Venous Thromboembolism and Heart Failure: Current Clinical Practice Guidelines

Presenters:

VTE GUIDELINES COMMITTEE
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HEART FAILURE COMMITTEE
Sean Collins, PT, ScD - University of Mass At Lowell, Lowell, Massachusetts
John Heick, PT, DPT, OCS, NCS - AT Still, Phoenix, Arizona
Disclosure

The speakers report no relevant financial relationships.
Our Team
Session Learning Objectives

1. List and describe major steps in the clinical practice guidelines (CPG) process.

2. Identify tools available in the CPG development process and the role the APTA can have in assisting in the process.

3. Describe the strengths and limitations of CPGs.

4. Apply the preliminary recommendations of the venous thromboembolism CPG to a patient.
Session Learning Objectives

5. Discuss evidence to support clinical decisions on mobility of individuals diagnosed with a lower extremity deep vein thrombus based on recommendations from the CPGs.

6. Discuss preliminary findings of evidence on exercise and heart failure.

7. Identify ways individuals can contribute to the CPG development process based on their education, clinical expertise, and time availability.
What is **YOUR** Objective for being here?
How Does a Therapist Make Decisions?
Clinical Practice Guidelines

• Recommendation intended to *optimize* patient care

• Based on a systematic review of evidence

• Includes an assessment of the benefits and harms of care options

• Improve clinical practice and patient care
Clinical Practice Guidelines

• Meant to assist, but not replace critical thinking of the clinician.

• Guide the decision making process of healthcare policy makers, third party payers and patients

• Identify areas that are well researched as well as topics where additional research is lacking
How Do You Change Clinical Practice?

- Select, tailor, implement interventions
- Assess barriers to knowledge use
- Adapt knowledge to local context

Knowledge Creation

Knowledge Inquiry

- Monitor knowledge use
- Evaluate outcomes
- Sustain knowledge use

- Identify problems
- Identify, review, select knowledge

Adapted from Graham I et al 2006
Steps of Guideline Development

1. Establish a multidisciplinary team to address the topic

1. Identify the clinical question(s)

1. Conduct a systematic review of evidence

1. Appraise and interpret evidence and come to consensus on it meaning

1. Draft guideline recommendations that align with the evidentiary base
Steps of Guideline Development

5. Complete an external review of the draft report among intended users and key stakeholders

6. Revise the guidelines in response to the external review

7. Read the final guideline report for distribution and dissemination

8. Prepare an implementation strategy.
# Levels of Evidence

<table>
<thead>
<tr>
<th>Level</th>
<th>Criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td>I</td>
<td>Evidence obtained from high-quality diagnostic studies, prognostic or prospective studies, cohort studies or randomized controlled trials, meta-analyses or systematic reviews</td>
</tr>
<tr>
<td>II</td>
<td>Evidence obtained from lesser-quality diagnostic studies, prognostic or prospective studies, cohort studies or randomized controlled trials, meta-analyses or systematic reviews</td>
</tr>
<tr>
<td>III</td>
<td>Case-controlled studies or retrospective studies</td>
</tr>
<tr>
<td>IV</td>
<td>Case studies and case series</td>
</tr>
<tr>
<td>V</td>
<td>Expert opinion</td>
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</table>
## Grades of Recommendations

<table>
<thead>
<tr>
<th>Grade</th>
<th>Recomm</th>
<th>Evidence Quality</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>Strong</td>
<td>A preponderance of level I studies</td>
</tr>
<tr>
<td>B</td>
<td>Moderate</td>
<td>A preponderance of level II studies</td>
</tr>
<tr>
<td>C</td>
<td>Weak</td>
<td>A single level II study or a preponderance of level III and IV studies, including consensus statements</td>
</tr>
<tr>
<td>D</td>
<td>Theoretical/foundational</td>
<td>A preponderance of evidence from animal or cadaver studies, from conceptual/theoretical models/principles, or from basic science/bench research, or published expert opinion.</td>
</tr>
<tr>
<td>P</td>
<td>Best Practice</td>
<td>Recommended practice based on current clinical practice norms</td>
</tr>
<tr>
<td>R</td>
<td>Research</td>
<td>An absence of research on the topic, or conclusions from higher-quality studies on the topic are in disagreement.</td>
</tr>
</tbody>
</table>
APTA involvement in Clinical Practice Guidelines

• Goal to develop clinical practice evidence based documents

• Reduce unwarranted care and focus payment in the right areas.

