PRACTICAL SUMMARIES IN

ACUTE CARE

A Focused Topical Review of the Literature for the Acute Care Practitioner

DVT: New Therapeutic Perspectives
Part II

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Introduction

Therapy for acute deep venous thrombosis continues to evolve. In the second part of this review, the roles of elastic compression stockings and early ambulation are discussed. Adjunctive therapy with venocaval filters and catheter-directed thrombolytic therapy is reviewed in detail. Clinical research on the new oral direct thrombin inhibitors is presented.

Graduated Elastic Compression Stockings for Postthrombotic Syndrome Prevention — Simple but Effective

Source: Prandoni P, et al. Below-knee elastic compression stockings to prevent the post-thrombotic syndrome: a randomized controlled trial. *Ann Intern Med* 2004;141:249-256.

The postthrombotic syndrome affects approximately 50% of patients with deep venous thrombosis (DVT) after 2 years. The elderly and those patients with recurrent ipsilateral DVT have the highest risk. Below-the-knee elastic stockings assist the calf muscle pump and reduce venous hypertension and venous valvular reflux. This reduces leg edema, aids the microcirculation, and prevents venous ischemia.

The authors conducted a randomized controlled trial (RCT) in an Italian university setting involving 180 patients who presented with a first episode of symptomatic proximal DVT. They sought to evaluate the efficacy of graduated below-the-knee elastic compression stockings (ECS) in the prevention of the postthrombotic syndrome (PTS). After conventional anticoagulation with heparin, patients were discharged on therapeutic warfarin for 3-6 months and randomly assigned to the control (no ECS) or the ECS group. Graduated compression stockings with ankle pressures of 30-40 mmHg were given to the participants, who were required to wear them daily on the affected leg over 2 years. Ninety percent of trial participants were compliant (wore the stockings for at least 80% of daytime hours) and 5-year cumulative data were evaluated to compare the incidence of PTS between the groups. A standardized validated scale was used to assess symptoms, severity, and/or progression of PTS. The postthrombotic syndrome occurred in 26% of patients who wore ECS as compared to 49% of patients without ECS. All PTS patients except one developed manifestations of the syndrome within the first two years after the initial diagnosis of DVT. The number of patients who need to be treated with ECS was estimated at 4.3 to prevent one case of PTS. The adjusted hazard ratio was 0.49 (CI 0.29-0.84, P = 0.011) in favor of the ECS. Almost 50% of their patients with proximal DVT developed PTS

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within 2 years. The regular use of graduated elastic compression stockings reduced the incidence of the syndrome by 50%.

The authors also noted that the benefit conferred by ECS was not related to the rate of recurrent DVT that was identical in both groups. The authors strongly recommend the early use and widespread implementation of graduated elastic stockings with adequate anticoagulant therapy for symptomatic proximal DVT to prevent the development of the postthrombotic syndrome.

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Commentary

The Seventh American College of Chest Physicians (ACCP) Conference on Antithrombotic and Thrombolytic Therapy observed that PTS occurs in 20-50% of patients with objectively confirmed DVT and assigned a grade 1A recommendation for the use of graduated elastic compression stockings for 2 years after the onset of proximal DVT. This RCT reaffirms the efficacy of this simple therapeutic intervention. The article adds to the current literature that also supports the use of graduated elastic compression stockings. With the adoption of outpatient therapy for proximal DVT, the initial management of DVT increasingly becomes the responsibility of the emergency physician. It, therefore, behooves us to prescribe graduated elastic compression stockings to all of our DVT patients at discharge.

Mobilizing Patients with DVT?

Source: Partsch H. Ambulation and compression after deep vein thrombosis: dispelling myths. *Semin Vasc Surg* 2005;18:148-52.

This study reviews the myths surrounding immediate ambulation and compression in the patient with newly-diagnosed DVT. It is well recognized from the older literature that almost 50% of patients with acute proximal DVT have evidence based on ventilation-perfusion (V/Q) pulmonary scanning of asymptomatic pulmonary embolism at baseline. Analyzing the effect of ambulation and compression in this patient cohort focuses on development of a new pulmonary embolism, relief of pain and swelling, and reducing the frequency and severity of the postthrombotic syndrome.

