original reports abstract

# Compression Therapy for HIV-Associated Kaposi Sarcoma Leg Lymphedema: Results of the Kenyan Improvised Compression for Kaposi Sarcoma Randomized Controlled Trial

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**PURPOSE** Evaluate the effectiveness of compression while receiving chemotherapy compared with chemotherapy alone in the treatment of HIV-associated Kaposi sarcoma (KS) lymphedema.

**METHODS** A randomized controlled trial was conducted in a single oncology clinic in western Kenya (NCT03404297). A computer-generated randomization schedule was used to allocate treatment arms. Randomized block design was used for stratification by lymphedema stage. Participants were HIV positive adults age ≥ 18 years on antiretroviral therapy with biopsy-proven KS associated with leg lymphedema and being initiated on chemotherapy. The intervention was 10 weeks of weekly clinic-based application of two-component paste compression bandages. The primary outcome was change in the Lower Extremity Lymphedema Index (LELI) score from week 0 to week 14. The secondary outcomes were change in the Lymphedema Quality of Life measure (LYMQOL) and change in the European Organisation for Research and Treatment of Cancer (EORTC) QLQ-C30 score from week 0 to week 14. Blinded outcome assessments were conducted.

**RESULTS** Of 30 participants randomly assigned, 25 eligible patients (chemotherapy [control], n = 13; compression plus chemotherapy [intervention], n = 12) returned at week 14. Change in LELI, LYMQOL, and EORTC QLQ-C30 scores between week 14 and week 0 did not significantly differ by arm. The mean (standard deviation) change in LELI score was –25.9 (34.6) for the control arm compared with –13.3 (29.5) for the intervention arm, $P = .340$. The difference (95% CI) in the change in LELI score was –12.6 (–39.3 to 14.1).

**CONCLUSION** Future studies evaluating a 14-week change in LELI for KS lymphedema should assume a standard deviation of approximately 30. Lessons learned from this pilot trial should inform the development of a larger, multicenter trial to evaluate the effectiveness of compression for KS lymphedema.

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ASSOCIATED CONTENT

Data Sharing Statement
Protocol

Author affiliations and support information (if applicable) appear at the end of this article.

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## INTRODUCTION

Kaposi sarcoma (KS) from HIV/AIDS is one of the most frequent cancers seen in sub-Saharan Africa.[1-5] HIV-associated KS has a high prevalence of lymphedema, ranging from 32% to 52%.[6-8] Lymphedema can cause considerable morbidity because of the associated functional impairment and physical discomfort. Swelling progresses to disfiguring skin changes and skin hardening from fibrosis, which can be complicated by poor wound healing and recurrent skin infections.[9] Lymphedema also has a significant impact on quality of life (QOL).[10-12] Even after treatment of HIV-associated KS with antiretroviral therapy and chemotherapy, lymphedema may persist.[8]

Compression therapy is a critical component of lymphedema management for all causes of lymphedema.[9] Although it has been studied in classic KS lymphedema,[13] it has yet to be evaluated in HIV-associated KS lymphedema. In western Kenya, wound care supplies are limited and locally available elastic stockings cost 1,000-1,500 Kenyan shillings ($10-$15 US dollars [USD]) per pair. Imported prepackaged two-component paste compression bandages (CB; eg, Unna boots) each cost 700-2000 Kenyan shillings ($7-$20 USD). In an effort to overcome the high cost of currently available options for compression therapy, the Academic Model Providing Access to Healthcare (AMPATH) in western Kenya used locally available wound care materials to develop two-component paste CB that would cost 200 Kenyan shillings ($2 USD) per bandage. Each bandage is designed to dress one affected leg for one

## CONTEXT

**Key Objective**

Are locally made two-component paste compression bandages effective in managing leg lymphedema from HIV-associated Kaposi sarcoma in western Kenya?

**Knowledge Generated**

We did not detect a statistical difference in the change in lymphedema with use of compression bandages. Because of challenges with obtaining clinic-based care, study participants expressed interest in self-care and home-based care models.

**Relevance**

This pilot study established the variability of the change in the Lower Extremity Lymphedema Index score in HIV-associated Kaposi sarcoma to inform future larger, multicenter trials and highlights the real-world challenges of conducting randomized controlled trials in western Kenya.

week.[14] AMPATH is a partnership between the Moi Teaching and Referral Hospital and Moi University College of Health Sciences in Kenya and a consortium of North American academic medical centers led by Indiana University. AMPATH, a President's Emergency Plan for AIDS Relief-United States Agency for International Development (PEPFAR-USAID)-supported implementing partner, collaborates with county-based ministries of health across western Kenya to serve a catchment population of over 20 million people and has supported HIV care delivery for over 200,000 patients at over 500 sites. Using the infrastructure and health care delivery model created through HIV care, AMPATH has expanded beyond HIV to provide comprehensive care.