• Provides financial support for the writing groups, workshops on the process and some mentoring
## Current CPGs in Physical Therapy

<table>
<thead>
<tr>
<th>Section Topic</th>
<th>Supporting Section</th>
<th>Application Submission Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aquatic Interventions for the Treatment of Primary Hip Osteoarthritis</td>
<td>Aquatics</td>
<td>Sept 2014</td>
</tr>
<tr>
<td>Core Set of Outcome Measures for Patients with Neurologic Conditions</td>
<td>Neurology</td>
<td>Sept 2013</td>
</tr>
<tr>
<td>Diabetic Foot Ulcer</td>
<td>Clinical Electro &amp; Wound</td>
<td>Sept 2014</td>
</tr>
<tr>
<td>GeriEDGE Evaluation of Fall Risk Assessment Tools and Fall Risk Abatement/Balance Outcome Measures</td>
<td>Geriatrics</td>
<td>March 2013</td>
</tr>
<tr>
<td>Identification and Evaluation of Post Intensive Care Syndrome</td>
<td>Acute</td>
<td>Sept 2013</td>
</tr>
<tr>
<td>Identification, Prevention and Treatment of Falls in Community Dwelling Older Adults</td>
<td>Geriatrics</td>
<td>Sept 2012</td>
</tr>
<tr>
<td>Management of Secondary Upper Quadrant Lymphedema</td>
<td>Oncology</td>
<td>Sept 2012</td>
</tr>
<tr>
<td>Pelvic Girdle Pain in the Post Partum Population</td>
<td>Womens Health</td>
<td>Sept 2014</td>
</tr>
<tr>
<td>PT for Adults following Acutely Decompensated Chronic Heart Failure</td>
<td>Cardiovascular and Pulmonary</td>
<td>Sept 2014</td>
</tr>
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# Current CPGs in Physical Therapy

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<tbody>
<tr>
<td>PT Management of Patients with Total Knee Arthroplasty in the Acute Post Operative Phase (7 days)</td>
<td>Acute</td>
<td>Sept 2014</td>
</tr>
<tr>
<td>Prevention, Assessment of Risk, and Physical Therapy Management with LE Venous Thromboembolism</td>
<td>Cardiovascular and Pulmonary and Acute</td>
<td>Sept 2012</td>
</tr>
<tr>
<td>Vestibular Rehabilitation for Peripheral Vestibular Hypofunction</td>
<td>Neurology</td>
<td>Sept 2012</td>
</tr>
<tr>
<td>Work Rehabilitation</td>
<td>Orthopedics</td>
<td>March 2014</td>
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Brief History of the VTE Guideline Development Group (GDG)

- Members of GDG were originally appointed by Section Executive Board based upon
  - Experience with guideline or similar type experience
  - Content expertise
  - Research expertise
- Members attended a 2 day workshop on guideline development provided by APTA in July 2012
  - Developed tentative focus of guideline
  - Develop format
- Wrote & obtained grant for partial funding from APTA
  - Funding also provided by Cardiovascular and Pulmonary Section for start up and continuance
Brief History of the VTE Guideline Development Group

Work BEGAN:

• Identified a grad assistant to provide ongoing structure for article and guideline reviews
• Identified tools to use for article and guideline reviews
• Put out call for volunteers to perform reviews
• Performed reliability testing on GDG members and volunteers.
• Received training on utilization of AGREE tool to review guidelines
Developing the VTE Guideline Focus: Identifying the Problem with VTE

- Focus started out very BROAD...we wanted EVERYTHING

- CURRENT: Prevention, Screening, Diagnosis and Mobility

- Reviewed articles and guidelines identified by our librarian for 1 ½ years.
- Surveyed members and executive boards for input
Developing the VTE Guideline Focus: Identifying the Problem with VTE

- Limited focus to LE DVT and exclude PE and UE DVT.

- Added evidence on compression as a component of treatment.
Purpose of the VTE Guideline

• Physical therapy community *needs* evidence based guidelines to assist in clinical decision making.

• Intended use: a reference document to guide physical therapy practice in the prevention of, screening for, and management of patients at risk for or diagnosed with LE DVT.

