

# MEASUREMENT OF ADHERENCE, HEALTH-RELATED QUALITY OF LIFE, AND HEALTH-CARE RESOURCE UTILIZATION DURING ANTICOAGULATION THERAPY IN CANCER-RELATED VENOUS THROMBOEMBOLISM

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SUPPORTIVE CARE IN CANCER



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# CONTENT

- Brief background review
- Study problem and objectives
- Study design and activities
- Timeline and updates

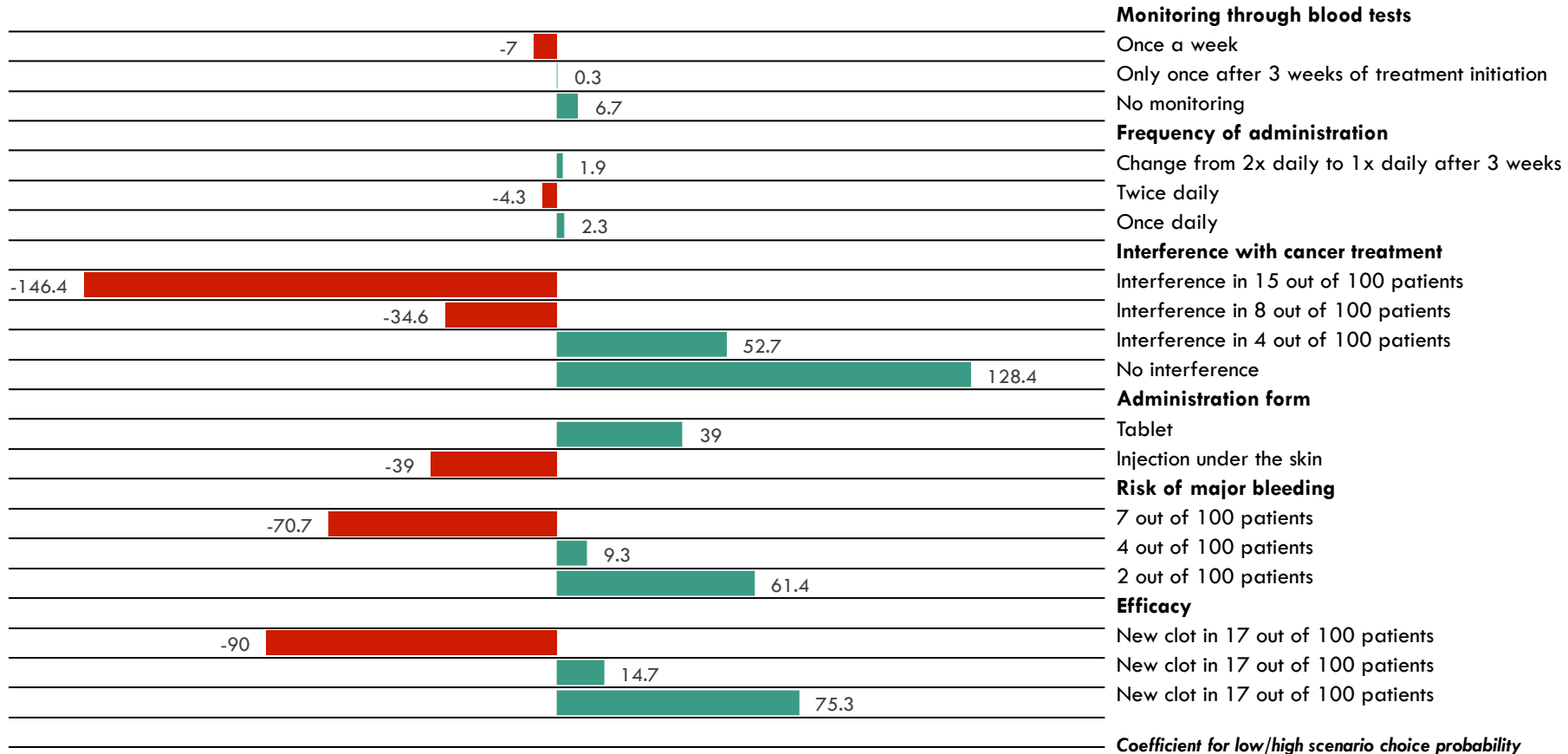
# BACKGROUND/CONTEXT

- Cancer-related venous thromboembolism (VTE) is a prevalent problem that occurs in 20-25% of patients with malignancy
- For cancer related-VTE, consensus guidelines (ASCO, ACCP, NCCN) recommend treatment with parenteral low molecular weight heparin (LMWH) for the initial and long term therapy (at least 6 months)