The author cited two small, previous studies that demonstrated that the incidence of a new pulmonary embolism after initiation of anticoagulant therapy with a low molecular weight heparin (LMWH) did not increase significantly in patients treated with early ambulation and compression. The author had previously reported his own prospective cohort study of 1289 patients with acute DVT treated as outpatients with LMWH, early ambulation and compression. Partsch reported that only 77 (5.9%) patients developed a new pulmonary embolism (PE), of which only 6 (0.4%) were symptomatic and only 3 deaths (0.23%) were attributed to the pulmonary embolism. This was not significantly different than historical controls. The authors concluded that early ambulation and compression is not associated with any significant risk of PE.

In Europe, early ambulation and compression has been the mainstay of adjunctive treatment for DVT. In North America, the unsubstantiated fear of dislodging clots by ambulation led clinicians to recommend

Correction

The disclosure information for Donald H. Schreiber, MD, CM, FRCPC, FACEP, was incorrect in the May 2007 issue. He received grant/research support from Abbott i-STAT and is on the speaker's bureau for Sanofi Aventis, Inc.

bed rest and leg elevation to their patients. The author explained that bed rest promotes venous stasis, which is a major risk factor for DVT. Therefore, this may actually enhance thrombus propagation and the risk of subsequent PE.

The author cited a number of other studies that revealed a significant decrease in leg swelling (using leg circumference measures) and pain (analog pain scales and quality of life scores) with early ambulation and compression. He also recognized the limited data that are available to assess the effect of early ambulation and compression on the subsequent development of the postthrombotic syndrome (PTS). In his own small trial, the author reported a trend toward a lower incidence of PTS. He conceded that a larger long-term study would be required. Nevertheless, the author strongly recommended early ambulation for patients, and having them wear compression dressings for a year.

Commentary

The majority of clinical trials in DVT have concentrated on pharmacologic therapeutic modalities and have rarely addressed the simple question of early ambulation and compression. The ACCP Consensus Conference on Antithrombotic and Thrombolytic Therapy for VTE recommends ambulation as tolerated for patients with DVT. The authors of this review article convincingly dispel the myth of bed rest and leg elevation for acute DVT. Although the trials cited were small or not randomized, the data are compelling. Early ambulation on day 2 after initiation of outpatient anticoagulant therapy with LMWH in addition to effective compression is strongly recommended. Compression is best achieved by applying elastic bandages or high quality compression stockings. It is emphasized that early ambulation without compression is not recommended. The fear of dislodging clots and precipitating a fatal pulmonary embolism is unfounded.

Vena Caval Filters — When, Where, and Which One?

Source: Rectenwald JE. Vena cava filters: uses and abuses. *Semin Vasc Surg* 2005;18:166-75.

In this article, Rectenwald reviews the plethora of approved vena caval filters and the ever-increasing list of indications for inferior vena cava (IVC) filter placement. In the mid 1900s before the adoption of anticoagulant therapy, DVT and PE were generally managed by laparotomy and vena caval ligation. Mortality rates were high. The next evolutionary step was the introduction of vena caval clips that were applied during laparotomy. These were meant to decrease the luminal diameter of the IVC but were associated with poor results.

The next step was the development of permanent filters inserted transvenously under simple local anesthesia. The current benchmark standard is the Greenfield filter. More than 20 years of long-term follow-up experience with this filter is available. Its design incorporates all the features of an ideal filter: maintain caval patency, trap emboli, preserve prograde caval blood flow, avoid stasis, and enhance thrombolysis of trapped emboli. The Greenfield filter achieved a long-term patency rate of 98%, with only a 4% incidence of recurrent pulmonary embolism. Surprisingly, there is only one randomized controlled study on venocaval filters by Decousus and coworkers published in 1998.[1] This trial randomized 400 patients with proximal DVT to filter or no filter groups. Both groups were anticoagulated with unfractionated heparin. This study design excluded patients with contraindications to anticoagulation which is one of the major indications for a veno-caval filter. After 12 days there was a statistically significant reduction in PE in the filter group (1.1% versus 4.8%, P = 0.03) but this disappeared at 2 years to become 3.4% versus 6.3%, P = 0.16. Significantly, there was a much higher incidence of later DVT in the filter group (21% versus 12%, P = 0.02).

