lymphatics

MDPI

Article

Non-Pneumatic Active Compression Device vs. Advanced Pneumatic Compression Device for Treating Lower Extremity Lymphedema: Impact on the Medicare-Eligible Population

Thomas S. Maldonado [1,*], Michael Barfield [2], Ron Winokur [3], Todd Berland [1], Sandi Davis [4], Vicky Ralph [5], Nancy Chatham [6] and Stanley G. Rockson [7]

1 New York University Langone Health, New York, NY 10016, USA
2 Department of Surgery, University of Tennessee Health Science Center, Nashville, TN 38163, USA
3 Weill Cornell Medical Center, New York, NY 10065, USA; rwinokur@gmail.com
4 Davis Care Physical Therapy, New York, NY 10018, USA; sandisheindavis@gmail.com
5 Physical Medicine and Rehabilitation, University of Colorado, Denver, CO 80045, USA
6 St. Johns Regional Wound Clinic, Hospital Sisters Health Center, Springfield, IL 62707, USA
7 School of Medicine, Stanford University, Stanford, CA 94305, USA; rockson@stanford.edu
* Correspondence: thomas.maldonado@nyulangone.org

Abstract

Objective: Chronic edema, whether systemic or localized, is often underrecognized by providers due to limited awareness of its prevalence and debilitating impact. As result, patients suffering from this condition live with suboptimal management, diminished quality of life, and increased healthcare costs. Non-pneumatic compression devices (NPCDs) have been shown to be safe and more clinically effective in treating lymphedema (LED) than advanced pneumatic compression devices (APCD) in multiple published studies. In the latest study, the TEAYS trial, NPCDs showed superior clinical utility, better outcomes, and higher patient adherence than APCDs for managing lower extremity swelling. This sub-analysis of the TEAYS study focuses on outcomes for patients aged 65 and above diagnosed with lymphedema in the lower extremity. **Methods:** This trial was a randomized, crossover, head-to-head study across nine sites in the US in 2023. Patients were subjected to an initial 4-week washout period and then randomized to either the NPCD or a commercially available APCD. Patients used the randomly assigned initial device for 90 days followed by a second washout period before a 90-day use of the second device. **Results:** Analysis included a total of 71 patients with lower extremity lymphedema, 27 of whom were aged 65 or above, and this subset comprises the study cohort for the current study. These patients achieved statistically greater mean limb volume reduction (353.9 $\pm$ 99.17 mL) while on NPCD vs. APCD ($-$10.7 $\pm$ 125.59 mL). NPCD also showed significantly better improvement in overall quality of life (1.43 $\pm$ 0.45) vs. APCD ($-$0.10 $\pm$ 0.34). Statistically significant improvement in adherence was also observed while on NPCD (77%) vs. APCD (23%). No device-related adverse events were reported. **Conclusions:** For adults aged 65 and older with lower extremity lymphedema, non-pneumatic compression devices (NPCDs) demonstrated superior clinical outcomes—including greater limb volume reduction, improved mobility, higher adherence, and patient satisfaction—compared to advanced pneumatic compression devices (APCDs), supporting NPCDs as an effective, patient-preferred solution.

Keywords: lymphedema; phlebolymphedema; non-pneumatic compression device; advanced pneumatic compression device; Medicare

Academic Editor: Shuhei Yoshida

Received: 29 May 2025
Revised: 20 July 2025
Accepted: 3 September 2025
Published: 13 September 2025

Citation: Maldonado, T.S.; Barfield, M.; Winokur, R.; Berland, T.; Davis, S.; Ralph, V.; Chatham, N.; Rockson, S.G. Non-Pneumatic Active Compression Device vs. Advanced Pneumatic Compression Device for Treating Lower Extremity Lymphedema: Impact on the Medicare-Eligible Population. *Lymphatics* **2025**, *3*, 27. https://doi.org/10.3390/lymphatics3030027

1. Introduction

Lymphedema (LED) arises as a consequence of various disruptions to the lymphatic system, including trauma, surgery, malignancy, and cancer-related treatments—particularly radiation therapy and oncologic surgery. When LED is driven by chronic venous insufficiency or deterioration of the venous system, it is classified as phlebolymphedema (PLED). A large retrospective analysis has identified PLED as one of the leading causes of lymphedema in the United States [1–6].

The chronic and progressive course of LED necessitates lifelong management strategies, commonly including the use of compression garments and compression therapy in the home setting. Recent advances in compression technology have introduced a mobile non-pneumatic compression device (NPCD), which has demonstrated clinical efficacy and safety in the treatment of LED. Dayspring® from Koya Medical is an NPCD system consisting of a programmable controller and a limb specific garment. It utilizes a combination of static compression, gradient sequential compression, and supports the movement and contractions of joints and muscles, enabling patients to ambulate and activate their calf pump during treatment. The NPCD technology uses shape memory alloy (nickel/titanium) actuators in its garment, which contract and relax to achieve sequential gradient compression in a distal to proximal manner when specified and energized by the controller. In use, the NPCD controller is battery powered and is designed to allow the patient to retain mobility while performing their activities for daily living versus immobilizing the patient in a supine position during a pneumatic compression treatment. In two multicenter, randomized, head-to-head trials comparing NPCDs to advanced pneumatic compression devices (APCDs)—currently regarded as the standard of care—NPCDs achieved superior outcomes in key measures. In the most recent study, the TEAYS trial, NPCDs were associated with enhanced clinical utility, greater efficacy in limb volume reduction, and improved patient adherence [7,8].