The Kenyan Improvised Compression for Kaposi Sarcoma (KICKS) study was conducted to evaluate the effectiveness of CB while receiving chemotherapy compared with chemotherapy alone in the treatment of HIV-associated KS lymphedema. This trial was registered at ClinicalTrials.gov (NCT03404297) on January 19, 2018.

## METHODS

### Trial Design

This was a randomized controlled trial with two parallel groups. Since chemotherapy can improve lymphedema, this study was designed to evaluate the role of compression therapy specifically. The intervention arm received 10 weeks of compression therapy during chemotherapy. The control arm received chemotherapy only. After the week-14 primary end point, the control arm received compression therapy. The primary end point was change in Lower Extremity Lymphedema Index (LELI) score from week 0 to week 14. Secondary end points were change in the Lymphedema Quality of Life (LYMQOL) and European Organisation for Research and Treatment of Cancer (EORTC) core quality of life questionnaire (QLQ-C30) scores from week 0 to week 14. The study was designed with the assumption that the chemotherapy course would require six cycles administered every 2 weeks with bleomycin-vincristine or gemcitabine, which was consistent with routine oncologic care for KS in western Kenya at the time of study design. To achieve an ethical study design that would evaluate compression therapy as an intervention while not withholding a potentially therapeutic intervention from half of study participants, the control arm received 10 weeks of compression therapy after chemotherapy. The full study protocol has been published.[15]

### Study Participants

Participants were recruited from the AMPATH Oncology clinic in Chulaimbo, located at the Chulaimbo subdistrict health center in western Kenya. Participants were recruited between March 2018 and November 2019. Eligible participants were HIV-positive adults age 18 years and older on antiretroviral therapy, with biopsy-proven KS associated with leg lymphedema that was consistent with Campisi Clinical Stage[16,17] IB, II, III, or IV, and being initiated on chemotherapy. Because of slow enrollment, the inclusion criteria were liberalized to include patients who were started on a course of chemotherapy within the past month.

Individuals with Campisi Clinical Stage IA or V were excluded. At these stages, lymphatic dysfunction is not yet clinically evident (Stage IA) or lymphedema has become permanently fibrotic, sclerotic, or indurated with verrucous change (Stage V). Full exclusion criteria are detailed in the published study protocol.[15]

### Random Assignment and Blinding

Consented participants were randomly assigned to either intervention or control arm with a 1:1 allocation as per a computer-generated randomization schedule. A randomized block design was used with stratification by lymphedema stage. Three stratifications were used on the basis of Campisi's lymphedema clinical staging: Stage IB and Stage II; Stage III; and Stage IV. Stage IB and Stage II were

 

combined into one stratum because fewer participants with Stage IB or Stage II were anticipated on the basis of clinical experience, compared with Stage III or Stage IV. If lymphedema involved both legs, then the leg with the lower Campisi stage was used for random assignment and analysis. If the Campisi stage was the same for both legs, then both legs were used for random assignment and analysis.

Random assignment occurred after enrollment and completion of baseline assessments, thus ensuring allocation concealment. Participants were randomly assigned using sequentially numbered, opaque, sealed envelopes, which were color-coded by stratified lymphedema stage. To ensure concealment, block sizes were not disclosed. Study personnel involved with sequence generation and allocation concealment had complete separation from study personnel involved with implementation of study group assignments.

Blinded outcome assessments for the primary and secondary end points at week 14 were conducted by a separate clinician not involved with providing the compression therapy during the intervention. Washing of the lymphedematous legs occurred before outcome assessments, such that residual zinc oxide paste on the limbs of participants in the intervention arm was removed before assessment.

### Intervention

The study intervention was 10 weeks of weekly clinic-based application of two-component paste CB (Fig 1). The inner layer of the bandage is zinc oxide–impregnated gauze. The outer layer is elastic crepe. These CB are assembled by AMPATH Pharmacy in Eldoret, Kenya, and delivered to AMPATH pharmacies throughout western Kenya.[14] The KICKS study research assistant applied the bandages at all study visits for all participants. Before the start of enrollment, the research assistant completed a training session with a board-certified dermatologist (A.Y.C) involving didactics on appropriate use and procedure for applying bandages, as well as a practicum with a volunteer study team member's leg. Concomitant skin care (washing the skin, infections, and ulcers) is detailed in the full study protocol.[15]

### Study Outcomes

The primary outcome was comparison of the change in LELI score[18] from week 0 to week 14 between the intervention and control arms. The LELI is calculated by taking the sum of the squares of the circumference in five areas of a lower extremity and dividing it by the body mass index. A higher score indicates a higher severity of lymphedema.

