Efficacy and Cost Analysis of Combined Thermal, Compression, DVT Preventative Therapy for Post-Surgical Patients

Cryotherapy and compression on soft tissue injuries is a common and standard of care practice for sports injuries, sprains and post-surgical applications. Because of this, numerous devices have been developed to maintain cold and compression on wound and injury sites. Most of these products consist of an ice driven, gravity fed or circulating cold water pump as well as a mechanical pneumatic compression pump.

By utilizing cold therapy, the temperature of the tissue is lowered and the rates of the chemical reactions that actually cause the inflammation are slowed. Therefore, more cells survive, the damage slows, and healing is accelerated.

Advances have been developed in thermal and compression technology to improve the functionality and design of these products, making them simpler and more effective for both patients and care givers. One such product is the VascuTherm line from ThermoTek, Inc. which improves post-surgical outcomes and offers safe, precise cooling as well as a pneumatic compression on the surgical site to reduce edema and additional pneumatic compression for the prevention of deep vein thrombosis (DVT) in high risk patients post surgically. In the remainder of this document the efficacy and cost analysis of cold and compression will be discussed, as well as the utilization of DVT prophylaxis in the home setting post surgically and the cost analysis thereof.

Clinical Benefits of Cold and Compression

Soft tissue trauma from injury, overuse, or surgical intervention causes an inflammatory response. At the cellular level, trauma causes disruption at the cell wall and can damage the cell and surrounding cells. As a response, the cell attempts to repair itself using anaerobic metabolism, which cannot be sustained. Because of this, the damaged cell cannot regulate the concentration gradients and allows water to pass through. As water dilutes the cells, the body releases a number of chemicals to correct the issue and get rid of cellular debris. As this happens, vasodilation occurs, increasing blood flow and transporting of fluid to the inflamed area. This process accounts for the redness and swelling sometimes associated with inflammation (Kathy Weber, 2008).

By utilizing cold therapy, the temperature of the tissue is lowered and the rates of the chemical reactions that actually cause the inflammation are slowed. Therefore, more cells survive, the damage slows, and healing is accelerated. The cold also acts as an analgesic and reduces the pain from any inflammation and the associated swelling (Kathy Weber, 2008).

It should be mentioned that cold is effective only if used properly. Using a device that is too warm is not therapeutic, while using a device that is able to get too cold can cause damage to the tissue and nerves. The VascuTherm is one of the only ice-free devices available on the market, so temperature is precise and stable, therefore removing the worry of running out of ice or running another device at a low temperature that could potentially cause frostbite. The VascuTherm is regulated to operate between specific

temperatures (43F-50F), therefore significantly reducing any risk of cold injury.

Compression also aids the effectiveness of the cold therapy by improving the contact of the cold therapy wrap with the skin. Compression also helps reduce the excess fluid that can be accumulated after soft tissue injury or trauma. The compression also addresses the musculoskeletal injury by reducing the blood flow and swelling, removing the edema and reducing post-operative blood drainage, which can be an ictus for infection or hematoma formation (Kathy Weber, 2008)The combination of cold and compression therapy is very beneficial for patients recovering from orthopedic surgery and has many far reaching benefits. In multiple clinical controlled and randomized studies, the combination of cold and compression therapy has been shown to improve outcomes in numerous ways, including lower VAS pain scores, reduction of analgesics and narcotics, lower suctioned blood loss, improved range of motion 14 days post operatively, reduce hospital stays on an average of 1.5 days, and faster independent ambulation (Joe E Block, 2010).

Economic Benefits of Cold and Compression

Because of the advantages of cold/compression therapy and the role it plays in accelerated healing, the economic ramifications should also be examined.

The most common theme in cold/compression therapy is the reduction of VAS pain scores and reduction of narcotic use. Narcotics are a controlled substance and although they are effective in reducing perceived pain, they can be potentially dangerous to patients as they are addictive and habit forming. The cost of this kind of medication ranges from $28 as an oral analgesic and up to $488 for an injected meperidine. In a knee ligament repair, it was shown that patients treated with cold/compression used 53% less injectable meperidine and 67% less oral hydroxyzine. Patients treated with cold/compression also made the transition from injectable to oral pain medications 1.2 days sooner than a control group. This can lead to a savings of over $1000 per patient when utilizing a cold and compression regime rather than narcotics alone (Joe E Block, 2010).