The study by Decousus and colleagues study propelled the development and introduction of temporary/optionally retrievable filters that provide temporary prophylaxis for PE yet avoid the longer term risk of later DVT. Unfortunately, there is a lack of randomized prospective studies evaluating the use of these retrievable filters despite their ever increasing use. Today there are more than 10 different retrievable vena caval filters available. This begs the question: who gets what filter? Furthermore, the author points out that despite the fact that these new filters are supposed to be removed or repositioned within 2-6 weeks, less than 50% are actually removed. The author then questions the rationale for placing a temporary filter for permanent use without long-term studies when there is more than 20 years of experience with the permanent Greenfield filter.

The major indications for vena caval filters are primarily for patients who have a contraindication to anticoagulation or for patients with major complications while anticoagulated (hemorrhage or heparin induced thrombocytopenia). The use of vena caval filters has expanded to include primary

venous thromboembolism (VTE) prophylaxis in special patient populations such as major trauma patients, major surgery patients, patients with advanced malignancy, and neurological or neurosurgical patients with paralysis or prolonged immobilization. These special patient populations are generally characterized by contraindications to anticoagulation, ineffective anticoagulant prophylaxis, hypercoagulable states, or other exceedingly high risks of PE.

For example, in major trauma patients the risk of VTE events are very high, but anticoagulant therapy and intermittent pneumatic compression devices may be contraindicated. IVC filter placement has been promoted to prevent PE through the patient's temporary risk period. However, only limited studies have been published that fully evaluate this strategy.

The author also reviews the use of intravascular and transabdominal ultrasound for correct placement of these filters. The advantage of both techniques is that the filters may be placed at the bedside in the ICU, thereby avoiding the pitfalls and difficulties of transporting the patient to the angiography suite. The transabdominal ultrasound machines are generally more readily available and do not require a separate femoral venous puncture. There also is more experience with their use. However, the patient's body habitus must provide adequate acoustic windows to permit the transabdominal approach.

In addition, the author extensively reviews the clinical experience with specific venocaval filters, including the Greenfield, the Bird's Nest, Simon Nitinol, TrapEase, and VenaTech filters.

The author concludes his review with a call for more study and more data on which filter to use. The temporary optionally retrievable filters have the ultimate advantage but currently are removed less than half the time and there are no proven long-term results.

Table 1. Primary Indications for Vena Cava Filter Placement in DVT or PE

- ❑ Contraindication to anticoagulation
- ❑ Failure of anticoagulant therapy ie recurrence despite adequate anticoagulation
- ❑ Major hemorrhagic complications
- ❑ Heparin-induced thrombocytopenia
- ❑ Acute massive PE where efficacy of anticoagulant therapy is reduced
- ❑ Reduced cardiopulmonary reserve where additional PE would not be tolerated
- ❑ Free floating large DVT or propagation to ileofemoral DVT despite anticoagulant therapy
- ❑ Failure of pre-existing filter and caval filter is still indicated
- ❑ Patients with recent DVT undergoing major surgery where anticoagulant therapy must be temporarily discontinued

Commentary

This well researched review article discusses current controversies and reviews the clinical experience with specific vena caval filters. It is important for the emergency physician to recognize the primary indications for vena cava filter placement and to consult the appropriate service. See **Table 1**. The ACCP also has recommended vena caval filter placement for similar indications. In addition, evidence is accumulating that vena caval filters should be used for true VTE prophylaxis in high-risk patients in whom anticoagulation and pneumatic compression devices are contraindicated or ineffectual. This ever growing list includes major trauma patients, those with gastric surgery for morbid obesity, neurological and neurosurgical patients with paralysis or prolonged immobilization, and certain cancer patients.

The author points out that filters may be placed at the bedside using intravascular or transabdominal ultrasound, thereby avoiding the pitfalls of transferring critically ill patients to the angiography suite.

Although extensive experience has accumulated with the Greenfield permanent filter, there is a significant advantage to the newer temporary/optionally retrievable filters. However, there have not been any randomized large trials that have fully evaluated this new technology despite the fact that they are being used in ever increasing numbers and in the majority of cases are not being removed. The question still remains; which filter is best?

