A Randomized, Prospective, Observational Clinical Outcome Study Comparing the Efficacy of Intermittent Pneumatic Compression Devices in the Prevention of Venous Thromboembolic Events

(Draft for Presentation Abstract)

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Introduction:

The purpose of this IRB approved, randomized, prospective study is to compare the effectiveness of two different types of intermittent pneumatic compression (IPC) devices, with different methodologies/technologies, along with the standard of care, in reducing the incidence of symptomatic venous thromboembolic events (VTEs) at a large community hospital. The study evaluated the efficacy of the manufacturer's thigh, calf and foot garments in reducing the incidence of deep vein thrombosis (DVT) and pulmonary embolism (PE) while the patient was hospitalized and for a three-month period after discharge. The study further evaluated patient compliance, nursing satisfaction, durability, and other issues.

Methods:

Over an 18-month period from April of 2002 through 2003, 1501 patients who were eligible by meeting inclusion/exclusion criteria were consented to participate in this study. **Patients were randomized to receive either the ALP® (Currie Medical Specialties, Inc.) or the SCD® (Kendall Healthcare) foot, calf, or thigh garments depending upon which device was ordered by the attending physician.** Each consented patient was followed daily while in the hospital by an impartial research assistant and was contacted at one and three month intervals after the device was initiated. Demographics, risk data, and all medications used while in hospital and post-discharge were collected on each subject. All symptoms and/or documented VTEs were recorded. Subjects and nurses recorded the amount of time that the device was worn, the ease of use and reliability, and rated the comfort of the device.

Results:

1471 patients were followed for the full 3 months after discharge for a 98% completion rate. The other 30 patients either refused to continue to participate or were lost to follow up before the 3 months. Of those 1471 patients participating in the completed study, 347 had been ordered foot IPCs, 75 were ordered calf garments and the remaining 1049 thigh garments while in the hospital. Within the treatment groups for both the foot, calf, and thigh garments, there were no significant differences between the groups in regards to age, sex, race, smoking history, BMI, risk score, length of stay, anti-thromboembolic stockings or pharmaceutical usage.

The overall incidence of VTEs was 1.5% (22 VTEs in 1471 subjects). **There was no significant statistical difference between the manufacturers within the foot, calf or thigh IPC groups, in terms of incidences of VTEs.** In thigh group of 1049 subjects, there were 9 VTEs (0.9%), 4 of 367 in the ALP® thigh group (1.1%) and 5 of 682 in the SCD® thigh group (0.8%). For the foot IPCs, there was an overall incidence of 3.7%, 13 in 347 patients. These were generally high-risk orthopaedic patients. There were 9 VTEs in 248 patients with the ALP® device (3.6%) versus 4 in 99 patients with the SCD® foot product (4%). Of the 75 in the calf group, there were no VTEs (0%).

There were differences in the patients' assessment of the time worn, ease of use, and comfort. Utilizing VAS scores on patients questionnaires, on a scale of 0 to 100, patients rated the ALP® products more comfortable to wear and easier to use, approximately 25% more than the SCD® devices, which resulted in increased compliance, i.e., increasing the amount of time that the garments were worn by approximately 8%.

Furthermore, a random sampling of the approximately 3000 floor staff, including nurses, techs, and physical therapists, the ALP® thigh device was selected by 81% of those surveyed over the Kendall SCD® product and the ALP® foot device was selected by 86% of those surveyed over the Kendall SCD/AVI foot wraps.

Conclusion:

This prospective, randomized study did not show any statistically significant differences in the efficacy of these two different types of IPC technologies in preventing symptomatic VTEs. The overall incidence of VTEs in this large metropolitan general hospital in patients who were at risk for VTE and had been ordered IPC's was 1.5%. Further, the incidence was 3.7% in the high-risk orthopaedic population despite prophylactic treatment. This study also demonstrated that one manufacturer's products were clearly preferred by both the patients and staff, and had increased compliance. Therefore, along with venous thromboembolism prevention, patient compliance and nursing satisfaction should also considered in selecting an IPC device.

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