In the US, patients aged 65 or older typically represent a substantial portion of lower extremity lymphedema population. On average, these Medicare-eligible patients' healthcare spending burdens are twice as large as those of non-Medicare households [9]. Opportunities to reduce costs associated with the management of a disease, such as lymphedema, and/or to reduce common complications associated with a chronic disease, become advantageous to the beneficiary as well as to Medicare at large, both financially and in regard to quality of life. This paper presents and discusses the results from a sub-analysis of the TEAYS trial, evaluating clinical outcomes and potential implications for patients who are 65 years old and above and diagnosed with LED [10].

2. Results

2.1. Patients and Demographics

A total of 121 patients were screened and 22 failed at screening; 99 patients entered the study. Over the entire study, 24 patients withdrew consent and 4 were lost to follow-up or were missing data. Of the 24 who withdrew, 3 dropped out of the study before the assignment of a treatment device, 6 during the APCD group, and 15 during the NPCD group.

All patients had a confirmed diagnosis of lymphedema and were on conservative therapy (including, but not limited to exercise, manual lymphatic drainage, compression garments, and elevation of limb) before day 0. In the final analysis, there were 27 patients (38%) who were in the Medicare-eligible population (ages 65 and above) and 44 patients (62%) who were below the Medicare-eligible age (65). For this subset analysis, the demographics of the Medicare patients compared to the non-Medicare patients are summarized in Table 1.

Table 1. Study demographics, Medicare subset vs. non-Medicare subset.

Medicare and Non-Medicare Subset Who Completed the Study	27 Medicare	44 Non-Medicare	
Age (mean ± SE) in years	72.3 ± 1.03	50.4 ± 1.86	$p < 0.05$
Gender: M (F)	6 (21)	13 (31)	p~Non-significant
Race/Ethnicity	---	---	---
Asian	1	1	N/A
Caucasian	24	35	N/A
African American	2	6	N/A
Hispanic	0	2	N/A
Average BMI	32.3 ± 1.76	32.7 ± 1.46	p~Non-significant
Lymphedema History (years since diagnosis)	9.9 ± 1.4	7.6 ± 1.23	p~Non-significant
Affected Limbs: Unilateral (L/R)/Bilateral	13 (5/8)/14	21 (13/8)/23	N/A
Lymphedema Clinical Stage I, II, III	5, 16, 6	8, 28, 8	N/A
PLED (Phlebolymphedema)	12 (44.4%)	23 (52.3%)	p~Non-significant

2.2. Primary Endpoints and Efficacy

2.2.1. Mean Limb Volume Reduction

When comparing non-Medicare-eligible to Medicare groups, the former achieved a significantly greater change in limb volume compared to the latter, for both NPCD as well as APCD (Table 2).

In the Medicare-eligible age group (age > 65), for the NPCD treatment group, the mean limb volume decreased with a standard error of 353.0 ± 99.17 mL ($p < 0.05$) and achieved with a median of 316 mL compared with −10.7 ± 125.59 mL ($p > 0.05$; non-statistically significant) and a median of 39 mL for the APCD treatment group (Figure 1). Statistical significance for comparing mean limb volume decreases between the treatment groups was achieved, favoring NPCD ($p < 0.05$).

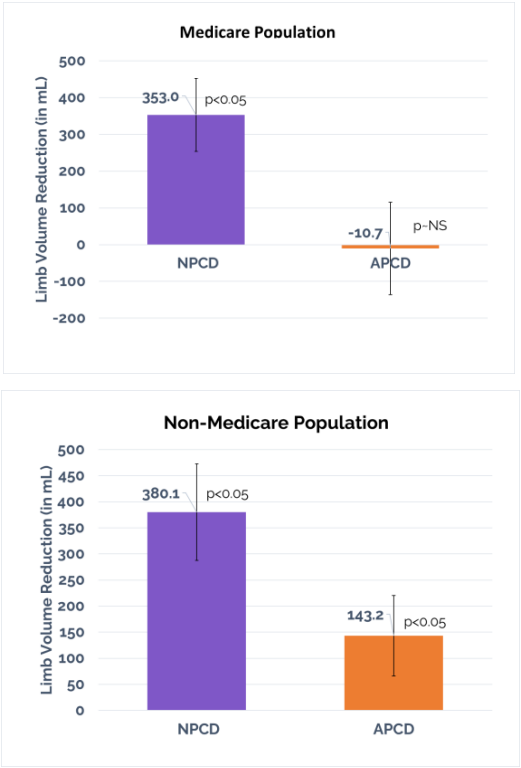

Figure 1. Change in limb volume compared to baseline, Medicare vs. non-Medicare subsets.

Table 2. Summary of data for Medicare and non-Medicare subsets for the NPCD and APCD groups.