Thrombolytic Therapy for Iliofemoral DVT

Source: Vedantham S, et al. Society of Interventional Radiology position statement: treatment of acute iliofemoral deep vein thrombosis with use of adjunctive catheter directed intrathrombus thrombolysis. *J Vasc Interv Radiol* 2006;17:613-616.

The authors present a position statement from the Society of Interventional Radiology (SIR) that supports the adjunctive use of

catheter-directed intrathrombus thrombolysis (CDT), in addition to anticoagulant therapy for carefully selected patients with acute iliofemoral deep vein thrombosis. The authors evaluated this therapeutic option in the context of the major therapeutic goals for the treatment of DVT (deep vein thrombosis): 1) provision of early symptom relief; 2) prevention of the postthrombotic syndrome (PTS); and 3) prevention of pulmonary embolism.

The ACCP had previously recommended systemic thrombolytic therapy for select patients with DVT in the clinical setting of massive iliofemoral DVT and associated limb ischemia or vascular compromise. CDT is an image guided therapy in which a thrombolytic agent is administered directly into the thrombus and enhances thrombus removal. Second, balloon angioplasty and stents may be used at the same time to treat any underlying venous obstruction that predisposes the patient to recurrent DVT. Direct intrathrombus delivery of the thrombolytic agent achieves higher drug concentration at the site of thrombosis with a lower total dose than would be used with systemic intravenous thrombolytic therapy. This is the suggested mechanism for the lower incidence of systemic and, in particular, intracranial hemorrhagic complications with CDT.

The authors cited a number of comparative studies that support the use of CDT to prevent postthrombotic syndrome (PTS) and provide rapid symptom relief. They explained that the natural history of iliofemoral vein DVT is different than isolated femoropopliteal DVT. In the latter group, recanalization and collateral venous blood flow limit the degree of PTS. However, in the iliac veins, adequate recanalization is unlikely and collateral venous blood flow is minimal. This leads to persistent venous outflow obstruction and an increased risk of PTS. Long-term studies of patients with iliofemoral DVT reported a 44% incidence of venous claudication at 5-year follow-up with standard anticoagulant therapy alone. Furthermore, the rate of recurrence of DVT is twice as high in patients with an iliofemoral DVT than in those with more distal, femoral-popliteal DVT. The authors referenced a meta-analysis that demonstrated a 90% success rate with CDT for thrombus removal as well as a case-control study that reported a decreased incidence of PTS compared to anticoagulant therapy alone.

SIR recognized that the main risk of adjunctive CDT is bleeding. Their pooled review of 19 published studies reported an 8% incidence of major bleeding and an intracranial bleeding rate of only 0.2% for CDT that is less than that reported for systemic thrombolytic therapy. Furthermore, the incidence of pulmonary embolism was 1.0%. That also is less than the incidence of pulmonary embolism complicating standard anticoagulant therapy. However, they conceded that no prospective randomized study has yet been conducted to evaluate CDT versus standard anticoagulant therapy for iliofemoral DVT. In conclusion, the SIR affirms that the available evidence defends a clinical benefit of CDT in the specific subgroup of patients with iliofemoral DVT, limb-threatening disease, and low bleeding risk.

Commentary

To consider CDT, the emergency physician must first establish the diagnosis of iliofemoral DVT. Ultrasound, the primary diagnostic modality for DVT, is limited to the diagnosis of DVT in the venous system distal to the inguinal ligament. The iliac veins cannot usually be visualized by ultrasound and a different diagnostic modality must be used. Herein lies the importance of CT venography from which venous occlusion proximal to the inguinal ligament may be detected. Alternatively, MRI may be used. The diagnosis of iliofemoral DVT should be considered if the ultrasound examination reveals thrombus extending into the superficial femoral vein at the inguinal ligament. A CT venogram should be obtained to assess for proximal thrombus. Once the diagnosis of iliofemoral DVT has been confirmed, an interventional radiology consultation may be considered for possible CDT.

The SIR authors acknowledged the lack of a randomized controlled study on CDT and discussed the bleeding risks. Although the pooled data cited an 8% cumulative bleeding rate, mostly at the catheter insertion site, the range of major bleeding reported was actually 0% to 24%. Adequate anticoagulant therapy alone does not dissolve the thrombus and the iliofemoral vein is often permanently damaged. It is therefore reasonable to assume that a targeted, image-guided approach, delivering a bolus of thrombolytic drug directly into the thrombosed vein, will provide immediate symptomatic relief as well as reestablish vessel patency. What is not known, however, is the frequency of fatal complications and the magnitude of benefit that this intervention provides.

