

# Development and Testing of a DVT Risk Assessment Tool: Providing Evidence of Validity and Reliability

Ruth McCaffrey, ND, ARNP-BC, Mary Bishop, RN, MSN, Marie Adonis-Rizzo, RN, MSN, Ellen Williamson, MSN, ARNP, Melanie McPherson, RN, BSN, Alice Cruikshank, RN, BS, Vicki Jo Carrier, RN, BSN, CNOR, CRNFA, Simone Sands, RN, BSN, Diane Pigano, RN, MSN, MBA, Patricia Girard, MSN, ARNP, Cathy Lauzon, MSN, ARNP

## ABSTRACT

**Background:** Hospital-acquired deep vein thrombosis (DVT) and pulmonary embolisms (PE) are preventable problems that can increase mortality. Early assessment and recognition of risk as well as initiating appropriate prevention measures can prevent DVT or PE.

**Aims:** The purpose of this research project was to develop a DVT risk assessment tool and test the tool for validity and reliability.

**Methods:** Three phases were undertaken in developing and testing the JFK Medical Center DVT risk assessment tool. Investigation and clarification of risk and predisposing factors for DVT were identified from the literature, expert nursing knowledge, and medical staff input. Second, item development and weighting were undertaken. Third, parametric testing for content validity measured the differences in mean assessment tool scores between a group of patients who developed DVT in the hospital and a demographically similar group who did not develop DVT. Interrater reliability was measured by having three different nurses score each patient and compare the differences in scores among the three.

**Findings:** The DVT group had significantly higher scores on the JFK DVT assessment scale than did those who did not experience DVT. Interrater reliability showed a strong correlation among the scores of the three nurses (.98).

**Discussion:** Providing a valid and reliable tool for measuring the risk for DVT or PE in hospitalized patients will enable nurses to intervene early in patients at risk. Basing DVT risk assessment on the evidence provided in this study will assist nurses in becoming more confident in recognizing the necessity for interventions in hospitalized patients and decreasing risk.

**Implications:** Nurses can now evaluate patients at risk for DVT or PE using the JFK Medical Center's risk assessment tool.

*Worldviews on Evidence-Based Nursing 2007; 4(1), 14–20. Copyright ©2007 Sigma Theta Tau International*

**KEYWORDS** deep vein thrombosis, pulmonary embolism, instrument development, parametric testing, risk assessment

## INTRODUCTION

Hospital-acquired deep vein thrombosis (DVT) and pulmonary embolism (PE) are preventable

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Ruth McCaffrey, Associate Professor, Christine E. Lynn College of Nursing, Florida Atlantic University, Boca Raton, FL. Mary Bishop, Chief Nursing Officer, Marie Adonis-Rizzo; Ellen Williamson; Melanie McPherson; Alice Cruikshank; Vicki Jo Carrier; Simone Sands; Diane Pigano; Patricia Girard; Cathy Lauzon. John F. Kennedy Medical Center, Atlantis, FL.

Address correspondence to Dr. Ruth McCaffrey, Florida Atlantic University, 777 Glades Road, Boca Raton, FL 33431; rmccaffr@fau.edu

Accepted 9 November 2006

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1545-102X/07

medical problems that can increase mortality. Yang (2005) considers PE as a result of untreated DVT, the most preventable reason for in-hospital mortality. While some cases of DVT resolve without complication and therefore are not part of hospital data, it is conservatively estimated that the incidence of DVT for hospitalized patients in the United States is approximately one person in 20 (Joint Commission Benchmark 2005). Figures on the incidence of DVT in Europe show that up to 20% of general surgery patients and 36–60% of patients with postoperative hip fracture and hip replacement get DVT; 70% of patients who have had a stroke get DVT in the leg on the affected side (American Geriatrics Society 2006).

Pulmonary emboli can arise from a DVT anywhere in the body. Therefore, prevention of DVT may reduce the number of pulmonary emboli and the mortality associated with this problem in hospitalized patients (Kyrle & Eichinger 2005). Women are affected by DVT roughly twice as often as are men, and DVT occurs most often in patients over 40 years old (Moll & Severson 2004). A valid and reliable tool to measure risk for DVT in hospitalized patients could advance nursing knowledge and improve patient outcomes. The purpose of this project was to develop an accurate tool to assess patient risk for DVT in hospitalized patients and to test the tool for validity and reliability.