	Device	Medicare	Non-Medicare	
Limb volume change (in mL)	NPCD	Mean with SE: 353.0 ± 99.17 Median: 316	Mean with SE: 380.1 ± 92.20 Median: 271	$p < 0.05$
	APCD	Mean with SE: −10.7 ± 125.59 Median: 39	Mean with SE: 143.2 ± 77.18 Median: 78	$p < 0.05$
	NPCD vs. APCD	$p < 0.05$	$p < 0.05$	
Change in Foot Region (Mid foot) in CM	NPCD	Mean: 0.62	Mean: 0.15	$p > 0.05$, Non-significant
	APCD	Mean: −0.04	Mean: 0.32	$p > 0.05$, Non-significant
	NPCD vs. APCD	$p < 0.05$	$p > 0.05$, Non-significant	
Change in Foot Region (Meta-tarsal) in CM	NPCD	Mean: 0.3	Mean: 0.22	$p > 0.05$, Non-significant
	APCD	Mean: −0.54	Mean: 0.38	$p > 0.05$, Non-significant
	NPCD vs. APCD	$p < 0.05$	$p > 0.05$, Non-significant	
Overall LYMQOL	NPCD	Mean: 1.43 ± 0.45 Median: 1.0	Mean: 0.75 ± 0.25 Median: 1.0	$p < 0.05$
	APCD	Mean: −0.10 ± 0.34 Median: 0	Mean: 0.33 ± 0.21 Median: 0	$p > 0.05$, Non-significant
	NPCD vs. APCD	$p < 0.05$	$p > 0.05$, Non-significant	
LYMQOL-Function	NPCD	Mean: −0.30	Mean: −0.20	$p > 0.05$, Non-significant
	APCD	Mean: 0	Mean: −0.12	$p > 0.05$, Non-significant
	NPCD vs. APCD	$p < 0.05$	$p > 0.05$, Non-significant	
LYMQOL-Appearance	NPCD	Mean: −0.31	Mean: −0.26	$p > 0.05$, Non-significant
	APCD	Mean: −0.01	Mean: −0.16	$p > 0.05$, Non-significant
	NPCD vs. APCD	$p < 0.05$	$p > 0.05$, Non-significant	
LYMQOL-Symptom	NPCD	Mean: −0.11	Mean: −0.19	$p > 0.05$, Non-significant
	APCD	Mean: 0	Mean: −0.06	$p > 0.05$, Non-significant
	NPCD vs. APCD	$p > 0.05$, Non-significant	$p < 0.05$	
LYMQOL-Mood	NPCD	Mean: −0.23	Mean: −0.07	$p > 0.05$, Non-significant
	APCD	Mean: 0.09	Mean: −0.11	$p > 0.05$, Non-significant
	NPCD vs. APCD	$p < 0.05$	$p > 0.05$, Non-significant	
Adherence (in %)	NPCD	Mean: 86 ± 4.9 Median: 93	Mean: 78 ± 3.5 Median: 85	$p > 0.05$, Non-significant
	APCD	Mean: 55 ± 6.8 Median: 66	Mean: 56 ± 5.4 Median: 51	$p > 0.05$, Non-significant
	NPCD vs. APCD	$p < 0.001$	$p < 0.001$	
Active During Treatment (in %)	NPCD APCD NPCD vs. APCD	Mean: 88 Mean: 0 $p < 0.001$	Mean: 93 Mean: 0 $p < 0.001$	$p > 0.05$, Non-significant
Portability of the Device (in %)	NPCD APCD NPCD vs. APCD	Mean: 96 Mean: 19 $p < 0.001$	Mean: 98 Mean: 11 $p < 0.001$	$p > 0.05$, Non-significant
Overall Preference (in %)	NPCD APCD NPCD vs APCD	Mean: 77 Mean: 23 $p < 0.001$	Mean: 79 Mean: 21 $p < 0.001$	$p > 0.05$, Non-significant
Less Compression Stocking Use (in %)	NPCD APCD NPCD vs. APCD	Mean: 69 Mean: 12 $p < 0.001$	Mean: 64 Mean: 7 $p < 0.001$	$p > 0.05$, Non-significant

In the non-Medicare-eligible age group, for the NPCD treatment group, mean limb volume decreased with a standard error of 380.1 ± 92.20 mL ($p < 0.05$), and a median of 271 mL was achieved, compared with 143.2 ± 77.18 mL ($p < 0.05$) and a median of 78 mL

for the APCD treatment group (Figure 2). Statistical significance for comparing mean limb volume decreases between the treatment groups was achieved, favoring NPCD ($p < 0.05$).

Changes in the foot were monitored by measurements at the metatarsal heads and midfoot for both treatment groups between day 0 and day 90. While no significant difference was detected between either group for the non-Medicare subset, statistical significance for foot volume decrease between the treatment groups was achieved, favoring NPCD ($p < 0.05$) in the Medicare age subset (Figure 2).