The secondary outcomes were patient-reported outcome measures: (1) comparison of change in leg lymphedema-specific QOL from week 0 to week 14 between intervention and control arms using a validated questionnaire developed specifically to measure QOL in individuals with leg lymphedema (LYMQOL)[19] and (2) comparison of change in overall QOL using the EORTC QLQ-C30 (version 3.0) from week 0 to week 14 between intervention and control arms. The EORTC QLQ-C30 is an internationally validated and widely used health-related QOL instrument to assess patients with cancer.[20]

The patient-reported outcome measures were verbally administered to all participants because multiple participants had low literacy or physical weakness from their health condition that prevented self-completion of the


**FIG 1.** The two-component paste compression bandage system includes (A) an inner layer bandage composed of zinc oxide–impregnated gauze, together with (B) an outer layer of elastic crepe.

surveys. The LYMQOL subscales for function, symptoms, appearance, and mood were used. Each question was scored from 1 to 4, with 4 being the worst score. Each subscale score was based on the mean score of the subscale-related questions. A higher score indicates a lower QOL rating for a given subscale. The EORTC CLC-Q30 overall QOL score was used; individual domains were not assessed. Scores were linearly converted to a range from 0 to 100. A higher score indicates a higher QOL rating.

### Study Procedures

Baseline assessment at week 0 occurred before random assignment and included data collection on demographics, KS disease history, medical history including HIV disease history, lymphedema assessment, and QOL assessment. Participants randomly assigned to the *intervention arm* received 10 weeks of weekly compression therapy while receiving chemotherapy. The lymphedema assessment (LELI) was administered every week (blinded at week 14). At week 6, week 10, and week 14 (blinded), the secondary outcome QOL measurement tools (LYMQOL and EORTC CLC-Q30) were administered. Participants randomly assigned to the *control arm* did not receive compression therapy until after completion of chemotherapy. The lymphedema assessment (LELI) was administered every 2 weeks at the time of routine oncology care (week 2, 4, 6, 8, 10, and 14-blinded). At week 6, week 10, and week 14 (blinded), the secondary outcome measurement tools (LYMQOL and EORTC CLC-Q30) were administered. At week 24, a survey was administered to participants by phone that asked questions regarding their experience with the CB.

### Study Oversight

The trial was approved by the Moi University/Moi Teaching and Referral Hospital Institutional Research and Ethics Committee in Eldoret, Kenya, and Indiana University Institutional Review Board in Indianapolis, United States; exempt from review by the University of California, San Francisco Institutional Review Board in San Francisco, United States. Written informed consent was obtained from all participants. CB were provided without charge to participants during the study period. Following completion of the study, participants were eligible for an additional 10 weeks of fully subsidized compression therapy though