## BACKGROUND AND SIGNIFICANCE

The pathophysiology of DVT was described by Virchow in 1846 as a triad of changes in the vessel wall (injury), changes in the pattern of blood flow (venous stasis), and changes in the constituency of blood (hypercoagulability; Yang 2005). The triad of physiologic changes that cause DVT can occur in hospitalized patients because of many different diagnoses, therapies, and treatments. Patients on bed rest may have changes in blood flow; patients on new medications may have changes in blood coagulation processes; or patients may have injury to a vessel wall due to surgery or other invasive treatments. Venous thrombosis of a bedridden patient can be asymptomatic, and the first symptom may be pulmonary embolism. Therefore, early intervention to prevent venous thrombosis is essential.

Pulmonary thromboembolism (PE) is not a disease, but rather a complication from underlying venous thrombosis. Pulmonary Embolus (PE) is the third most common cause of death in the United States and Europe with at least 950,000 deaths annually (Cardin & Marinelli 2004). It is the most common cause of unexpected death in hospitalized patients. Many patients who develop PE have not had any diagnostic workup for this problem, nor have they received any preventive treatment (Riedel 2001). Autopsy evidence shows that a substantial number of patients dying in a hospital have had a PE, but that the diagnosis was missed.

Because DVT, and the follow-up complication of PE are preventable, nursing assessments and follow-up interventions for patients at risk for DVT while hospitalized are essential (Deagle et al. 2005). Nurses should not use clinical judgment alone to accurately assess a patient's risk for development of DVT because there are facts related to the patient's family history and past medical history that may increase the individual risk for DVT in a particular patient.

Miron et al. (2000) studied the use of the Wells' score, a formal score based on items given a fixed value compared to an empirical assessment based on a predefined list of

items weighted based on an individual patient's situation. Two hundred and seventy outpatients were studied. Final prevalence of DVT in this group was 21.1%. While agreement between the two groups based on the scores of each assessment were poor, accuracy of diagnosing DVT was excellent in both.

Developing a tool that is reliable and valid in predicting the risk for DVT is an important aspect of evidence-based nursing practice. Using a tool that has been prepared based on nursing knowledge and experience without testing the tool for reliability and validity may not provide an accurate measure of risk leading to less-than-effective results when assessing risk for DVT or PE in hospitalized patients.

Heightening the awareness of nurses who care for patients at risk for DVT or PE may promote the early and effective implementation of nursing interventions for this life-threatening and costly problem. An accurate, valid, and reliable tool to measure patients' risk for DVT can enable nurses and other providers to obtain information to assist in reducing the incidence of this life-threatening event in hospitalized patients.

## INSTRUMENT DEVELOPMENT

The nursing research committee at JFK Medical Center in Atlantis, Florida, USA, established prevention of DVT in hospitalized patients as a priority. The committee determined that hospital length of stay, multiple patient diagnoses, treatment of patients by multiple physicians, multiple medications, and drug regimens during the hospital stay increased the need for a nursing DVT risk assessment tool. Such a tool could assist in the development of a coordinated effort to reduce the risk of DVT and to improve patient outcomes in this area.

Research committee members believed that using a tool to accurately determine the risk of DVT in each hospitalized patient might assist nurses in intervening earlier and preventing complications. After a review of current risk assessment tools collected, the committee believed that these tools did not accurately stratify the risk of DVT or PE in individual hospitalized patients. In many cases, every patient admitted to the hospital was at high risk for DVT or PE, whereas hospital statistics of DVT or PE acquired during the hospital stay are about 5%. While reduction in the percentage of hospital-acquired DVT is desirable, simply evaluating almost every patient as high risk will divert attention from those who need careful assessment and intervention.