• In addition to providing practice recommendations, this guideline addresses *gaps in evidence* and areas that require further investigation.
Scope of VTE Guideline

Specifically the Scope:

• Is Applied to ADULTs across all practice settings,
• Does NOT address nor apply to those who are pregnant or to children.
• Does NOT discuss the management of pulmonary embolism (PE), upper extremity DVT (UE DVT) or chronic thromboembolism pulmonary hypertension (CTEPH).
• Identifies areas of research that are needed to improve the evidence base for physical therapy management of patients at risk for or diagnosed with VTE.
WHY Guidelines for VTE???
Why VTE? What is the Importance of Developing a Guideline?

• Venous thromboembolism is a life-threatening disorder
  – ranks #3: most common CV illness after ACS and stroke.
• Venous thromboembolism: consists of 3 interrelated primary conditions caused by venous blood clots: DVT, PE and PTS
• Deep vein occurs when a blood clot forms in a deep vein, most commonly in the calf, thigh, or pelvis.
• PE is a life threatening, acute complication of LE DVT.
  – Clot dislodges, travels through the venous system and causes a blockage in the pulmonary circulatory system.
Why VTE? What is the Importance of Developing a Guideline?

• A **proximal** lower-extremity DVT (in popliteal vein & above)
  – associated with 50% risk of PE if not treated
  – risk of PE is 20% to 25% if **calf** vein thrombi.

• One in 5 with acute PE die immediately; 40% will die within three months.
Why VTE? What is the Importance of Developing a Guideline?

• VTE has secondary conditions including:
  – Post PE syndrome
  – Chronic Thromboembolic Pulmonary Hypertension (CTEPH).

• Survivors of PE often develop significant cardiopulmonary morbidity: CTEPH most often
Why VTE? What is the Importance of Developing a Guideline?

• Major risk factors associated with VTE include:
  – previous VTE,
  – immobility,
  – hospitalization,
  – surgery/trauma,
  – cancer,
  – travel,
  – obesity,
  – age greater than 45, and
  – presence of a thrombophilic disorder.
Why VTE? What is the Importance of Developing a Guideline?

• Both hospitalized and non-hospitalized patients may be affected by VTE.
  – Half of new VTE cases are hospital-acquired or occur within 90 days of a hospital stay or surgical procedure.
  – VTE accounts for 5% to 10% of all deaths during hospitalization.
Why VTE? What is the Importance of Developing a Guideline?

Acute medical illness is associated with an 8X increased risk of VTE:

- One-fourth of all VTE events in the community
- Cancer alone: 4.1-fold risk of thrombosis
- Chemotherapy increases the risk 6.5-fold.
- Age >45 incidence increases to 5-6 per 1000,
- > risk in men than women in older adults
- Survivors of first VTE: 10% to 30% develop another VTE within 5 years.
Why VTE? What is the Importance of Developing a Guideline?

• Both hospitalized and non-hospitalized patients may be affected by VTE:

  – Immobilization for 3 or more days is one of a number of risk factors for VTE in hospitalized medical patients

  – Immobilization secondary to long-distance air travel is also a risk factor
When to Mobilize after Diagnosis of VTE?

• **OLD assumption:** early mobilization could cause the DVT to dislodge,

• **OLD Assumption:** Strict bed rest was prescribed with early ambulation being considered a contraindication when a LE DVT was documented.
When to Mobilize after Diagnosis of VTE?

• Recent meta-analysis and systematic review:
  – no greater risk of PE in anti-coagulated patients who are mobilized early versus those who remain on bed rest.

• Early mobilization in patients with LE DVT who are anti-coagulated prevents adverse effects of bed rest.

• Early mobilization reduces risk of extension of DVT proximally as well as the more long term effects of PTS.
VTE Guidelines

Include:

• Identification of high risk for purpose of prevention interventions
• Risk Assessment
• Clinical Decision making based upon RISK
• Screen for Signs/Symptoms
• Identification of Anticoagulation
• Indications for Mobility based upon anticoagulant
• Identification of IV Filters and indication for mobility
• Identification of Falls Risk
• Interventions with Mechanical Compression
Current Status of VTE Guideline

• A DRAFT document has been developed and sent for External Review January 5, 2015

• The External Review is almost complete and the Committee is reviewing the comments and suggestions

• The Second Draft should be sent out for Review at the end of February 2015.