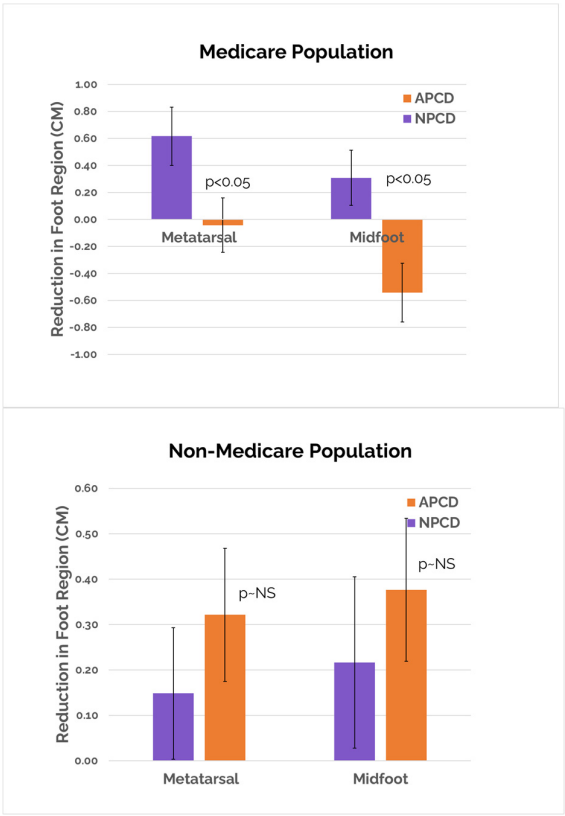

Figure 2. Mean change in the foot region, Medicare vs. non-Medicare subsets.

2.2.2. Quality of Life (LYMQOL)

Quality of Life outcomes were measured using the LYMQOL questionnaire, a validated clinical tool [11], and 1.0 point (the lowest count) in the overall score was considered clinically meaningful. (Figure 3). In the Medicare-eligible age group, significant improvement in QoL scores was achieved for NPCD treatment compared to APCD treatment; overall, LYMQOL score improvements were 1.43 ± 0.45 with a median of 1.0 for NPCD vs. -0.10 ± 0.34 for APCD ($p < 0.05$). Significant improvements in LYMQOL functional sub-scores were mixed for both treatment groups. Statistical significance for comparing the LYMQOL functional sub-score improvements between the two treatment groups was achieved in function, appearance, and mood, favoring NPCD ($p < 0.05$), but not in symptoms (Figure 3).

Finally, the older Medicare-eligible cohort derived significant improvements in LYMQOL scores compared to the non-Medicare-eligible group irrespective of treatment used; overall, LYMQOL score improvements were 1.43 ± 0.45 vs. 0.75 ± 0.25 ($p < 0.05$) for NPCD and 0.33 ± 0.21 vs. -0.10 ± 0.34 ($p < 0.05$) for APCD. Refer to Table 2 and Figures 4 and 5 for a summary of the primary outcomes.

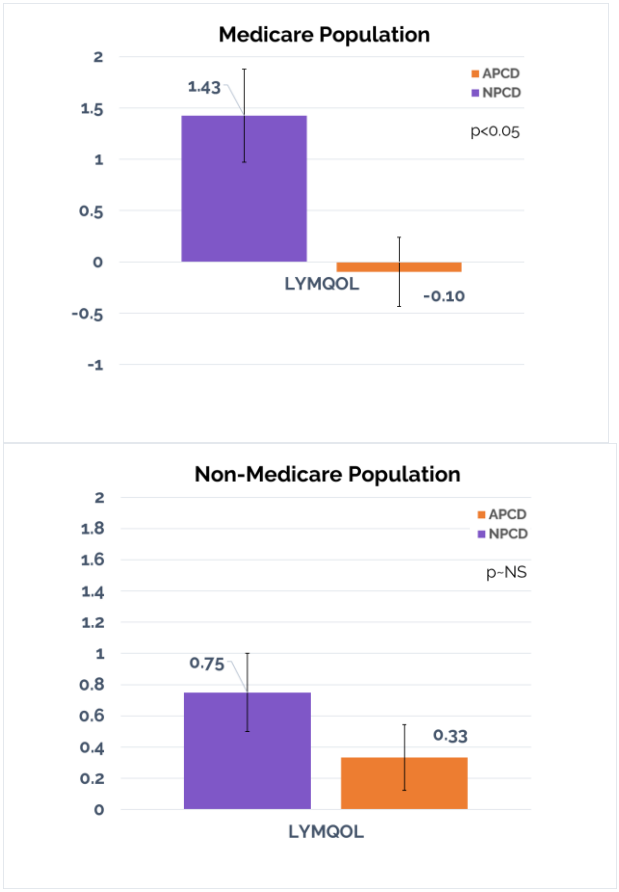

Figure 3. Overall LYMQOL scores, Medicare vs. non-Medicare subsets.