Furthermore, does restoring venous patency prevent PTS? The dichotomy arises in patients with iliofemoral DVT but without vascular compromise. These patients are usually treated conservatively with anticoagulant therapy alone. But younger patients in this cohort with extensive iliofemoral DVT may derive the most long-term clinical

benefit from CDT even in the absence of vascular compromise. In selected cases of iliofemoral DVT, interventional catheter-directed thrombolysis can achieve all the goals of therapy for DVT, but without larger randomized trials, emergency physicians must use their best clinical judgment and evaluate the risk of complications against the potential benefits. More importantly, however, emergency physicians should consider the diagnosis of iliofemoral DVT, order the most appropriate imaging study, recognize the indications for CDT, and consult when necessary.

New Anticoagulant for DVT: Ximelagatran — An Oral Direct Thrombin Inhibitor

Source: Fiessinger JN, et al. Ximelagatran vs low-molecular-weight heparin and warfarin for the treatment of deep vein thrombosis: a randomized trial. *JAMA* 2005;293: 681-689.

The Thrombin Inhibitor in Venous Thromboembolism (THRIVE) study was an international, multi-center, doubled-blinded, randomized trial that compared the efficacy and safety of ximelagatran, an oral direct thrombin inhibitor, to enoxaparin/warfarin in 2489 patients with objectively confirmed DVT. Patients were treated for 6 months with either ximelagatran 36 mg twice daily and placebo enoxaparin/warfarin, or enoxaparin/warfarin and placebo ximelagatran. Efficacy and safety were assessed by means of recurrent VTE, bleeding, and mortality. Bilateral lower extremity ultrasound examinations and ventilation/perfusion lung scans were performed at baseline. One-third of the patients had concomitant pulmonary embolism. Monthly liver function tests were monitored, and for those patients whose results were greater than twice the upper limit of normal, liver function tests (LFTs) were monitored weekly. INR was monitored per usual clinical practice. To keep the physicians double-blinded, computer generated "sham" INRs were provided to physicians for patients on ximelagatran. The recurrence rate for VTE was 2.1% in the ximelagatran group and 2.0% in the enoxaparin/warfarin group. The absolute difference was 0.2% (95% CI: -1.0% to 1.3%); that met the prespecified criterion for non-inferiority. Corresponding values for major bleeding were 1.3% in the ximelagatran group versus 2.2% in those receiving enoxaparin. Although there was a trend observed toward decreased bleeding in the ximelagatran group, this was not statistically significant. The corresponding mortality rates were 2.3% and 3.4%; this also showed a trend (but not statistically significant) in favor of ximelagatran. Alanine aminotransferase (ALT) levels exceeded 3 times the upper limits of normal in 9.6% of ximelagatran patients versus 2% of those on enoxaparin/warfarin. An increased rate of myocardial ischemia/infraction was noted in the ximelagatran group (10 patients, 0.008%) versus the enoxaparin/warfarin group (1 patient, P = 0.006). The authors concluded that oral ximelagatran administered in a fixed dose is as effective as enoxaparin/warfarin for the treatment of DVT with or without pulmonary embolism and showed similar low rates of major bleeding. Liver function tests require regular monitoring. Prospective assessment of coronary events and the mechanism of liver and cardiac abnormalities require further study.

Commentary

This study substantially adds to the literature on oral direct thrombin inhibitors. This is the largest randomized double-blind trial to date evaluating the use of an oral direct thrombin inhibitor in the treatment of DVT. The patient groups were well-matched and were representative of those seen in the emergency department setting. The authors concluded that ximelagatran was as effective as standard therapy with enoxaparin/warfarin for the treatment of objectively confirmed DVT with or without PE. The incidence of major bleeding was similar, although there was a trend in favor of ximelagatran. The previously reported elevation of ALT on long-term therapy also occurred in this study with an incidence of almost 10% but no permanent liver damage was noted and liver function tests returned to normal whether or not the drug was discontinued. A disconcerting incidence of adverse coronary events (myocardial ischemia or infarction) also was reported (0.008%, 10/1240 patients) in patients on ximelagatran. Further evaluation of the pathophysiologic basis for these findings will be required. The adverse cardiac events may be related to the paradoxical procoagulant Protein C effect noted in earlier pharmacologic studies. The U.S. Food and Drug Administration (FDA) has refused to approve ximelagatran. The company sponsor has withdrawn all applications for approval in the United States and Europe and has discontinued all clinical trials. Nevertheless, this class of drugs is an attractive alternative to warfarin. Ultimate approval in the United States will depend on the development of similar drugs without the hepatotoxic