THE COMBINATION OF COLD AND COMPRESSION THERAPY HAS BEEN SHOWN TO IMPROVE OUTCOMES IN NUMEROUS WAYS, INCLUDING LOWER VAS PAIN SCORES, REDUCTION OF ANALGESICS AND NARCOTICS, LOWER SUCTIONED BLOOD LOSS, IMPROVE RANGE OF MOTION 14 DAYS POST OPERATIVELY, REDUCE HOSPITAL STAYS ON AN AVERAGE OF 1.5 DAY, AND FASTER INDEPENDENT AMBULATION

Cold and compression also reduces drainage output post operatively, which can maintain hemoglobin levels and reduces the formation of hematomas. This could potentially save some patients from transfusion as well as a secondary drainage procedure. According to recent figures, the loaded cost of blood is over $600 (Reitan JF, 2013) and often leads to longer hospital stays, which can cost up to $1900 per day according to the Henry Kaiser Foundation (Henry Kaiser Foundation, 2010). Cold and compression therapy was also shown to reduce hospital stays as much as 1.5 days on average, so there is an inherent cost savings in the use of these therapies as well (Joe E Block, 2010).

Overall, cold and compression therapy accelerates healing and therefore speeds recovery time. Patients have better outcomes and are able to

ambulate more quickly, go home sooner, and by the time they are back for a follow up visit, range of motion is better and the reduction of manipulation procedures will follow. By reducing the need for narcotics, blood, longer hospital stays, and fewer follow up procedures, costs are reduced on an institutional level. All of this is accomplished by a relatively inexpensive VascuTherm, which could save hospitals thousands of dollars per patient.

Deep Vein Thrombosis (DVT) Risk for Patients Undergoing Orthopedic Surgery

Orthopedic surgeries, specifically total joint replacements and fractures, are known to be the highest risk patients to suffer from DVT complications. In fact, in the absence of preventative treatments, 40%-60% of patients will suffer from DVT complications (Craig J Della Valle, 1998).

Deep Vein Thrombosis and Pulmonary Embolism (DVT/PE) are often underdiagnosed and serious, but preventable medical conditions. Deep vein thrombosis (DVT) is a medical condition that occurs when a blood clot forms in a deep vein. These clots usually develop in the lower leg, thigh, or pelvis, but they can also occur in the arm. It is important to know about DVT because it can happen to anybody and can cause serious illness, disability, and in some cases, death (CDC - Centers for Disease Control and Prevention, 2017).

This type of post-surgical complication is very common and is an epidemic causing more deaths than HIV, breast cancer and automobile accidents combined (American Public Health Association, 2003). The positive aspect of this epidemic is that there are numerous preventative measures that can be taken to significantly reduce the risk of a DVT. Some of these preventive measures include mechanical IPC, pharmacological agents or a combined approach, which is considered a best practice.

Pharmacological agents, such as LWMH (low weight molecular heparin), warfarin, etc. are routinely prescribed to patients to prevent DVT, with LWMH being the most common. This is due to the predictable dose response and proven efficacy in both clinical trials and cost analysis. However, there is a risk of bleeding complications noted in some patients ((Frederick Anderson). This is important to note in orthopedic surgeries, specifically those done without a tourniquet or other hemostatic agents, as these types of procedures cause soft tissue damage, causing an average of 663 ml of blood loss (Narayana Prasad, 2006). Even with the use of a tourniquet or other hemostatic method, hidden blood loss can cause the need to readmit a patient to evacuate a hematoma. Therefore risk factors of such bleeding complications should be evaluated prior to choosing a method of DVT prevention.

AORN also suggests that a patient's risk factors for DVT should be evaluated prior to surgery as well. Those patients that are 40-60 years old and facing a minor surgery would be considered at moderate risk while those facing major surgery and are 60 years or older were considered high risk. Other factors and comorbidities should also be examined to assess the risk beyond age and surgery such as a BMI greater than 25, smoking, hormone replacement therapy, family history of DVT, blood disorders, cancer, and/or other disease history (AORN Clinical Guidelines, 2007).

It is recommended by AORN that those patients at moderate risk should receive LWMH as well as IPC pre/intra/post op. The highest risk patients should follow this same regimen, but the amount of LWMH should be increased and more frequent. Patients at moderate and high risk should also be monitored by nurses while recovering as an

inpatient and while in recovery at home to prevent a DVT (AORN Clinical Guidelines, 2007).

Recently, the American College of Chest Physicians (ACCP) made the suggestion that patients undergoing total hip and total knee surgeries should have DVT prophylaxis for a minimum of 14 days (American Colllege of Chest Physicians, 2012). In fact, the coagulation cascade remains activated for 5-6 weeks after major orthopedic surgery. If anti-thrombic prophylaxis is stopped a week or two after surgery, there can be a secondary surge in procoagulant activity and this can lead to asymptomatic DVT, which affects half of all patients who have a DVT (James Muntz, 2009). This long period of procoagulation activity reflects the need for longer DVT prophylaxis, including in the home setting, as 45-80% of all symptomatic VTE events occur after hospital discharge. Of these events, 25% of these patients didn't exhibit any VTE symptoms while in the hospital. In a study of 1,897 patients with a confirmed VTE, 73.7% of these patients suffered a DVT in the outpatient setting within the 3 months of being discharged from the hospital. Of this percentage, 23.1% had undergone surgery (Frederick A. Spencer, Darlene Lessard, Cathy Emory, George Reed, & Robert J. Goldberg, 2007).