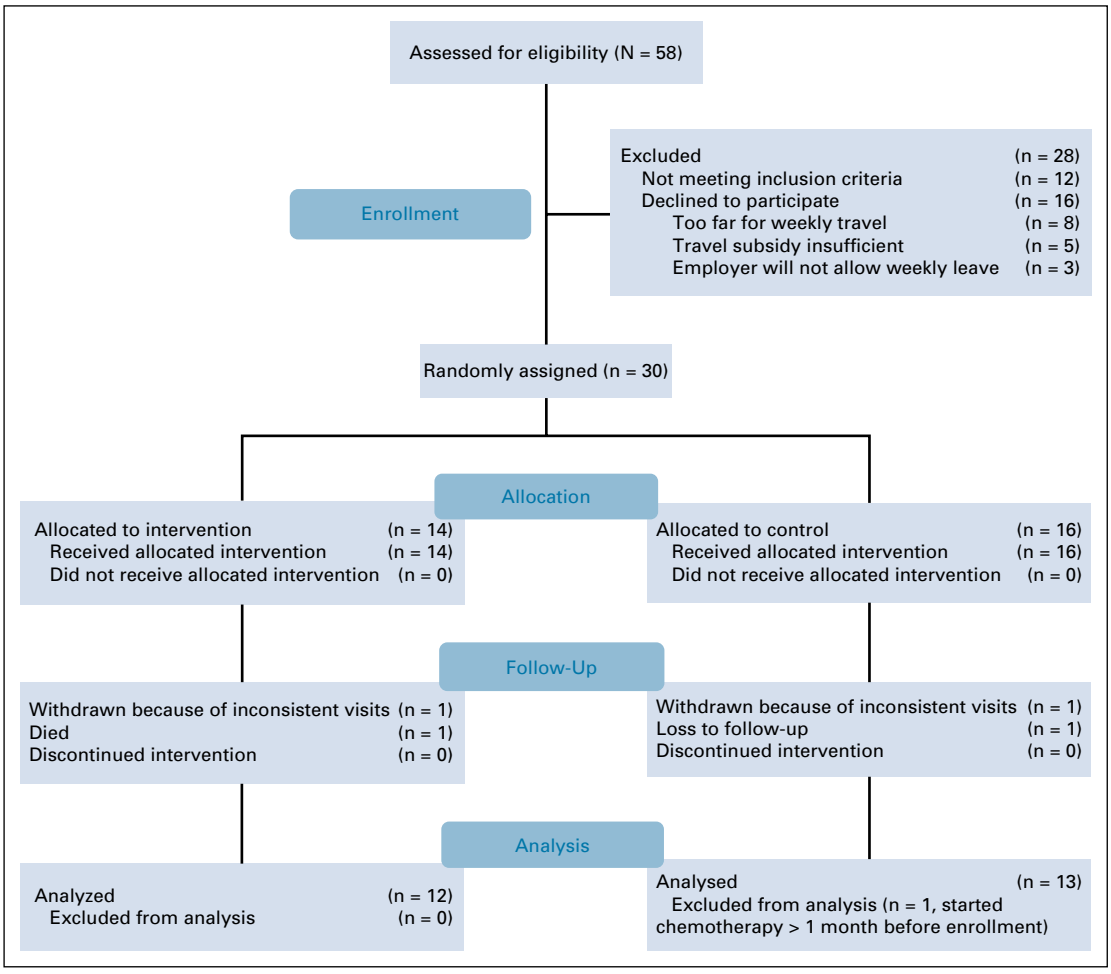


**FIG 2.** CONSORT flow diagram.

 

**TABLE 1.** Participant Characteristics at Week 0

| Characteristic | Delayed (n = 15) | Immediate (n = 14) | Total (N = 29) |
|---|---|---|---|
| Sex, No. (%) | | | |
| Female | 2 (13) | 6 (43) | 8 (28) |
| Male | 13 (87) | 8 (57) | 21 (72) |
| Age, mean (SD) | 37.1 (7.2) | 33.9 (6.2) | 35.6 (6.8) |
| BMI, median (IQR) | 19.8 (19.0-23.8) | 22.5 (2.3) | 22.0 (3.3) |
| Karnofsky score, median (IQR) | 60.0 (50.0-70.0) | 60.0 (60.0-70.0) | 60.0 (60.0-70.0) |
| Randomized leg,[a] No. (%) | | | |
| Left | 6 (40) | 6 (43) | 12 (41) |
| Right | 4 (27) | 5 (36) | 9 (31) |
| Both | 5 (33) | 3 (21) | 8 (28) |
| Campisi score for randomized leg, No. (%) | | | |
| IB | 1 (7) | 0 | 1 (3) |
| II | 2 (13) | 2 (14) | 4 (14) |
| III | 7 (47) | 8 (57) | 15 (52) |
| IV | 5 (33) | 4 (29) | 9 (31) |
| Most recent viral load, lower than detectable limits, No. (%) | | | |
| Yes | 13 (87) | 12 (86) | 25 (86) |
| No | 2 (12) | 2 (14) | 4 (14) |
| Duration between most recent viral load date and week 0 (days), median (IQR) | 122.0 (112.0-255.0) | 192.5 (156.0-260.0) | 175.0 (112.0-260.0) |
| Duration between HIV diagnosis and onset of leg swelling (days), median (IQR) | 29.0 (–271.0 to 457.0) | 515.0 (–155.0 to 1,129.0) | 54.0 (–181.0 to 787.0) |
| Prior chemotherapy, No. (%) | | | |
| Yes | 1 (7) | 2 (14) | 3 (10) |
| No | 14 (93) | 12 (86) | 26 (90) |
| ARV regimen at week 0, No. (%) | | | |
| Lamivudine, abacavir, atazanavir/ritonavir | 1 (7) | 0 | 1 (3) |
| Lamivudine, zidovudine, lopinavir/ritonavir | 0 | 1 (7) | 1 (3) |
| Lamivudine, zidovudine, nevirapine | 1 (7) | 2 (14) | 3 (10) |
| Lamivudine, tenofovir, atazanavir/ritonavir | 0 | 2 (14) | 2 (7) |
| Lamivudine, tenofovir, dolutegravir | 2 (13) | 0 | 2 (7) |
| Lamivudine, tenofovir, efavirenz | 11 (73) | 9 (64) | 20 (68) |
| Travel cost—round trip (Kenyan shillings), median (IQR) | 700.0 (600.0-1,000.0) | 500.0 (400.0-800.0) | 600.0 (500.0-950.0) |
| Travel time—one way (minutes), median (IQR) | 120.0 (90.0-240.0) | 120.0 (60.0-180.0) | 120.0 (90.0-180.0) |

NOTE. There were no significant differences between arms for participant characteristics (all $P > 0.10$).

Abbreviations: IQR, interquartile range; SD, standard deviation.