- Recommendations in VTE guidelines are based on efficacy and safety data, but scant (to none) information on quality of life, patient's preference and adherence to therapy outside clinical trials
- Although LMWH are effective agents for the treatment of cancer-related VTE, they are often difficult to tolerate and might be inconvenient for long-term use by cancer patients

Yu YB, Gau JP, Liu CY, et al. A nation-wide analysis of venous thromboembolism in 497,180 cancer patients with the development and validation of a risk-stratification scoring system. *Thrombosis and haemostasis* 2012;108:225-35.

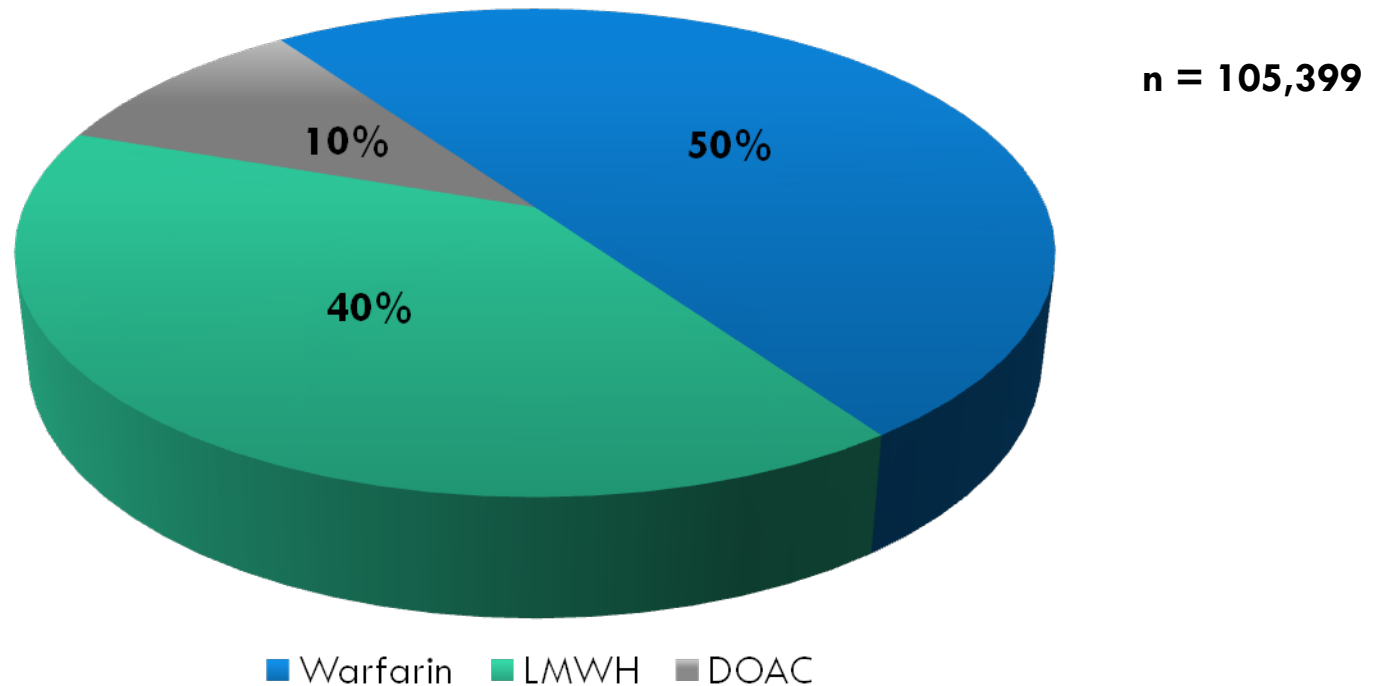
Lyman GH, Khorana AA, Kuderer NM, et al. Venous thromboembolism prophylaxis and treatment in patients with cancer: American Society of Clinical Oncology clinical practice guideline update. *J Clin Oncol* 2013;31:2189-204.

