Patient Safety Tip of the Week

June 18, 2013

DVT Prevention in Stoke – CLOTS 3

Patients with acute stroke present us with a number of difficult decisions. In addition to investigations on the underlying pathophysiology of the stroke and treatment aimed toward that pathophysiology, much of the care of the stroke patient is aimed at preventing complications such as aspiration, decubiti, urinary tract infections, and venous thromboembolism (DVT and pulmonary embolism). Patient with acute stroke, particularly those with significant lower extremity weakness, are at very high risk for DVT and pulmonary embolism. This applies to both acute ischemic infarcts and intracerebral hemorrhages. And in both types there is either significant risk of hemorrhagic transformation or worsening of hemorrhage when pharmacological prophylaxis is used.

So we have long faced this dilemma in determining the best course of action to prevent VTE in stroke patients. Guidelines have suggested use of pharmacoprophylaxis in patients at high risk for VTE who are low risk for bleeding. Yet identification of such patients is almost impossible. Potential mechanical alternatives or adjuncts include graduated compression stockings and intermittent pneumatic compression devices (IPC's).

Our What's New in the Patient Safety World column for July 2009 "Unintended Consequences of a DVT Prevention Strategy" reported on a study (CLOTS trial 1) which showed that not only do thigh-high graduated stockings not prevent DVT in stroke patients, they actually cause harm. Skin breaks, ulcers, blisters, and skin necrosis were significantly more common in patients allocated to GCS than in those allocated to avoid their use.

But then the CLOTS Trial 2 published results that confused the issue (see our October 2010 What's New in the Patient Safety World column "Graduated Compression Stockings: CLOTS Confuses Clinicians"). Clots Trial 2 compared thigh-length graduated compression stockings to below-knee stockings and **found fewer cases of VTE with the thigh-length stockings**. The study populations and protocols for the two trials were the same, though the sites differed. The CLOTS Trial 2 was discontinued early because of the results of CLOTS Trial 1 but had already reached its predetermined enrollment goal. Proximal DVT, the primary study outcome, had an absolute risk reduction in the thigh-

length group of 2.5% and the relative risk reduction was 31%. There were no differences in distal DVT, pulmonary emboli or deaths between the 2 groups. There were more cases with skin problems in the thigh-length group but these were relatively mild.

The controversy continued with a series of papers highlighted in our April 19, 2011 Patient Safety Tip of the Week "DVT Prophylaxis in Acute Stroke: Controversy Reappears". These discussed the issues associated as much with pharmacoprophylaxis as with mechanical prophylaxis. We ended that column by stating that, in the interim, we'd probably advocate for use of pneumatic compression stockings pending the results of the CLOTS-3 Trial, which is looking at both the efficacy and safety of pneumatic compression stockings in stroke patients.

Well, the results of the CLOTS-3 Trial have now been published. That prospective randomized single-blind controlled trial demonstrates a **significant reduction in DVT in immobile hospitalized stroke patients treated with intermittent pneumatic compression devices (IPC's)**. The primary end point, DVT in a proximal vein, occurred in 8.5% of patients in the IPC group, compared to 12.1% in the no-IPC group. That 3.6% absolute difference in the primary end point translates to a **number need to treat (NNT) of 28** to prevent one proximal DVT.

The study also showed a trend toward lower mortality at 30 days in those in the IPC group (11% vs. 13%), though this was not statistically significant (the study was not powered to demonstrate a mortality benefit).

As somewhat anticipated there more skin complications in the IPC group (3% vs. 1% in the no-IPC group). There was no difference in falls with injury between the two groups.

As pointed out in the accompanying editorial (Stevens 2013) one of the biggest problems with IPC's is adherence to their use. Only about a third of the patients in CLOTS-3 were able to keep the IPC's on for the entire intended duration.

While IPC's had been shown to reduce VTE in several surgical populations, this is really the first study to demonstrate such an effect in medical patients. While it is tempting to extrapolate these results to other medical patients, stroke patients may differ enough to make such extrapolation unwise. Stroke patients are particularly at risk for DVT. Their paralysis may differentiate them from other medical patients who are immobile but may still have the capability of muscular contraction in their legs.

Many stroke centers have already begun to utilize IPC's as their primary VTE prevention intervention. It's nice to know that there is now an evidence base to back up that practice.

Some of our previous columns on patient safety issues in stroke:

July 2009 "Unintended Consequences of a DVT Prevention Strategy"

October 2010	"Graduated Compression Stockings: CLOTS Confuses Clinicians"
April 19, 2011	"DVT Prophylaxis in Acute Stroke: Controversy Reappears"
June 26, 2007	"Pneumonia in the Stroke Patient"
June 15, 2010	"Dysphagia in the Stroke Patient: the Scottish Guideline"
April 2011	"Harm from NPO Orders"
February 2012	"Swallowing Evaluation in Stroke"
July 2012	"Progress on Swallowing Testing in Stroke"
November 6, 2012	"Using LEAN to Improe Stroke Care"
March 2012	"Helicopter Transport and Stroke"
September 2012	"Obstructive Sleep Apnea in Stroke Patients"
December 21, 2010	"More Bad News About Off-Hours Care"
October 7, 2008	"Lessons from Falls from Rehab Medicine"
June 2013	"Barriers to CAUTI Prevention"

References:

The CLOTS Trials Collaboration. Effectiveness of thigh-length graduated compression stockings to reduce the risk of deep vein thrombosis after stroke (CLOTS trial 1): a multicentre, randomised controlled trial. The Lancet 2009; 373:1958 - 1965, 6 June 2009 http://www.thelancet.com/journals/lancet/article/PIIS0140-6736(09)60941-7/abstract

The CLOTS (Clots in Legs Or sTockings after Stroke) Trial Collaboration. Thigh-Length Versus Below-Knee Stockings for Deep Venous Thrombosis Prophylaxis After Stroke A Randomized Trial. (CLOTS 2) Annals of Internal Medicine 2010. Published early on line September 21, 2010 http://www.annals.org/content/early/2010/09/20/0003-4819-153-9-201011020-00280.full?aimhp

CLOTS Trials Collaboration. Effectiveness of intermittent pneumatic compression in reduction of risk of deep vein thrombosis in patients who have had a stroke (CLOTS 3): a multicentre randomised controlled trial. The Lancet 2013; Early Online Publication 31 May 2013 doi:10.1016/S0140-6736(13)61050-8 http://www.thelancet.com/journals/lancet/article/PIIS0140-6736%2813%2961050-8/abstract

Stevens SM, Woller SC. Intermittent pneumatic compression in patients with stroke. The Lancet 2013; The Lancet, Early Online Publication, 31 May 2013 doi:10.1016/S0140-6736(13)61099-5 http://www.thelancet.com/journals/lancet/article/PIIS0140-6736%2813%2961099-5/fulltext

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