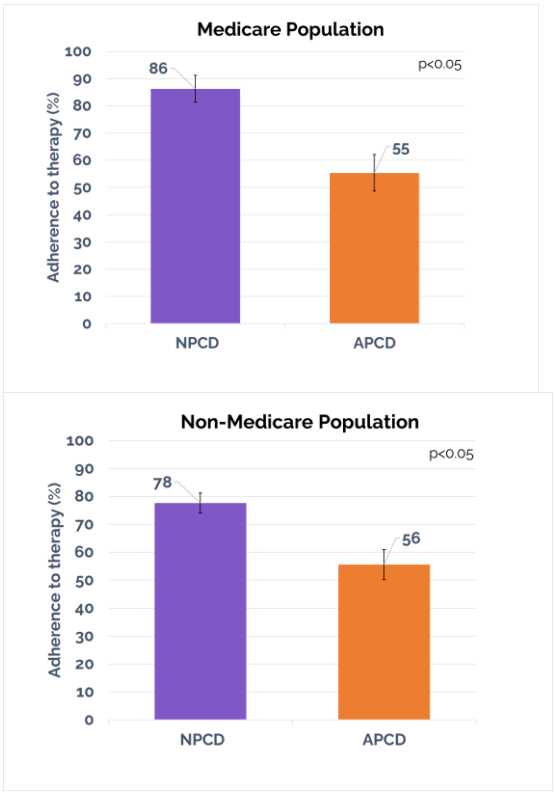

Figure 4. Adherence to treatment, Medicare vs. non-Medicare subsets.

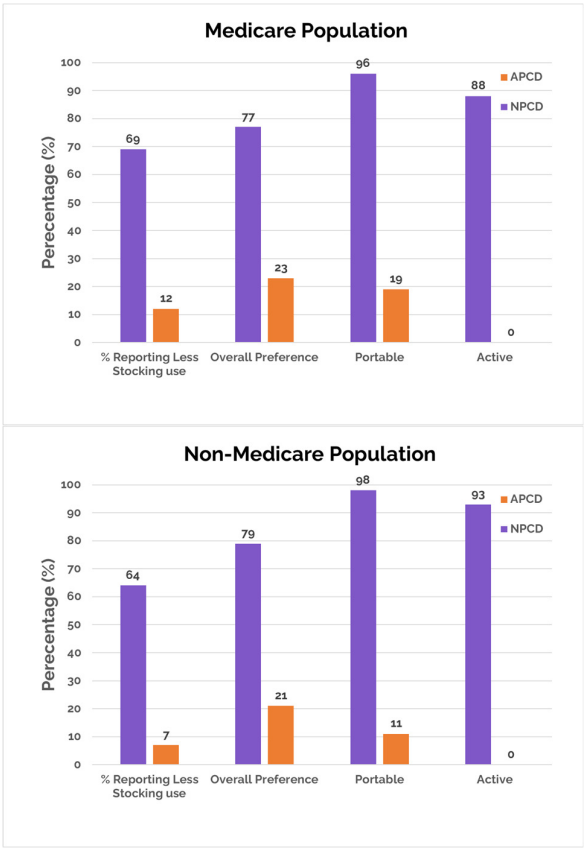

Figure 5. Subject preference questionnaire, Medicare vs. non-Medicare subsets.

2.2.3. Treatment Adherence

In the Medicare-eligible age group, treatment adherence was reported as 86% ± 4.9% with a median of 93% for NPCD and 55% ± 6.8% with a median of 66% for APCD. Statistical significance was achieved by comparing adherence for the two treatment groups, favoring NPCD ($p < 0.001$).

In the non-Medicare group, treatment adherence was reported as 78% ± 3.5% with a median of 85% for NPCD and 56% ± 5.4% with a median of 51% for APCD. Statistical significance was achieved by comparing adherence for the two treatment groups, favoring NPCD ($p < 0.001$) (Figure 4).

2.3. Safety and Secondary Endpoints

No device-related adverse events (AEs) or device-related severe AEs (SAEs) were reported in either treatment groups.

No truncal swelling or worsening was reported (compared with baseline) for any patients for either treatment group or either of the subset populations (Medicare or non-Medicare).

For the patient survey, which was administered at the end of the study, a majority of the patients (88% in the Medicare group and 93% in the non-Medicare group) reported being active during NPCD treatment compared to zero for APCD treatment (0% for APCD treatment for Medicare and non-Medicare groups). Patients also reported their overall treatment preference, with a majority preferring NPCD as their treatment choice (77% in the Medicare group and 79% in the non-Medicare group) compared to those who preferred APCD (23% in the Medicare-eligible age group and 21% in the non-Medicare-eligible age group).

Additionally, patients also reported decreased use of compression stockings in both groups. For the Medicare subset, 69% of patients on NPCD treatment reported decreased

use of compression stockings compared with 12% of patients on APCD treatment who reported decreased use of compression stockings. Similarly, for the non-Medicare subset, 64% of patients on NPCD treatment reported decreased use of compression stockings compared with 7% of patients on APCD treatment reporting decreased use of compression stockings (Figure 5).

2.4. Disease-Related Health Episodes and Resource Use

Select disease-related health episodes and resource utilization data were also collected at the beginning of the study as well as after 90 days of treatment with each device. The baseline average number of episodes in the 12 months prior to study initiation was 0.6 ± 0.1 episodes for cellulitis and 0.3 ± 0.1 episodes for ulceration. Baseline average number of days in the 12 months prior to study initiation for hospitalization associated with complications from lymphedema was 1.0 ± 0.4 days, and for use of compression stockings, it was 304.3 ± 14.6 days. The average number of lymphedema-related physical therapy visits in the 12 months prior to study initiation was 19.5 ± 3.7 visits.

During the NPCD treatment period, for both the Medicare and non-Medicare subsets, no episodes of cellulitis, ulceration, or hospitalization were reported. Average lymphedema-related physical therapy visits during this 90-day study period were found to be 0.48 visits for the Medicare-eligible age cohort and 0.02 visits for the non-Medicare-eligible age cohort.