# PATIENT'S PREFERENCE FOR CANCER-VTE TREATMENT



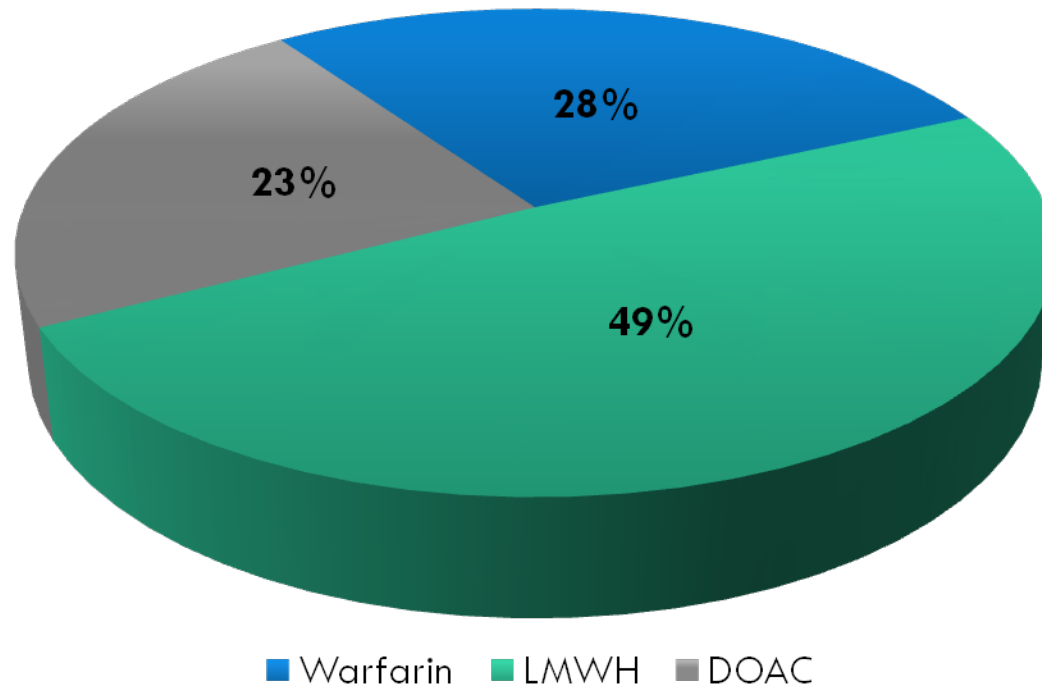
# U.S. PRESCRIPTION PATTERNS FOR CANCER-VTE