Statistically speaking, patients undergoing TKA generally show symptoms of a DVT by day 17 post op and for THA by day 27 if they are going to have any complications with DVT. It is suggested that high risk patients have DVT prevention for 28-35 days post operatively in order to thwart any clotting risk (James Muntz, 2009).

Costs Associated with DVT and PE

Deep vein thrombosis is the most common reason for hospital re-admittance with nearly 20% of all hospital readmissions being for either DVT or PE. The costs of readmission can add up, and for those patients that suffer from DVT, about 14% of them will be readmitted more than once within the next 12 months after the first occurrence (Alex C Spryopoulos, 2007).

For orthopedic patients, DVT rates are still high and the mortality rate can be as high as 5%. When a patient survives such an occurrence, there are costs associated with the primary diagnosis and treatments, not to mention the secondary diagnosis, etc.

THE MEDIAN MEDICAL COSTS OF PATIENTS DURING AND AFTER A DVT OR PE EVENT WERE $17,512 AND $18,901, RESPECTIVELY. FURTHERMORE, A RECURRENT DVT EVENT WAS ASSOCIATED WITH 21% GREATER COSTS AS COMPARED WITH THE INITIAL DVT EVENT.

A study of administrative claim records from January 1, 1997 through March 31, 2004, found that the median medical costs of patients during and after a DVT or PE event were $17,512 and $18,901, respectively. Furthermore, a recurrent DVT event was associated with 21% greater costs as compared with the initial DVT event (Alex C Spryopoulos, 2007).

Not only is this a huge sum for annual healthcare costs, but soon DVT will not be covered by many insurance plans if it is a patient presenting after a hospital stay or surgical intervention. This is due to CMS adopting the non-reimbursement policy for certain "never events" which is defined as "non-reimbursable serious hospital acquired conditions." This was established in order to motivate hospitals and care givers to improve patient safety and to standardize protocols (Alan Lembitz, 2009). Deep vein thrombosis following TKA and THA procedures are listed as a "no pay" event and therefore, not only is this an insurance or payer cost, but incidences like these will end up being a financial burden on the hospital and

physician. Therefore, it is imperative to provide patients with the right DVT prophylaxis in order to keep these "never events" from occurring in the first place.

DVT Prophylaxis: Pharmacological, Mechanical, or Combined Approach

Because of the enormous costs associated with a patient having a DVT complication post surgically, it is important to examine the best practices in order to keep the rates of occurrence down as best as possible. Traditionally, prophylaxis was purely thought of as a pharmacological agent given for 7-10 days post procedurally. Recently, more guidelines have suggested beginning prophylaxis prior to surgery and incorporating IPC intra operatively and post operatively, *only* when the patient was in recovery in the hospital. However, given the recent suggestions by ACCP and other studies which account for DVT being an issue most commonly occurring in the home setting, it is more common for patients to receive LWMH at least 14 days post operatively (American Colllege of Chest Physicians, 2012).

EVEN WITH THIS ADDITIONAL PHARMACOLOGICAL PREVENTION, DVT RATES ARE STILL HIGH, AT ABOUT 2-12% AFTER ELECTIVE ORTHOPEDIC SURGERY. IT IS SUGGESTED BY ACCP THAT THESE RATES CAN BE FURTHER REDUCED BY UTILIZING A COMBINATION THERAPY OF BOTH ANTITHROMBOTIC AGENTS AS WELL AS INTERMITTENT PNEUMATIC LEG COMPRESSION.

Even with this additional pharmacological prevention, DVT rates are still high, at about 2-12% after elective orthopedic surgery. It is suggested by ACCP that these rates can be further reduced by utilizing a combination therapy of both antithrombotic agents as well as intermittent pneumatic leg compression. In a review of 11 randomized controlled or clinical controlled studies it was found that by combining methods, DVT rates dropped from 4.1% to 1.6% and PE rates dropped from 2.7% to 1.1% when IPC was used in combination with pharmacological agents. Because of these findings, it is suggested that combined modalities should be used in prevention of DVT in high risk groups of patients (Kakkos SK, 2008).

Furthermore, other studies suggest that the different modalities can prevent DVT in different ways. Proximal DVT is prevented more effectively utilizing an antithrombotic drug, while calf DVT is prevented with more success utilizing IPC. These findings suggest that by using a combination approach, both proximal and calf DVT can be prevented with success and because of the cost associated with getting a DVT, there should be no spared prevention to reduce rates significantly (CW Francis, 1992).