Based on a review of hospital data, the committee discovered that some areas of the hospital, such as orthopedic surgical areas, which are traditionally seen as high risk for DVT or PE, had a heightened sense of awareness about risk

and therefore, the incidences were lower than the hospital norm. In other areas, where the awareness of risk was low, such as on the cardiovascular units, a higher-than-normal incidence of DVT was present. Many of the risk assessment tools that were reviewed identified risk factors for DVT or PE in only a single patient group, such as surgical patients, obstetrical patients, orthopedic surgical patients, and cancer patients. The committee was concerned that current assessment tools did not consider the multiple problems and diagnoses typical of most hospitalized patients. Patients may not be adequately assessed by a tool that measures only one type of risk (orthopedic, surgical, cancer) and inadequately measures overall patient risk for DVT or PE.

Therefore, the committee decided to undertake the development of a reliable and valid risk assessment tool for nurses to use in all hospitalized patients to evaluate the overall risk for DVT. The goal of the committee was to develop the tool, measure reliability and validity, and then design prevention objectives for patients at different levels of risk.

Instrument development and testing took place in three phases: (a) investigation and clarification of the risks and predisposing factors for DVT and PE, (b) item development and weighting of each item to develop a total score, and (c) testing the newly developed instrument for validity and reliability.

### **Phase 1: Investigation and Clarification of Risk and Predisposing Factors**

To clarify the predisposing factors that increase risk for DVT, a literature search was undertaken. Parameters of the search included articles from four computer databases: OVID, Cumulative Index of Nursing and Allied Health Literature (CINAHL), ELSEVIER, and WEB of SCIENCE. Literature from years 2000 through 2005 was reviewed including theoretical papers, as well as qualitative and quantitative studies from nursing and medicine. Additionally, local hospitals and hospitals within the HCA network were asked to share DVT risk assessment tools they were using. In all, 15 DVT risk assessment tools were found and evaluated.

Findings from this literature review and the review of existing tools to measure DVT risk indicated that deep vein thrombosis occurs in the hospital setting most often in older patients, those who are immobile and confined to bed rest, and those who have increased body mass index (Crowther & McCourt 2005). General medical patients placed on bed rest for a week, patients in critical care areas of the hospital, patients admitted to coronary care after myocardial infarction, and patients who have had a coronary artery bypass are at greater risk for acute DVT (Leizorovicz

& Mismitte 2004). Patients with a family or personal history of DVT or PE or a genetic thrombophilia are at higher risk for a repeat problem. Diagnoses that increase the risk of DVT include surgery (especially orthopedic, pelvic, or cancer), cardiovascular disease, cancer, infection, trauma, pregnancy, post partum, chronic obstructive pulmonary diseases, and systemic lupus erythematosus. Medications and drugs that increase risk for DVT include estrogens, oral contraceptives, IV drug abuse, and heparin-induced thrombocytopenia. The wide range of patients at risk for DVT when hospitalized would benefit from an overall DVT risk assessment, which would heighten nursing awareness of DVT risk factors.

### **Phase 2: Item Development and Weighing**

The DVT risk assessment tool was developed as a group project by the research committee at the hospital. Based on the previous review of literature, the committee determined that there are many risk factors for DVT, and the committee determined that almost every hospitalized patient had some risk for DVT or PE. Additionally, the committee found a variety of tools with an assortment of content items and different ways of determining the overall risk of DVT and PE.

One of the major concerns for the group was that every patient admitted to the hospital could be assessed as being at risk for DVT and awareness of increased risk would be diluted. Therefore, the group determined that a more useful way to measure overall risk was to stratify the risk factors individually as 1 (low risk factor), 2 (moderate risk), or 3 (high risk factor). The numbers were assigned to each risk factor based on current evidence in the research literature, nursing judgment, and input from medical staff.

Once the risk factors were weighted and points assigned, the points for each factor would be added to determine an overall risk for DVT. The overall risk was again rated as low risk (overall score less than 6), moderate risk (overall score from 7–12), and high risk (overall score greater than 12).