and adverse cardiac effects. The oral direct thrombin inhibitors have the potential to facilitate and simplify long-term anticoagulation for patients and physicians.

Conclusion and Recommendations

The primary indications for vena caval filter placement include contraindication to anticoagulation, severe complications of anticoagulant therapy, and thrombus extension or massive PE despite adequate anticoagulation. The introduction of temporary/optionally retrievable vena caval filters has resulted in a dramatic increase in filter utilization despite a paucity of published randomized trials. Nevertheless, they offer the advantage of prophylaxis for pulmonary embolism without the long-term risks of DVT.

The use of elastic compression stockings and the role of ambulation are often overlooked. The evidence presented here underscores their importance in reducing the risk of the postthrombotic syndrome.

Catheter-directed thrombolysis is recommended for specific patients with iliofemoral DVT where traditional anticoagulant therapy is not as effective. The emergency physician should consider this diagnosis when duplex ultrasound reveals extensive proximal thrombus. CT venography or MRI is required to establish the diagnosis and appropriate referral to interventional radiology is recommended thereafter.

Ximelagatran, an oral direct thrombin inhibitor, potentially offers an attractive alternative to oral Vitamin K antagonists as no laboratory monitoring is required. However, adverse hepatotoxic and cardiac effects require further study before this drug can be approved.

Reference

1. Decousus H, et al. A clinical trial of vena caval filters in the prevention of pulmonary embolism in patients with proximal deep-vein thrombosis. Prevention du Risque d'Embolie Pulmonaire par Interruption Cave Study Group. *N Engl J Med* 1998;338:409-15.

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CME QUESTIONS

31. When recommending elastic compression stockings to DVT patients in the ED, it is important for patients to understand that:

a. there is sufficient evidence to show that the stockings increase the risk of PE.
b. they must wear them daily.
c. they are not at risk for postthrombotic syndrome (PTS).
d. the elastic stockings can be a substitute for oral anticoagulation therapy.

32. A vena cava filter is indicated in which one of the following patients?

a. Patient with a new acute DVT and a history of intracranial hemorrhage within the past 4 weeks
b. Patient with a recent DVT on oral warfarin therapy and a subtherapeutic INR who presents with segmental PE
c. Healthy patient undergoing laparascopic cholecystectomy
d. Patient with acute PE and no cardiorespiratory instability

33. Long-term vena caval filters in DVT are associated with:

a. reduced incidence of pulmonary embolism at 2 years.
b. increased incidence of pulmonary embolism at 2 years.
c. reduced incidence of recurrent DVT at 2 years.
d. increased incidence of DVT at 2 years.

34. Your discharge instructions to a patient with an acute DVT should emphasize:

a. bed rest with leg elevation and limited ambulation.
b. physical therapy for the affected limb.
c. early ambulation without elastic stocking compression.
d. early ambulation as tolerated with elastic stocking compression.

35. In patients with ultrasound evidence of a large proximal DVT but no clinical evidence for PE, the emergency physician should first:

a. screen the patient for exclusions to thrombolytic therapy.
b. initiate outpatient anticoagulant therapy with enoxaparin.
c. consider CT venography or MRI to rule-out ileofemoral DVT.
d. admit the patient for inpatient anticoagulant therapy with unfractionated heparin.

Answers:

31. b; 32. a; 33. d; 34. d; 35. c

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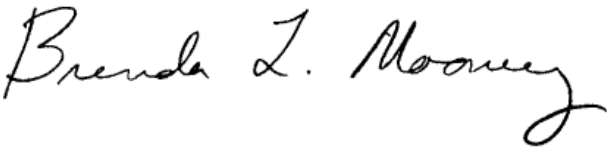

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