ThermoTek's VascuTherm 4

Given that cold and compression is a common, beneficial, and cost effective modality for patients having elective orthopedic surgery and that a combined mechanical DVT prevention approach is also a beneficial, cost effective therapy for these patients for 14-35 days post-op, the next step is finding the right product to provide these therapies to patients in the home setting. A solution to all of these therapeutic modalities is the VascuTherm 4, which is the only product that effectively combines these therapies and qualifies for acceptable HCPCS codes for insurance reimbursement.

The VascuTherm 4 offers proprietary solid state technology which eliminates the need for ice and allows for precise and regulated temperature control for patient safety and comfort. It also offers standardized compression which can be used at low (15 mmHg), medium (35 mmHg), and

high (50 mmHg), as well as mechanical DVT prophylaxis on the foot or calf. These modalities are all totally programmable and are as easy for a patient to use as pressing “start therapy” on the intuitive touch screen.

All three modalities can be used simultaneously, independently, or any combination thereof, making this system ideal for use in the home. Although all 3 modalities can be used independently, the DVT therapy always works in tandem with the standardized compression, which is localized on the post-surgical site. The cycle will rapidly inflate and deflate the left DVT wrap, then the right DVT Wrap, and then inflate the thermal/compression wrap. This will effectively allow the mechanical DVT therapy to run without being interfered or compromised by the standardized compression at the surgical site.

Conclusion

By combining thermal, standardized compression and DVT prophylaxis in one easy and safe to use device, like the VascuTherm 4, patients will receive the necessary post-surgical orthopedic treatments in one simple and cost effective package. Not only will their clinical outcomes be improved, but costs will be reduced on an institutional level because patients will be more ambulant, use fewer narcotics, and readmitted less due to the use of extended mechanical DVT prophylaxis.

Scientific Literature Cited

AORN Clinical Guidelines. (2007, March). *Aorn Journal*.

Alan Lembitz, T. J. (2009). Claryfing"never events" and introducing "always events". *Patient Safety Surgery*.

Alex C Spryopoulos, M. F. (2007). Direct Medical Costs of Venouse Thromboembolism and Subsequent Hospital Readmission Rates: An Administrative Claims Analysis from 30 Managed Care Organizations. *Journal of Managed Care*, 475-486.

American Colllege of Chest Physicians. (2012). *Antithrombotic Therapy and Prevention of Thrombosis.* ACCP.

American Public Health Association. (2003). *Deep-Vein Thrombosis: Advancing Awareness to Protect Patient Lives.* Washington, D.C.: APHA.

Craig J Della Valle, M. D. (1998). Thromboembolism After Hip and Knee Arthroplasty: Diagnosis and Treatment. *Jornal of American Academy of Orthopedic Surgery*, 327-336.

CW Francis, M. e. (1992, June 3). Comparison of Warfarin and External Pnuematic Compression in Prevention of Veneous Thrombosis after Total Hip Replacement. *JAMA*, pp. 2911-2915.

Frederick A. Spencer, M., Darlene Lessard, M., Cathy Emory, R., George Reed, P., & Robert J. Goldberg, P. (2007, July 23). Venous Thromboembolism in the Outpatient Setting. *Arch Intern Med*, pp. 1471-1475.

Frederick Anderson, J. P. (n.d.). Best Practices: Preventing Deep Vein Thrombosis and Pulmonary Embolism. A Practical Guide for Improvement. *University of Massachusetts; Center for Outcomes Research of the Center for Advanced Clinical Technology*.

Henry Kaiser Foundation. (2010). *Hospital Adjusted Expenses per Inpatient Day*. kff.org.

James Muntz, M. F. (2009, August). Thromboprphylaxis in Orthopedic Surgery: How Long is Long Enough? *American Journal of Orthopedics*, pp. 394-400.

Joe E Block, P. (2010, January). Cold and Compression in the Management of Muskoskeletal Injuries and Orthopedic Operative Procedures: A Narative Review. *Open Access Journal of Sports Medicine*, pp. 105-113.

Kakkos SK, C. J. (2008). Combined intermittent pnuematic leg compression and pharmacological prophylaxis for prevention of venous thromboembolism in high-risk patients. *Cochrane Collaboration*.

Kathy Weber, M. M. (2008). *The Technical Benefits of Icing.* Chicago: Rush Medical Center.

Narayana Prasad, V. P. (2006). Blood loss in Total Knee Arthroplasty; An analysis of risk factors. *Int Orthop*, 39-44.

Reitan JF, K. F. (2013). The Burden of Blood Transfusion: a Utilization and Economic-a pilot study in patients with chemotherapy-induced anemia. *J Med Econ*, 633-8.

CDC - Centers for Disease Control and Prevention (2017). Venous Thromboembolism (Blood Clots) https://www.cdc.gov/ncbddd/dvt/facts.html