During the APCD treatment period, there were a total of three cases (~4%) of cellulitis reported and one case of ulceration reported (~1%), all of which were resolved with medical intervention. Two cases of cellulitis were observed in the Medicare subset and one case of cellulitis was observed in the non-Medicare subset. One case of ulceration was observed in the Medicare subset while none in the non-Medicare subset. A total of eight hospitalization days were also reported during the APCD treatment period, all of which occurred with the Medicare subset. Average lymphedema-related physical therapy visits during this 90-day study period were found to be 3.31 visits for the Medicare subset and 2.16 visits for the non-Medicare subset.

3. Discussion

The results of this subset analysis highlight the meaningful clinical benefits and improved outcomes of utilizing NPCD compared to APCD for the self-management of lymphedema in the Medicare-eligible age population. In the key measures, the mean limb volume reduction achieved was 353.9 ± 99.17 mL for NPCD compared with -10.7 ± 125.59 mL for APCD over the 3-month study duration. These findings corroborate earlier published findings comparing NPCD with APCD and demonstrate the potentially synergistic effects of the NPCD's ability to reduce limb volume through multimodal clinical mechanisms of action, which combine static and active gradient compression as well as supporting muscle pumping activation in a single treatment session.

Quality of life is another key outcome measure in effectively managing chronic diseases, particularly among older adults, where the physical, psychological, and social impacts of illness are often magnified. The same is true for managing lymphedema, which often results in patients experiencing significantly impaired quality of life through disfigurement, discomfort, and mobility limitations—factors that are especially burdensome for Medicare beneficiaries managing multiple comorbidities. Patients often report delays in diagnosis and treatment with predictable adverse consequences in clinical presentation, disease progression, and financial costs [11–13]. For the Medicare-eligible age subgroup, the non-pneumatic compression device (NPCD) cohort demonstrated a clinically meaningful improvement in overall quality of life (LYMQOL: $+1.43 \pm 0.45$ points) compared to a slight decline in the APCD cohort (-0.10 ± 0.34). Moreover, while NPCD results

in improved overall QOL for all subjects, its use appears to be especially impactful in enhancing quality of life in the Medicare cohort (+1.43 ± 0.45 Medicare vs. +0.75 ± 0.25 points non-Medicare), suggesting that this older group of patients may stand to benefit even more than their younger counterparts. Additionally, in both the Medicare-eligible and the non-Medicare-eligible age groups, patients reported significantly higher treatment adherence while on NPCD vs. APCD, suggesting potentially lower barriers for NPCD treatment. This strong preference and sentiment are also reflected in the qualitative patient survey, for which both Medicare-eligible and non-Medicare-eligible age groups preferred NPCD over APCD, citing greater comfort, mobility, and ease of use as the main reasons.

While this study did not directly compare device costs nor evaluate the economics of healthcare utilization, assessment of disease-related health episodes and utilization also suggest that patients in both the Medicare-eligible and non-Medicare-eligible age groups may experience decreased episodic disease-related complications such as hospitalizations as well as decreased utilization of scarce health resources. No adverse events were reported in this subset analysis.

While the TEAYS study from which this sub-study draws was statistically powered to compare NPCD to APCD for treatment of lower extremity lymphedema, the current subgroup analysis is inherently limited by the small sample size (27 in the Medicare vs. 44 in the non-Medicare group). While these groups appeared well matched (see Table 1), a more balanced comparison between equal numbered groups and a larger sample size would strengthen conclusions. Finally, the results are limited to 90-day follow-up. While the increased compliance for NPCD is promising, longer follow-up is required to determine how compliance or lack thereof might impact real-world clinical outcomes for both treatment modalities. Additionally, in nearly half (see Table 1) of the patients in both cohorts (Medicare and non-Medicare), PLED was identified as the leading cause for their lymphedema. Further research will continue to evaluate the PLED subgroup.

4. Materials and Methods

The study design for the TEAYS study, a prospective, multicenter, randomized, single, crossover clinical trial conducted across nine study sites in the United States, has been previously described and detailed again in the sections below [8]. The study protocol was approved by an institutional review board and followed a single protocol performed per good clinical practices. Eligible patients with a confirmed diagnosis of primary or secondary unilateral or bilateral lower extremity lymphedema were included. The current study focuses specifically on the sub-analysis of the cohort of patients over the age of 65.

Primary efficacy outcomes assessed in this study included change in affected limb volume between baseline (day 0) and end of treatment (day 90), change in Lymphedema Quality of Life Questionnaire (LYMQOL), and treatment adherence. Calculation of limb volume by circumference measure was performed by a trained therapist using a calibrated tape measure. Measurements were taken every 4 cm, and the volume of a truncated cone is calculated according to the Kuhnke formula [10], summing the eight neighboring circumference measures. Measurements were performed for all affected limbs, regardless of whether lymphedema was unilateral or bilateral.