Risk factors for DVT were grouped according to body system. Risks were grouped together and weighted equally if the committee believed that the risks were related physiologically, equally determinant of risk, and not cumulative in effect. Factors outside of body systems known to contribute to DVT and PE risk were added as individual groups. These included weight as body mass index (BMI) and age. At JFK Medical Center, BMI is calculated by the computer and placed in the patient's record during the admission assessment. Any BMI over 30, which indicates obesity, was evaluated at the highest risk level. BMI less than 30 did not receive any points. Age was grouped into three levels: Ages 40–65 years are a lower risk for DVT or PE, ages 66–70

years are at greater risk, and those over 70 years are at the highest risk in the age category.

Once the JFK DVT risk assessment tool was complete, the committee began to develop methods for measuring the validity and reliability of the tool to determine if the score did indeed indicate an increased risk for DVT and whether the tool consistently determined who was at high risk for DVT. Table 1 shows the tool in its final form to date.

### Phase 3: Testing the Tool for Validity and Reliability

There is little research on the effectiveness of nursing assessment in patients at risk for hospital acquired DVT or PE (Boscainos et al. 2006). Many assessment tools have been developed based on the pathophysiology of DVT and PE and on current nursing experience. However, these tools do not establish which combination of risk factors is most indicative of a high risk for the development of DVT or PE, nor have these tools been tested for reliability and validity. The extent to which any tool or instrument used in nursing has been tested for validity and reliability has a profound influence on the usefulness of the measurements produced. The use of invalid measures produces inaccurate generalizations about the population and therefore affects the ability of the measure to improve clinical practice.

The overall reliability, validity, and accuracy of currently used tools reviewed by the committee had not been assessed. Therefore, the purpose of phase three in this study was to test the capability of the newly developed JFK DVT risk assessment tool to accurately reflect which patients were at low, moderate, or high risk for DVT and PE, and to determine if the results of the risk assessment were consistent when assessed by different nurses for the same patient.

Why is it necessary to test a tool for validity and reliability if we are measuring risk factors that have already been identified in the literature? There are many DVT risk factors that have been identified in hospitalized patients; however, the weight of each factor is not equal in determining overall risk. Simply assessing for risk factors does not account for combinations of risk factors in the same patient. Simply compiling a list of risk factors and adding them up does not provide an adequate picture of the risk for DVT in any individual patient. The newly developed JFK DVT risk assessment tool provides weighted elements of risk so that stratification could be achieved to determine who was at high, medium, or low risk.

A tool is considered valid when it measures what it is supposed to measure; in this case whether the JFK DVT risk assessment tool allows accurate identification of those patients at low, medium, and high risk for DVT. Using measurement tools that have strong evidence of validity increases confidence in findings because the researchers

**TABLE 1**

JFK Medical Center DVT Assessment Tool

Age	
—1—	40–65
—2—	66–70
—3—	Over 70
Surgical	
—1—	GI surgery, splenectomy, gynecological surgery
—1—	General anesthesia
—2—	Burns
—3—	Neurosurgery—Acute spinal injury with surgery
—3—	Orthopedic surgery patient
Cancer	
—1—	Cancer surgery, Taking tamoxifen, tumor
—2—	Undergoing chemotherapy, radiotherapy
Cardiovascular	
—2—	Acute MI, heart failure, valvular disease, chest pain
—2—	History of varicose veins
—2—	History of nonhemorrhagic stroke or carotid artery disease
—3—	Atrial fibrillation
Obesity	
—3—	Obese- BMI >30
Respiratory/Renal	
—1—	Nephrotic syndrome
—2—	Moderate-to-severe pneumonia or COPD
—2—	Renal failure/hemodialysis
—2—	Smoker (current or history of)
—3—	Mechanical ventilation
Infection, Inflammation, and Immobility	
—1—	History of inflammatory diseases (lupus, inflammatory bowel disease, rheumatoid arthritis, scleroderma)
—3—	Sepsis
—3—	Current immobility (bed rest, paralysis)
—3—	Cast/traction/splint/collar
—3—	Leg ulcers or venous stasis
—3—	Decreased mobility
Trauma, Thrombophilia and Thromboembolism	
—2—	Family history of DVT or pulmonary embolism
—3—	Multiple injuries and lower extremity or pelvic fractures
—3—	History of prior DVT or pulmonary embolism
—3—	Long bone fracture
Other	
—1—	Postpartum < 1 month or current pregnancy
—2—	ALL central venous catheters/PICC lines
—3—	Taking birth control medications or hormone replacement therapy
Length of Stay (Days)_____	
Scores indicated the following:	
1–6 =	low risk
7–12 =	moderate risk
>12 =	high risk

know that they are measuring what they intended to measure.