[a]Leg with lowest Campisi score was randomized. When the score was the same in both legs, both legs were randomized.

transportation was not subsidized. Details regarding the transportation subsidy are in the full study protocol.[15]

### Statistical Analysis

Change in the primary and secondary outcome measures was calculated as week 14 score minus week 0 score. Arms were compared for primary and secondary end points using two-sample, two-sided, t-tests. If both of the participants legs were used for random assignment (ie, the Campisi clinical stage was the same for both legs), the average LELI score for the two legs was used for analysis. For comparison of participant characteristics between arms, a *t*-test was used for continuous parametric variables, Wilcoxon rank sum test for all other nonparametric continuous variables, and Fisher's exact test for categorical data.

Week 14 was chosen as the primary and secondary end point because this is typically the first follow-up oncology visit after completion of the course of chemotherapy. Because of multiple health care worker strikes during the study period, six out of 15 participants in the control arm

**TABLE 2.** LELI and QOL Measures, Mean (SD) by Study Arm

| Outcome Measure | Control Arm (chemotherapy) N = 13 | Intervention Arm (compression plus chemotherapy) N = 12 | *P*[a] |
|---|---|---|---|
| LELI | | | |
| Week 0 | 308.4 (44.8) | 305.6 (43.0) | .876 |
| Week 14 | 282.5 (28.6) | 292.3 (36.6) | .462 |
| Change between week 14 and week 0 | –25.9 (34.6) | –13.3 (29.5) | .340 |
| Difference in change (95% CI) | –12.6 (–39.3 to 14.1) | — | |
| LYMQOL-function | | | |
| Week 0 | 3.0 (0.6) | 3.0 (0.5) | .762 |
| Week 14 | 2.0 (0.6) | 2.3 (1.0) | .360 |
| Change between week 14 and week 0 | –1.1 (0.8) | –0.7 (0.9) | .247 |
| Difference in change (95% CI) | –0.4 (–1.1 to 0.3) | — | |
| LYMQOL-appearance | | | |
| Week 0 | 2.7 (0.7) | 2.6 (0.5) | .764 |
| Week 14 | 2.1 (0.6) | 2.4 (1.0) | .372 |
| Change between week 14 and week 0 | –0.6 (0.8) | –0.2 (1.1) | .332 |
| Difference in change (95% CI) | –0.4 (–1.2 to 0.4) | — | |
| LYMQOL symptoms | | | |
| Week 0 | 2.9 (0.3) | 2.9 (0.6) | .894 |
| Week 14 | 2.0 (0.7) | 2.2 (1.0) | .499 |
| Change between week 14 and week 0 | –0.9 (0.8) | –0.7 (0.9) | .560 |
| Difference in change (95% CI) | –0.2 (–0.9 to 0.5) | — | |
| LYMQOL mood | | | |
| Week 0 | 2.1 (0.7) | 2.1 (0.7) | .950 |
| Week 14 | 1.6 (0.6) | 2.0 (1.0) | .214 |
| Change between week 14 and week 0 | –0.5 (0.9) | –0.1 (0.8) | .221 |
| Difference in change (95% CI) | –0.4 (–1.1 to 0.3) | — | |
| EORTC QLQ C30 | | | |
| Week 0 | 36.5 (11.0) | 41.7 (21.9) | .462 |
| Week 14 | 48.7 (20.4) | 60.4 (26.6) | .228 |
| Change between week 14 and week 0 | 12.2 (21.1) | 18.8 (31.2) | .541 |
| Difference in change (95% CI) | –6.6 (–28.5 to 15.3) | — | |

Abbreviations: EORTC QLQ C30, European Organisation for Research and Treatment of Cancer Core Quality of Life questionnaire; LELI, Lower Extremity Lymphedema Index; LYMQOL, Lymphedema Quality of Life; SD, standard deviation.

[a]Two-sample *t*-test comparing arms.

and six out of 14 participants in the intervention arm were receiving chemotherapy at week 14 and four participants had their week 14 visit delayed to week 15 or week 16. For these four participants, the data from week 15 and 16 were used in analysis. For another participant, the week 0 secondary outcome measures were assessed 6 weeks before the primary outcome measure was assessed because the participant was found to have severe anemia requiring transfusion before starting chemotherapy and the secondary outcome measures were not repeated when the primary outcome measure was assessed at the time of chemotherapy initiation.

Study power and sample size were estimated on the basis of the assumption that the standard deviation (SD) of the change in LELI score would be 10, which was based on the assumption that the within-subject correlation coefficient is 0.875. No references on the SD of the change score were available a priori. With a two-sample t-test using an alpha level of 0.05 and an assumed SD in the LELI change score of 10, this study with 15 participants in each arm would be able to detect a change in LELI of 10.6 points with 80% power assuming 100% follow-up rate, 11.5 points with a 90% follow-up rate, and 12.0 points with 80% follow-up rate.

