-dihydropyridine calcium channel blockers for the prevention of arterial spasm during coronary angioplasty
- Identify the stakeholders and processes involved in performing a non-inferiority study in a rural hospital
St. Vincent Healthcare

- 286-licensed bed hospital (204 staffed beds)
- Level II trauma center
- Cardiothoracic and vascular medicine center
- 30 primary care and specialty clinics

Cardiac Cath Lab

- Cardinal artery becoming preferred access site versus femoral
- Major complication of radial access is radial artery spasm (RAS)
- RAS prevented by intra-arterial heparin, nitroglycerin, and verapamil
- Diltiazem another non-dihydropyridine calcium channel blocker studied for this use

Background


Objectives

- Investigate the non-inferiority of diltiazem compared to verapamil in the prevention of radial artery spasm during percutaneous coronary interventions.
- Examine the impact that each medication has on blood pressure and heart rate 10 minutes after administration.
- Observe the incidence of procedural success of radial artery access when each medication is used.

Methods

- Design was a single site, randomized, non-inferiority study of 12.5 mg diltiazem versus 2.5 mg verapamil in percutaneous coronary interventions (PCI).
- Primary outcome: Incidence of radial artery spasm.
- Secondary outcomes:
  - Change in vital signs 5-10 minutes after injection.
  - Burning sensation at injection site.
  - Successful procedure using radial artery.
Methods (cont.)

- Inclusion criteria:
  - Inpatient subjects age ≥ 18
  - Planned radial PCI
  - Positive Barbeau test

- Exclusion criteria:
  - Prior calcium channel blocker therapy
  - Emergency procedures
  - Pregnant females
  - Severe systolic dysfunction (LVEF ≤ 20%)
  - Systolic blood pressure ≤ 90 mmHg
Randomization and Blinding

• Randomized list of diltiazem/verapamil created for 120 patients
• Diltiazem is refrigerated; verapamil stored at room temperature
  • Pharmacy technicians used for input on blinding
• Cath lab staff would receive 5 mL vial of clear IV solution
• Primary investigator would review charts for primary and secondary outcomes
• 340B coordinator consulted for not charging items

Stakeholders

• Primary author and pharmacy department
• Investigational review board (consent form requirements)
• Chief cardiologist
• Interventional cardiologists
• Nurse practitioners charged with gathering consent
• Cath lab nursing staff

Results

Intention to treat • 96 consecutive patients
Patients consented and enrolled • 5 patients total
Patients that received therapy • 0 (all met exclusion criteria)
Discussion: Lessons Learned

• Know your stakeholders and what they think of the study
  • Get all cardiologists on board early
• Ensure your exclusion criteria will allow for enough patients
  • Verify that previous studies easily met power
• Understand where the majority of subjects come from
  • Standardization of workflow
• Communicate with each member of the team!
  • Regular emails on where we were with patient enrollment

Conclusions

• There were no patients that completed the trial and formal evaluation was incomplete
• Future trials bolstered by provider involvement are needed to validate diltiazem non-inferiority to verapamil

Future Opportunities for Residency Projects

• Attempt a retrospective analysis of medication interventions
• Utilize strategic planning to optimize workflow
• Pursue input from outside of the department
• Investigate areas where medications are used and pharmacy is not involved
Questions and Contact Information

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