For the QoL assessment, a limb-specific LYMQOL survey was used [12]. The LYMQOL is a 20-item clinically validated disease-specific survey tool that was administered at days 0 and 90 for each device treatment period. The survey assesses the effects of lymphedema on QOL through both an overall score (scored 1–10) and four sub-scores: symptoms (pain, swelling, numbness), body image and appearance, function (activities of daily living, e.g., eating, writing, and dressing), and mood (e.g., sleep disruption, depression, and irritability). The subdomains are scored from 1 (not at all) to 4 (a lot). The total score is

calculated by summing all scores and dividing by the total number of items. The domain-specific sub-scores reflect improvement as a lower score, and the overall QOL score reflects improvement by a higher score. Changes from day 0 to day 90 for the total score and each sub-score were calculated.

Treatment adherence was reported through patient diaries over the 90-day course of treatment for each device. Adherence was calculated as the percentage of reported daily use (minimum of 1 h) over the treatment period (i.e., patients who used the device for the entire 90 days achieved 100% adherence, whereas those who used the device every other day reported 50% adherence).

Secondary outcomes included safety, as measured by device-related adverse events (AEs) (e.g., pressure-induced wounds, allergic reactions to garments, pain from use of device, or burns) throughout the course of study, and a patient survey administered at the end of the study. The survey evaluated the patient's preference for treatment modality as well as their perceived mobility and device portability during treatment and whether they experienced decreased use of their compression garments during each treatment period. Reports on truncal swelling before and after device use were also collected.

Additional disease-related health episodes and resource utilization were collected, including episodes of cellulitis, ulceration, hospitalization, lymphedema-related physical therapy visits, and compression stocking use over the past 12 months before device use and during the study duration with each device treatment.

4.1. Randomization and Treatment

An initial 30-day washout period was established in which no compression devices were used. During this period, patients were allowed to continue their conservative care, which included the use of compression garments, without any physical therapy visits. After this initial 30-day period, each patient was randomized to receive either the NPCD or the APCD treatment for 90 continuous days. Randomization was performed using STATA (StataCorp LLC, College Station, TX, USA). A biostatistician generated the allocation sequence using a computer-generated random number approach. At the end of the treatment duration (day 90), another 30-day washout period was established in which no compression device was used, and patients were subsequently crossed over to the alternate device treatment. For each device treatment group, measurements were collected at day 0 and day 90, except for the patient study survey, which was performed at the end of the study. All patients were trained in how to use the devices and don/doff the respective device accessory garments. Study devices included either the NPCD (Dayspring, Koya Medical, Dallas, TX, USA) or a commercially available APCD (of the 71 patients who completed the study, 2 used an Airos E0652 device, 1 used a Lymphapress E0652 device, and the remaining 68 patients used the E0652 Flexitouch plus [PG32-G3] device). Patients were instructed to use the assigned device once daily on the study limb for a minimum of 60 min. Patients were permitted to continue the use of compression garments and the general duration of use was captured using the patient survey at the end of the study.

4.2. Statistical Analysis

The software packages used for data analysis for this prospective study were Microsoft Excel (Microsoft Corp, Redmond, WA, USA) and STATA (StataCorp, College Station, TX, USA). Changes in measured outcomes from day 0 to day 90 for both groups and categorical variables were presented as proportions, with normally distributed continuous variables presented as mean $\pm$ standard error and skewed continuous variables presented as median (interquartile range). Assumptions were checked; nonparametric alternatives were considered as needed for skewed distributions. Univariate and multivariable analyses

were performed with candidate variables and outcome measures. Statistical significance was tested using a two-sided alpha level of 0.05 with an appropriate multiple-testing correction (Bonferroni or Benjamini–Hochberg) approach when needed, with each limb considered a unique observation.

5. Conclusions

Lymphedema is a progressive and costly condition that, if poorly managed, leads to serious physical, emotional, and financial strain. Limited access to trained providers and restrictive Medicare coverage worsens these challenges. Effective self-management is key to preventing complications like infections and hospitalizations, which drive up healthcare costs. Medicare beneficiaries with lymphedema face heightened risk of hospital-acquired conditions (HACs), which one study [14] estimated adds $20.5 million annually to Medicare spending. These patients are also more likely to exhaust their Part A benefits. Supporting at-home lymphedema care is essential to improving outcomes and reducing costs for both patients and the healthcare system.

Managing lymphedema poses unique challenges for older adults, making ease of use, consistent outcomes, and quality of life in addition to reduction of swelling critical. For Medicare beneficiaries, effective home-based care is essential to prevent complications like infections, skin breakdown, and hospitalizations—events that increase both personal and system-wide healthcare costs. Non-pneumatic compression devices (NPCD) offer a clinically proven, user-friendly solution that promotes independence and more comprehensive fluid management. In Medicare-eligible age patients with lower extremity lymphedema, NPCD use led to greater limb volume reduction, greater improvement in QoL, better adherence, improved mobility, and stronger patient preference over traditional pneumatic compression. These outcomes support better daily functioning, reduce reliance on healthcare services, and can translate into overall lower Medicare costs by minimizing preventable complications.

NPCD can empower Medicare beneficiaries to manage lymphedema with minimal disruption to daily life—improving health, preserving independence, and reducing healthcare resource use. For aging populations, accessible, low-burden management options are vital to sustaining physical health, emotional well-being, and long-term engagement in self-care.