## Anticoagulation prescription patterns (2009-2014)



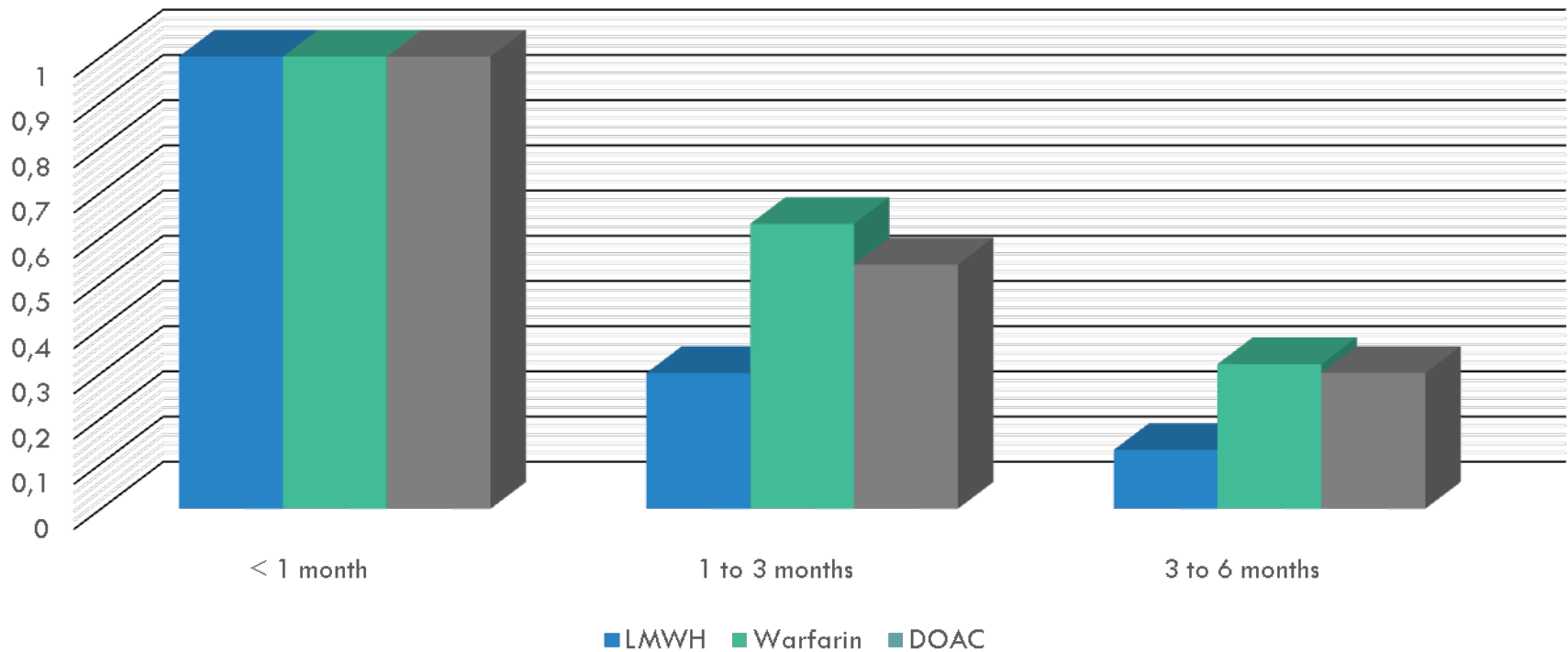
# U.S. PRESCRIPTION PATTERNS FOR CANCER-VTE

## Anticoagulation prescription patterns (2013-2014)



# U.S. PRESCRIPTION PATTERNS FOR CANCER-VTE

Proportion of patients on anticoagulation from cancer-VTE diagnosis



# BACKGROUND/CONTEXT

- Some reports based on expert experience have described that reasons for non-adherence to guidelines might be:
  - Reluctance to impose daily injections on fragile patients
  - The complexity of the medical care organization and pathway (cost related issues, patient's preference, level of awareness, etc.)
  - Strength of habit
  - Lack of knowledge or confidence in treatment guidelines
  - Concerns about bleeding, dose adjustments in specific circumstances (i.e.: thrombocytopenia, concurrent coagulopathy, drug interactions)



# PROBLEM

- There is a need for further investigation of the treatment adherence, health related quality of life (QoL) and health care resources utilization during long term anticoagulation for cancer-related VTE
- Knowledge gap in the impact of QoL and treatment adherence in cancer-thrombosis related outcomes:
  - Recurrent venous thromboembolism
  - Clinical relevant bleeding

# PROBLEM: TARGET POPULATION

- Adult ( $\geq 18$  years) female or male subjects
- Confirmed symptomatic proximal or distal lower extremity deep venous thrombosis with or without pulmonary embolism or other venous thromboses
- Active cancer or diagnosed within 2 years prior to VTE
- Intention for long-term treatment (at least 3 months) with anticoagulation
- Setting: Hospital/outpatient clinic/anticoagulation clinic

# STUDY OBJECTIVES

## ■ PRIMARY

- To assess self-reported adherence to long term anticoagulation treatment for cancer related-venous thromboembolism

## ■ SECONDARY

- To assess anticoagulation self-reported adherence changes over time, by the anticoagulant type used (parenteral versus oral)
- To assess if other patient, tumor and anticoagulation-related outcomes are associated with self-reported adherence to anticoagulation treatment
- To assess the QoL variables in patients for cancer-related VTE treated with anticoagulation
- To measure the number of outpatient visits, emergency center visits and hospitalization episodes related to the management of anticoagulation complications during the study period

# STUDY DESIGN

Assessments	Completed by	Time 1	Follow-up at 30 day	Follow-up at 3 months	Follow-up at 6 months	Follow-up at 12 months
Consent	Patient	X				
Screening Questionnaire	Research coordinator	X				
QoL variables	Patient	X	X	X	X	X
Adherence report	Patient		X	X	X	X
Documentation of visits for anticoagulation complications	Research coordinator		X	X	X	X

- Prospective observational (non-interventional) study
- Multiple centers will be participating
- 260 patients
- Potential participants in the study will be identified through a list of daily diagnostic doppler ultrasonography and computerized tomography studies.