## RESULTS

A total of 30 participants were randomly assigned; however, one participant was excluded from analysis for having

 

**TABLE 3.** Descriptive Statistics for the Week 24 Survey

| Survey Question | Control Arm (n = 9), No. (%) | Intervention Arm (n = 11), No. (%) | All Participants (N = 20), No. (%) |
|---|---|---|---|
| Did wearing CB prevent you from doing your job? | | | |
| No | 8 (89) | 8 (73) | 16 (80) |
| Yes | 1 (11) | 3 (27) | 4 (20) |
| Did wearing CB prevent you from doing household tasks? | | | |
| No | 9 (100) | 8 (73) | 17 (85) |
| Yes | 0 (0) | 3 (27) | 3 (15) |
| Did wearing CB prevent you from walking? | | | |
| No | 9 (100) | 11 (100) | 20 (100) |
| Yes | 0 (0) | 0 (0) | 0 (0) |
| Did you find it difficult to keep CB dry? | | | |
| No | 6 (67) | 5 (45) | 11 (55) |
| Yes | 3 (33) | 6 (55) | 9 (45) |
| Did you find it difficult to keep CB clean? | | | |
| No | 6 (67) | 4 (36) | 10 (50) |
| Yes | 3 (33) | 7 (64) | 10 (50) |
| If your transportation to clinic had not been subsidized, would you have come to clinic for dressings? | | | |
| No | 6 (67) | 5 (45) | 11 (55) |
| Yes | 3 (33) | 6 (55) | 9 (45) |
| If we trained you, do you think you could have managed to do your own washing and dressings? | | | |
| No | 2 (22) | 2 (18) | 4 (20) |
| Yes | 7 (78) | 9 (82) | 16 (80) |
| If you could perform the weekly cleaning and dressing changes with other people with lymphedema from Kaposi sarcoma near where you live, would you participate? | | | |
| No | 1 (11) | 0 (0) | 1 (5) |
| Yes | 8 (89) | 11 (100) | 19 (95) |
| Think of a family member or friend. If we trained this person, do you think this person could have managed to do your washing and dressings? | | | |
| No | 0 (0) | 1 (9) | 1 (5) |
| Yes | 9 (100) | 10 (91) | 19 (95) |
| If the study did not exist and if you did not have transportation costs, how much would you pay per wrapping? (Kenyan Shillings), median (IQR) | 600 (600-800) | 500 (500-700) | 600 (500-750) |

NOTE. Participants in the control arm received 10 weeks of weekly CB after Week 14.
Abbreviations: CB, compression bandages; IQR, interquartile range.

already received five cycles of chemotherapy at time of enrollment compared with 0-2 cycles for all other participants. This participant had been enrolled because of a miscommunication regarding the liberalization of the inclusion criteria discussed in the Methods section. Twenty-five participants were evaluable at week 14 and included in the primary and secondary end point analyses (Fig 2), resulting in an 86% follow-up rate for participants (25 out of 29).

There were no significant differences between arms for participant characteristics (all $P > .10$; Table 1). No participants had a known history of diabetes, hypertension, hyperlipidemia, chronic obstructive pulmonary disease, asthma, congestive heart failure, chronic kidney disease, liver disease, or current tobacco use. Ninety percent of participants (26 of 29) had no prior history of chemotherapy treatment for KS, of whom 69% were being initiated on bleomycin-vincristine (18 of 26), 27% had received cycle 1 of bleomycin-vincristine (7 of 26), and 4% were being initiated on gemcitabine (1 of 26). In 86% of participants (25 of 29), the most recent HIV viral load was lower than the detectable limit. The median (interquartile range) duration between most recent viral load date and week 0 of the study was 175 (112-260) days.

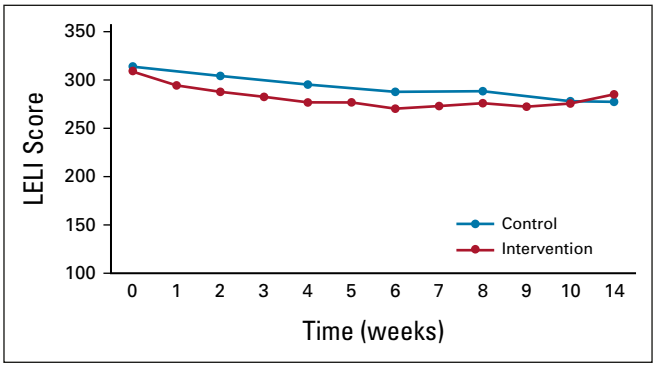


**FIG 3.** LELI score through week 14 by arm. A higher score indicates a higher severity of lymphedema. LELI, Lower Extremity Lymphedema Index.