Reliability determines if the DVT risk assessment tool is consistent in its measurement. Does the tool measure

DVT risk in the same way each time it is used? Therefore, testing an instrument's reliability enables researchers to feel confident that the instrument will be consistent in the evaluation of each participant each time the instrument is administered.

## THE STUDY

In order to test the DVT risk assessment tool for reliability and validity, two groups of patients were compared. Using diagnoses codes, the medical records of 72 patients who had been diagnosed with a hospital-acquired DVT or PE within the first 6 months of 2004 were compiled. Second, the medical records of 72 patients who had not been diagnosed with a hospital-acquired DVT or PE were compiled. The two groups were similar in gender and diagnosis. An ANOVA indicated that no significant difference in the mean age between the two groups ( $f = .027, p = .871$ ) existed. Table 2 shows differences in demographic data.

The postdischarge chart of each patient was scored using the JFK DVT risk assessment tool. Included in the scoring was the length of stay in number of days. Using a contrasted group approach, content validity of the JFK DVT risk assessment tool was measured. An ANOVA showed the variance in the means of the total scores of each of the two groups. There was a significant difference between the mean total scores of the DVT/PE group when compared to the scores of the non-DVT/PE group, with the scores of the DVT/PE group being significantly higher ( $f = 30.31, p = .001$ ). Measuring the difference between mean scores on the DVT assessment tool, using a  $t$  test for each indi-

vidual measure, the greatest differences between the mean scores of the two groups were a greater length of stay in the DVT/PE group compared to the non-DVT/PE group ( $f = 17.1, p = .001$ ). Body mass index (BMI) was included in the total score for those people with a BMI over 30, and no significant difference was found between the two groups on this measure ( $f = .128, p = .721$ ). The mean BMI in the DVT/PE group was 29.2 and in the non-DVT/PE group the mean was 28.6. Table 3 shows an analysis of differences between the two groups.

To measure the reliability of the instrument and thereby determine the degree of consistency between the scores obtained at two or more independent times of testing, interrater reliability was measured. This was considered to be the best measure of reliability because the instrument was completed by nurse collection and scoring of data from the medical record. In order for an instrument of this type to be reliable, data must be systemically recorded and scores must be relatively the same for each assessment made no matter who is completing the instrument. Interrater reliability is important for minimizing bias in data collection between different nursing staff. To determine whether different nurses scored the test in the same way, three different nurses independently scored each of the 144 charts at different times and without knowledge of each other's efforts. Statistically significant correlations between the means of the three observers produced an interrater reliability estimate of .94 indicating a high level of agreement among observers. This means that when scored independently by three different nurses, the scores were relatively the same.

## DISCUSSION

Accurate assessment of the risk for DVT or PE in all hospitalized patients could provide nurses with a valuable method to assist in the prevention of a common problem that increases morbidity and mortality. The tool is simple to use and adapts well to computerized charting. While other measurement tools are currently being used in hospitals, there are few, if any, that have been tested for validity and reliability in a variety of patients. Because of this lack of testing, one has less confidence in the tool's capability in consistently predicting risk levels for DVT or PE.