# STUDY OUTCOMES MEASUREMENT

- **SELF –REPORTED ANTICOAGULATION ADHERENCE**

Do you ever forget to take your medicine?	Yes/No
Are you careless at times about taking your medicine?	Yes/No
When you feel better, do you sometimes stop taking your medicine?	Yes/No
Sometimes if you feel worse when you take the medicine, do you stop taking it?	Yes/No

- The Morisky scale is a validated, self-reported measure that can be integrated in a medical visit.
- It is composed of four dichotomized item/questions with good predictive validity for medication adherence (alpha reliability=0.6)
- This adherence scale has been previously used in patients on oral long term anticoagulation and shown to provide correlation with anticoagulation control

# STUDY OUTCOMES MEASUREMENT

## ■ HEALTH CARE RELATED QoL: DVTQOL TOOL

- A questionnaire that includes a total of 29 questions.
- For each question, responses are arranged on a seven-point Likert scale:
  - Severity of the degree of distress  
not at all, minor, mild, moderate, moderate severe, severe, extremely severe
  - Frequency of the problem  
never, hardly ever, occasionally, sometimes, frequently, most of the time, all of the time
- The item-questions are grouped in six domains: Emotional distress, symptoms, limitations in physical activity, hassle with monitoring, sleep disturbance, and dietary problems.
- The DVTQOL has a good internal consistency reliability (alpha, 0.79 to 0.93) and it correlates well with other well validated tools for the evaluation of health related QoL, such as SF-36 and EQ-5D

# TIMELINE & UPDATES

- Protocol approved at MD Anderson Cancer Center (USA) in October 2017
- Applied for local Survivorship Program funding
- Screening and enrollment of participants started in November 2017
- At May 31, 2018:
  - A total of 339 patients screened for eligibility
  - 12 subjects are currently participating
  - 6 subjects have completed surveys for 30-day follow-up visits
  - 2 subjects have withdrawn from the study

# TIMELINE & UPDATES

<b>Characteristics</b>	<b>N</b>	<b>%</b>
<b>Female</b>	<b>6</b>	<b>50</b>
<b>Age [min., max]</b>	<b>[43, 78]</b>	
<b>Type of malignancy</b>		
<b>Solid</b>	<b>10</b>	<b>83</b>
<b>Hematologic</b>	<b>2</b>	<b>17</b>
<b>Active cancer therapy</b>	<b>9</b>	<b>75</b>
<b>Anticoagulation of choice</b>		
<b>LMWH</b>	<b>9</b>	<b>75</b>
<b>DOAC</b>	<b>3</b>	<b>25</b>
<b>Location of index DVT</b>		
<b>Proximal lower extremity</b>	<b>7</b>	<b>58</b>
<b>Distal lower extremity</b>	<b>5</b>	<b>42</b>
<b>Concurrent pulmonary embolism</b>	<b>7</b>	<b>58</b>



# TIMELINE & UPDATES

- At 30-day follow up: 100% self-reported adherence to treatment (6 subjects)
- Health related QoL features:
  - Frequent moderate to moderate-severe distress in the domains of physical symptoms and limitation to physical activity
  - Frequent moderate emotional distress related to anxiety about own health

# TIMELINE & UPDATES

- Sites initiating IRB approval and activation (2018):
  - Mitchell Cancer Institute (Alabama, USA): Dr. Butler
  - Hospital Clinic (Barcelona, Spain): Dr. Font
  - Virgen del Rocio Hospital (Seville, Spain): Dr. Jara-Palomares
  - Valle del Lili Clinic (Cali, Colombia): Dr. Chavarro-Dominguez

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THANKS FOR YOUR  
ATTENTION