There were no significant differences in week 0 LELI score or QOL scores between study arms (Table 2). The primary outcome measure of change in LELI scores between week 14 and week 0 did not significantly differ by arm (Table 2). The mean (SD) change in LELI score was –25.9 (34.6) for the control arm compared with –13.3 (29.5) for the intervention arm, $P = .340$ (Table 2). The difference (95% CI) in the change in LELI score between control and intervention arms was –12.6 (–39.3 to 14.1). QOL measures did not significantly differ by arm (all $P > .20$, Table 2). The LELI score and QOL scores depicted by week between the intervention and control arms are shown in Figures 3-5. Two participants reported itching after the compression bandage was exposed to water. Itching resolved after application of a new bandage. Participants' responses to the week-24 survey regarding experiences with compression therapy are shown in Table 3.

## DISCUSSION

In this study, we did not detect a statistical difference in the change in lymphedema, as measured by the change in LELI from week 0 to week 14, with use of CB for patients with HIV-associated KS lymphedema recently initiated on a course of chemotherapy. We were surprised that the difference in LELI, although statistically insignificant, favored the control group. When we designed this study, we assumed that the SD in the LELI change from week 0 to week 14 would be one third as large as observed. Future studies evaluating a 14-week change in LELI for KS lymphedema should assume an SD of approximately 30, not 10 as we assumed.

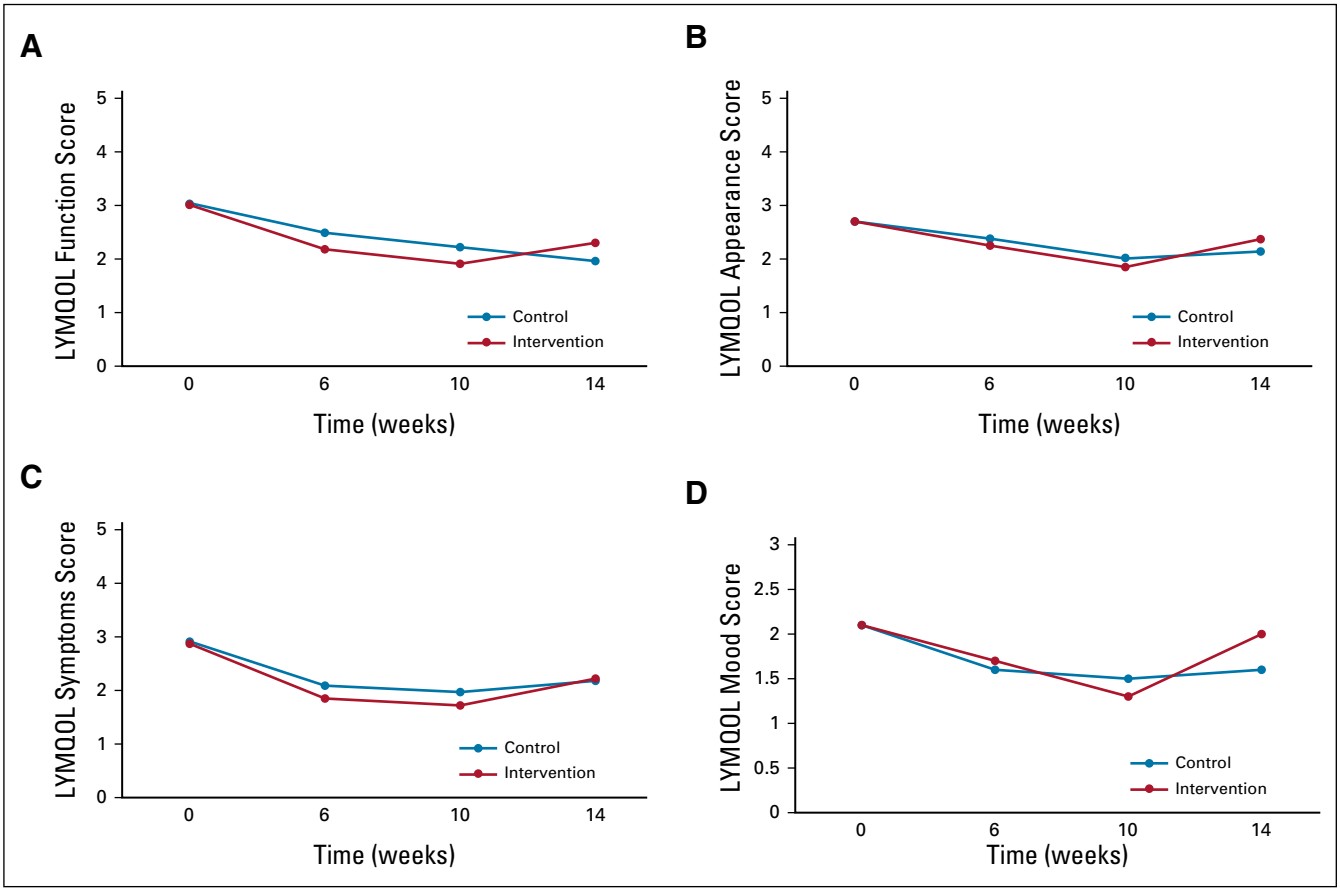


**FIG 4.** (A) LYMQOL function, (B) appearance, (C) symptoms, and (D) mood scores through week 14 by arm. A higher score indicates a lower QOL rating. LYMQOL, Lymphedema Quality of Life.