• Final Draft is expected to be turned into the PT Journal for publication in March 2015
OVERVIEW OF THE GUIDELINE:
THE SPECIFICS
Overview of VTE Guidelines: The Specifics

• Guideline is divided into
  – Overview and background of VTE problem
  – Algorithms to be utilized clinically
  – Key Actions statements
    • Action Statement #: RECOMMEND ............
    • Full statement with evidence and recommendation
    • Action Statement Profile
      – Aggregate Evidence Quality:
        Benefits:
        Risk, Harm, Cost:
      – Benefit-Harm Assessment:
        Value Judgments:
        Intentional Vagueness:
        Role of Patient Preference:
        Exclusions:
  – Each action statement is then followed by paragraphs explaining the summary of the evidence
Key Action Statement

http://prezi.com/hamsi_9046kd/?utm_campaign=share&utm_medium=copy&rc=ex0share
Major Findings of the CPG

• Physical therapists should play a large role in identifying patients who are high risk of a VTE.
  – Prevention is key
• Recognize signs and symptoms of a LE DVT and determine likelihood of DVT
• Mobilize as soon as possible
• Complications post DVT can continue for years or even a lifetime.
  – Prevention is key
Heart Failure Clinical Practice Guideline Update

Sean Collins, PT, ScD, CCS
UMASS-Lowell, Massachusetts

John Heick, PT, DPT, OCS, NCS
A. T. Still University, Mesa, Arizona
Disclosure

• No relevant financial relationship exists
Guideline Development Team

- Sean Collins, ScD, CCS
- John Heick, PT, DPT, OCS, NCS
- Michael Shoemaker, PT, PhD
- Kristin Lefevbre, PT, PhD, CCS
- Lawrence Cahalin, PhD, CCS
Physical Therapy for Adults Following Acutely Decompensated Chronic Heart Failure

• Focus:

• Evidence-based clinical practice guideline (CPG) for physical therapy clinical decision making and intervention in adults with chronic heart failure (HF).
Why Heart Failure?

• HF is a condition of national priority
  – high and predicted escalations in prevalence and cost
  – major cause of hospitalization and hospital readmission

• Physical Therapist clinical decision making regarding the safety and effectiveness of implementing intervention for adult patients with HF is generally considered a topic of great confusion among physical therapists in different care settings (e.g. hospital, SNF, home care)
Questions (1 of 2)

- Is it safe to proceed with physical therapy at this time?

- address recommendations related to a patient’s readiness

- particularly important for patients following an acutely decompensated HF

- include recommendations on criteria to determine what interventions a patient is ready for at various stages in their condition
Questions (2 of 2)

• If the patient is ready for physical therapy, what interventions are recommended?

• address which interventions are recommended for a patient with chronic heart failure

• include recommendations regarding physical therapy interventions across the spectrum of the condition and the continuum of care (acute care through outpatient settings)
Approach / Methodology

1. Guideline International Network (G-I-N)

2. AGREE II (Appraisal of Guidelines, Research and Evaluation)

3. Kaplan et al’s special communication in Pediatric Physical Therapy Journal (particularly important for specific concerns relevant to physical therapy)
Heart Failure CPG - Proposed Timeline

**CPG Questions & Grant Development**

- Preliminary list of topics/questions from GPG
- Send to Cardio section executive board and CPPT editorial board for review and seeking additional topics and questions
- Remove redundant topics/questions - create list
- Conduct survey for ranking importance of the topics/questions to section membership; also seek outside opinions on ranking importance from a nurse, physician and patient representative
- Collate and analyze results of feedback - finalize a list of topics/questions to be included in the CPG

- **December 2014 - April 2015**
- Reviewer Prep
  - Recruit reviewers
  - Start training reviewers
  - AGREE tool online training
  - PU training with McMaster
  - Use selected articles to test reliability of reviewers
  - Re train/mentor reviewers with reliability < 0.90
  - Re test reliability of any reviewers requiring re training/mentoring

**Comprehensive Search & Initial Appraisal of the Literature**

- Work with librarian's to come up with search terms and strategy
- Librarian's conduct search
- Invite searches from section membership
- Cross reference search results come up with initial list based on inclusion/exclusion criteria

- **March 2015 - October 2015**
- Update Comprehensive Search & Appraisal of the Literature
  - Update search results come up with second list
  - GPG reviews abstracts (divide in half and have two reviewers/abstract; ties can be broken by a third reviewer)
  - Obtain and archive all full text papers for inclusion - need database that entire GPG can access