Author Contributions: Conceptualization, T.S.M. and S.G.R.; methodology, T.S.M. and S.G.R.; formal analysis, T.S.M., investigation, T.S.M., M.B., R.W., T.B., S.D., V.R., N.C. and S.G.R.; data curation, T.S.M.; writing—original draft preparation, T.S.M.; writing—review and editing, T.S.M., M.B., R.W., T.B., S.D., V.R., N.C. and S.G.R.; supervision, T.S.M.; project administration, T.S.M.; funding acquisition, T.S.M. and S.G.R. All authors have read and agreed to the published version of the manuscript.

Funding: This work was funded by Koya Medical. Koya medical was not involved in manuscript writing. TEAYS Study: ClinicalTrials.gov Identifier: NCT05507346.

Institutional Review Board Statement: This study was conducted in accordance with the Declaration of Helsinki and approved by the Institutional Review Board (or Ethics Committee) of NYU Langone Health (protocol code i22-01274; 23 November 2022).

Informed Consent Statement: Informed consent was obtained from all subjects involved in this study.

Conflicts of Interest: TM and SR serve on advisory board for Koya Medical. The remaining authors/contributors have no conflict of interest to declare. The funders had no role in the design of the study; in the collection, analyses, or interpretation of data; in the writing of the manuscript; or in the decision to publish the results.

References

1. Farrow, W. Phlebolymphedema—A common underdiagnosed and undertreated problem in the wound care clinic. *J. Am. Coll. Certif. Wound Spec.* **2010**, *2*, 14–23. [CrossRef] [PubMed]
2. Lee, B.B. Phlebolymphedema: Neglected Outcome of Combined Venous and Lymphatic Insufficiency. *Vasc. Spec. Int.* **2020**, *36*, 1–3. [CrossRef] [PubMed] [PubMed Central]
3. Sleigh, B.C.; Manna, B. Lymphedema. In *StatPearls [Internet]*; StatPearls Publishing: Treasure Island, FL, USA, 2024; [Updated 19 April 2023]. Available online: https://www.ncbi.nlm.nih.gov/books/NBK537239/ (accessed on 18 December 2024).
4. Singh, A.; Zahra, F. Chronic Venous Insufficiency. In *StatPearls [Internet]*; StatPearls Publishing: Treasure Island, FL, USA, 2024; [Updated 27 April 2023]. Available online: https://www.ncbi.nlm.nih.gov/books/NBK587341/ (accessed on 18 December 2024).
5. Dean, S.M.; Valenti, E.; Hock, K.; Leffler, J.; Compston, A.; Abraham, W.T. The clinical characteristics of lower extremity lymphedema in 440 patients. *J. Vasc. Surg. Venous Lymphat. Disord.* **2020**, *8*, 851–859. [CrossRef] [PubMed]
6. Ulloa, J.; Cifuentes, S. Phlebolymphedema: And up-to-date review. *Phlebolymphology* **2021**, *28*, 49–60.
7. Rockson, S.G.; Whitworth, P.W.; Cooper, A.; Kania, S.; Karnofel, H.; Nguyen, M.; Shadduck, K.; Gingerich, P.; Armer, J. Safety and effectiveness of a novel non-pneumatic active compression device for treating breast cancer-related lymphedema, a multi-center randomized, crossover trial (NILE). *J. Vasc. Surg. Venous Lymphat. Disord.* **2022**, *10*, 1359–1366. [CrossRef] [PubMed]
8. Barfield, M.; Winokur, R.; Berland, T.; Davis, S.; Ralph, V.; Chatham, N.; Rockson, S.; Maldonado, T.S. Results from a comparative study to evaluate the treatment effectiveness of a nonpneumatic compression device vs an advanced pneumatic compression device for lower extremity lymphedema swelling (TEAYS study). *J. Vasc. Surg. Venous Lymphat. Disord.* **2025**, *13*, 101965. [CrossRef] [PubMed]
9. Ochieng, N.; Cubanski, J.; Damico, A. *Medicare Households Spend More On Health Care Than Other Households*; KFF Kaiser Family Foundation: San Francisco, CA, USA, 2024.
10. Kuhnke, E. Volumenbestimmung aus Umfangmessungen. *Folia Angiol.* **1976**, *24*, 224–232.
11. Keeley, V.C.S.; Lytle, L.A.; Gross, C.R.; Ahmed, R.L.; Troxel, A.B.; Schmitz, K.H. A quality of life measure for limb lymphoedema (LYMQOL). *J. Lymphoedema* **2010**, *5*, 26–37.
12. Bowman, C.; Rockson, S.G. The lymphedema patient experience within the healthcare system: A cross-sectional epidemiologic assessment. *Sci. Rep.* **2024**, *14*, 12600. [CrossRef] [PubMed]
13. Schreiner, N.; DiGennaro, S.; Harwell, C.; Burant, C.; Daly, B.; Douglas, S. Treatment burden as a predictor of self-management adherence within the primary care population. *Appl. Nurs. Res.* **2020**, *54*, 151301. [CrossRef] [PubMed]
14. Coomer, N.M.; Kandilov, A.M.G. Impact of hospital-acquired conditions on financial liabilities for Medicare patients. *Am. J. Infect. Control* **2016**, *44*, 1326–1334. [CrossRef] [PubMed]