 

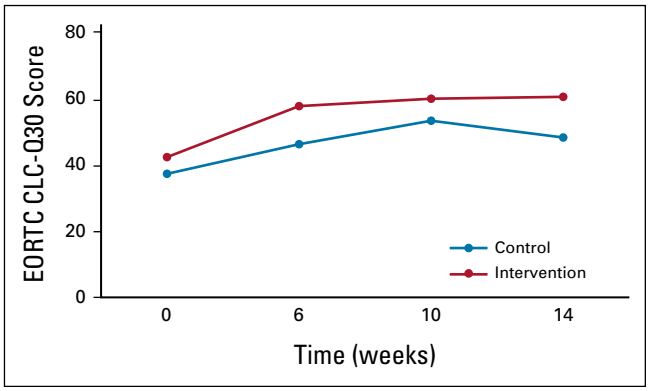


**FIG 5.** EORTC CLC-Q30 score through week 14 by arm. A higher score indicates a higher QOL rating. EORTC, European Organisation for Research and Treatment of Cancer.

The AMPATH Oncology clinic at Chulaimbo serves patients from a 100-200 km radius around the clinic. Study participants traveled anywhere from 30 minutes to 300 minutes for a one-way trip to clinic, and their round trip travel costs to/from clinic ranged from 100 to 1,350 Kenyan shillings. Eight eligible patients declined participation because of clinic being too far for weekly travel, and five eligible patients declined because of the travel subsidy of 750 Kenyan shillings being insufficient. Given the time and financial burden associated with weekly clinic-based care, home-based and group care models are worth consideration. In the week-24 survey, nearly every respondent indicated that, if trained, a family or friend could perform the leg washing and dressing changes, and most respondents also felt they could personally perform this task if trained. Interest in weekly group dressing changes with other patients with KS lymphedema near their home was almost unanimous. Self-care and home-based care models have been successful for lymphedema from lymphatic filariasis,[21-25] podoconiosis,[26,27] and cancer.[22,28] In low- and middle-income countries, self-bandaging for lymphedema from lymphatic filariasis[24] and podoconiosis[26,27] has been included in home-based care models but has yet to be evaluated for cancer-related lymphedema.

There are additional limitations to our study. First, because of multiple health care worker strikes during the study period, there was irregular administration of chemotherapy such that participants did not receive chemotherapy in the anticipated frequency of every 2 weeks, which resulted in some participants missing doses of chemotherapy during the study period and some participants still receiving chemotherapy at the primary end point. The health care worker strikes did not affect the administration of compression therapy. Second, the outcome measures were assessed after participants had traveled to clinic, with their legs to gravity and relatively immobile, which may have led to an increase in leg swelling, discomfort, and pain. This may have affected the LELI measurement and lymphedema-specific QOL scores. Participants were also receiving chemotherapy, which may have affected their overall health-related QOL score. Since long-distance travel to KS clinics is unavoidable in western Kenya, future studies should consider performing assessments at participants' homes. Third, because of limited workforce and financial resources, we were unable to identify and involve a locally available certified lymphedema therapist nor purchase a portable interface pressure measuring device to measure the compression pressure being delivered. The same research assistant applied the CB for all participants; so, this eliminated interoperator variability, but the possibility of intraoperator variability cannot be excluded. Fourth, we were unable to obtain an HIV viral load or CD4 count for participants at the time of enrollment because of limited resources and needed to rely on the most recent available viral load from clinical data, either found within the AMPATH electronic medical record or reported by the study participant if they did not receive HIV care at an AMPATH clinical site.

This pilot trial established the variability of the change in LELI over 14 weeks in this patient population, which will be a valuable resource for others wishing to study interventions for KS lymphedema. Our study results in favor of the control arm could be consistent with random chance and does not exclude the possibility of a clinically significant effect in favor of compression therapy. Lessons learned from our study should inform the development of a larger, multicenter trial evaluating the role of compression therapy for management of KS lymphedema. Considering the challenges of clinic-based care models, self-care, home-based, and group care models for KS lymphedema should also be evaluated in future studies.


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