**Data Extraction - Evidence Tables**

- **April 2015 - November 2015**

**Synthesis & Interpretation of Evidence**

**Guideline Development**

- GPG training in Bridge wiz
- Write the CPG

- **November 2015 - April 2016**

**Review and Dissemination of the CPG**

- Phase 1: review by content and methods experts (includes non PTFs), include at least 2 rounds of reviews
- Phase 2: Publication and journal review process
- Phase 3: Post publication application to Guidelines.gov

- **April 2016 - September 2015**

**Coordination of CPG Revisions**

- Ongoing

- **Completed: November 2017**
Data Extraction - Evidence Tables

Synthesis & Interpretation of Evidence

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Coordination of CPG Revisions
- Ongoing

April 2015 - November 2015

November 2015 - April 2016

April 2016 - September 2016

September 2016 - January 2017

February 2017 - November 2017

Completed: November 2017
Evidence Selection Criteria

- Populations
- Interventions
- Comparisons
- Outcomes
- Settings
- Timeframe
- Design
- Publication Status
- Study Status
- Language
- Date
Searching the Literature

• Two Reference Librarians

• Independently develop and conduct a search based on the evidence selection criteria

• Invitation of Cardiovascular and Pulmonary Section Members to submit a search, including terms, databases used, number of studies excluded and full history
Critical Appraisal of Evidence

• Appraisal team
  – Recruitment
  • Survey
  – Evaluation
  – Testing reliability
• Appraisal Tool (specific to type of evidence evaluated)
Data Extraction & Presentation

• Databases will be generated (Evidence Tables) of all articles, reviewers, critical appraisers score, and all relevant variables for guideline content

• G-I-N Evidence Table Definition: "Methodological and outcome summaries that present data from a number of related studies. They answer a well-defined question in a consistent format, aim to demonstrate overall trends in the evidence, and enable the process of making recommendations”

• Based on G-I-N recommendations we anticipate at least two evidence tables, at least one for each question
Synthesis & Interpretation of Evidence

- Qualitative synthesis

- Quantitative synthesis when appropriate considerations include:
  - Participants of the studies are similar with respect to patient characteristics (stage of disease, age, sex) and other important clinical factors (performance status, previous treatment)
  - Study interventions are similar and any other co-interventions
  - Study control groups also similar (standard treatment, placebo, or observation)
  - Studies report the similar outcomes (defined in a similar fashion or can they be converted to similar units of measurement)
Developing Recommendations

• Consideration given, but limited, to:
  – quality, consistency, directness, magnitude, generalizability of evidence
  – trade offs, comparisons to alternatives, acceptability to patients, clinicians, managers and resource allocations
Developing Recommendations

- Bridgewiz 2.0 System

- requires statement of recommended action with explicit selection of action verbs; objects consequences of recommended actions; target population and incorporation of the strength of evidence based on GRADE methodology

- GRADE methodology requires that the degree to which recommendations are based directly on evidence vs the opinion and consensus of the developers will be stated explicitly

- In addition, we plan on articulating the rationale for any recommendations made by opinion and consensus due to a realization that sound mechanistic reasoning often underlies such opinions
Interested in Appraising?

Contact jheick@atsu.edu
References


References


References


Include current references in AMA style at the end of the presentation
How to Get Involved
How to Get Involved?

• Feedback needed on implementation of this CPG in your clinical practice

• *Cardiovascular & Pulmonary Specialty Section website “drop box”
How To Get Involved?

• Disseminate this CPG (e.g. references; algorithms) among:
  • colleagues at your facility (physicians, nurses, PAs, PT/OT/Speech....)
    – to support/alter existing policies and procedures (e.g. quality assurance /utilization review committees)
    – colleagues as a timely CEU topic (e.g. brain brunches; APTA State affiliate conferences)
    – patients and their care-givers for educational purposes
    – students in DPT and PTA Programs for infusion into existing curricula

• Scrutinize the public media that may be sharing outdated and/or inaccurate information and issue a response accordingly
Guidelines: How do we utilize these with clinical practice?

- Open access to the CPG and all reference materials.
- Creation of Pocket Guide for physical therapist about VTE
- Creation of patient brochures and information flyers about the role of physical therapists in preventing VTE and managing patients with LE DVT
- Production of podcasts about the CPG aimed at physical therapists.
- Presentations on the CPG by the GDG at regional seminars
- Recorded presentations on the CPG by the GDG
- Creation of checklist and sample evaluation forms incorporating the recommendations of the CPG