Stratifying risk of DVT or PE can assist nurses in choosing the most effective and least costly method of prevention based on a patient's level of risk. Many levels of therapy for the prevention of DVT or PE exist; however, some are more costly and complicated than others. It is important to know the most appropriate type of treatment for DVT prevention, such as "blood thinning" medication to lower risk, or less costly interventions like frequent ambulation and thromboembolic stockings. Nurses are being asked to coordinate

**TABLE 2**  
Demographic data

GROUP	MEAN AGE STANDARD DEVIATION (SD)	GENDER	ADMITTING DIAGNOSIS
DVT/PE Group ( <i>N</i> = 72)	77.4 (SD – 3.2)	48 Women 24 Men	58% Cardiovascular 17% Renal or Pulmonary 16% Inflammation/Infection 9% Cancer 42% of patients had surgery
Non-DVT/PE Group ( <i>N</i> = 72)	78.2 (SD – 2.1)	42 Women 30 Men	57% Cardiovascular 20% Renal or Pulmonary 18% Inflammation/Infection 5% Cancer 44% of patients had surgery



**TABLE 3**

Analysis of variance between groups

Variable	MEAN DVT GROUP N 71	MEAN NON-DVT GROUP N 71	DF	SD DVT GROUP	S D NON-DVT GROUP	F	SIGNIFICANCE
BMI	29.20	28.66	1	8.82	8.89	.128	.721
Length of Stay	9.18	5.35	1	8.89	3.64	17.74	.000
Total Score on Instrument	12.71	8.23	1	5.32	4.31	30.31	.000
Total Number of Diagnosis	3.21	2.23	1	1.27	1.13	22.92	.000

patient care, monitor patient safety, and improve overall patient outcomes. This simple tool has shown accuracy and consistency in identifying a serious potential problem and allows nurses to intervene early, possibly preventing DVT, a costly and problematic side effect.

The JFK DVT risk assessment tool developed and tested in this study has shown overall reliability and validity in the measurement and stratification of risk for the development of DVT in hospitalized patients. The overall score for patients that had developed DVT or PE while being hospitalized was significantly higher than the scores of patients of the same age with similar diagnoses. Interrater reliability was also indicated by a comparison of the scores for each of the patients in both groups by three different nurses who scored information from patient records independently of each other.

### LIMITATIONS AND CONSIDERATIONS FOR FURTHER RESEARCH

Limitations in this study include the fact that participants came from only one hospital, and sample size was small. Further study should be undertaken to establish validity and reliability using a larger, more diverse sample. This type of study would further establish the reliability and validity of this measure. Second, a post hoc analysis should be undertaken to determine current levels of DVT preventative treatments for different types of patients in different hospitals so that an overall treatment plan based on the use of this JFK DVT risk assessment tool could be developed.

Currently at the hospital where this tool was developed, each patient is being assessed using this tool on admission and every 3 days after admission. Results of risk assessments are posted on the front of the chart for the physician to acknowledge. The next step in this hospital's process will be to work with physicians to develop treatment protocols based on the assessment tool and study of the effectiveness of these protocols.

### CONCLUSIONS

Nurses have a responsibility to provide assessment and prevent problems in hospitalized patients. Deep vein thrombosis and pulmonary embolism are two problems that pose a great threat to hospitalized patients and increase mortality in this group. The most effective method to reduce DVT or PE in hospitalized patients is prevention. Therefore, a risk assessment tool was developed and tested for validity and reliability to provide confidence that the tool does measure risk for DVT or PE and that the risk is consistently measured regardless of who is obtaining the data.

Evidence-based nursing is the process by which nurses make clinical decisions using the best available research evidence, their own clinical expertise, and patients' preferences. To develop the JFK DVT risk assessment tool, nurses used evidence from research, nursing expertise, and collegial dialogue with physicians. Inherent in evidence-based nursing is the continual assessment of the validity and reliability of daily practice activities. As nurses confront questions about assessment, treatment, prevention, and the cost effectiveness of care, measurement tools that are valid and reliable will allow nurses to practice based on evidence. The JFK Medical Center DVT risk assessment tool is an example of the ability of nurses to develop, test, and use a tool that is helpful for assessing risk for DVT and PE.

### INDICATIONS

- The most successful therapy for success in hospitalized patients at risk for DVT and PE is careful assessment and early intervention.
- The JFK DVT Risk Assessment Tool is simple to use and is easily adapted to computerized charting.
- The JFK DVT Risk Assessment Tool has shown content validity. The overall score for patients who had developed DVT or PE while hospitalized was significantly higher than were the scores of patients of the same age with similar diagnoses.

- Interrater reliability was shown when three different nurses independently assessed different patients and obtained the same scores.

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