Réseau de cancérologie Rossy

Rossy Cancer Network

Effect of Early Compression Therapy and Individualized Exercise on Incidence of Lymphedema in Patients Treated for Gynecological Cancer: a Randomized Controlled Trial

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INTRODUCTION

- The incidence of **lower limb lymphedema** after treatment for gynecological cancer is estimated at **10% to 38%**
- Persistent issues associated with lymphedema may include swelling, achiness, poor mobility, and recurrent skin infections
- These negative outcomes make it essential to identify strategies to reduce the risk of lymphedema development in this population

Rationale: No published studies have evaluated the effect of early compression therapy combined with individualized exercise on the incidence of lower limb lymphedema in patients treated for gynecological cancer.

OBJECTIVES

Evaluate the effect of **early compression therapy with individualized exercise** on the incidence of **lower limb lymphedema** over 12 months post-operatively in **patients treated for gynecological cancer**

METHODS / INTERVENTIONS

This is a pilot (n=50) **randomized controlled trial**. Patients are currently being recruited from the McGill University Health Centre (MUHC) Royal Victoria Hospital and the Jewish General Hospital in Montreal, Quebec.

Inclusion criteria: Patients scheduled to undergo surgical lymph node dissection for gynecological cancer and having one of the following diagnoses:

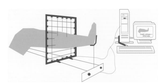
- Grade 2 or 3 endometrial cancer, or high grade type (serous or clear cell);
- Stage 1b1 or stage 2a cervical cancer;
- Stage 1, 2 or 3 vulvar cancer

Study participants are evaluated by a physician and a physiotherapist specialized in lymphedema therapy at the MUHC Lymphedema Support Centre at **five time points**: **T1** - prior to surgery; **T2** - four to six weeks post-operatively; **T3** - three months post-operatively; **T4** - six months post-operatively; **T5** - one year post-operatively. Information on demographic factors, medical history, cancer diagnosis and treatment history is collected at T1 and T2.

Intervention: At T2, both groups receive standard education on lymphedema risk reduction. Participants in the intervention group receive:

- **Compression class 1 (18-21 mmHg) stockings:** Stockings recommended to be worn on both lower limbs 12 to 16 hours daily for at least 6 months post-operatively
- **Individualized education on exercise:** 150 minutes of moderate-intensity (brisk walking, bike riding) aerobic physical activity per week, in bouts of 10 min or more, recommended
- **Self-lymphatic drainage by exercise for the leg**: A modified Casley-Smith routine(1) for the legs is given and demonstrated

MEASUREMENT TOOLS

Measurement Tool	Description	Outcome Measures
Circumferential measures	Serial circumferential measurements (10 cm apart from ankle to groin). The volume of each segment or truncated cone is calculated and the total volume of the leg is the summation of these segments.	Limb volume
Bioelectrical impedance spectroscopy (BIS)	BIS measures intracellular impedance (Ri) and extracellular impedance (R0), for the limbs. Extracellular/intracellular fluid ratios can be derived and compared over time and between legs	Limb extracellular fluid volume
Perometry 	An imaging device that contains rows of infra-red light emitting diodes on two sides and rows of sensors on the opposite two sides. The limb casts shadows in two planes and using the cross-sectional information obtained, a computer produces a volume picture of the entire leg.	Limb volume
Cancer specific Questionnaire	**Description**	**Score**
EORTC QLQ-C30[4]	QOL in cancer; 30 items; 5 functional scales, 9 symptom scales/items, 1 global health status scale	0-100

STATISTICAL ANALYSES

Analyses of primary and secondary outcomes will be performed using an intention-to-treat analyses. Mean average changes (from T1 to T5) in limb volume and extracellular fluid will be compared between the experimental group and the control group using an analysis of variance (ANOVA). Incidence of lymphedema, incidence of cellulitis infections, mean limb volume and mean EORTC QLQ-C30 scores at different time points will also be compared between the experimental group and the control group using ANOVA.

RESULTS

Recruitment Flow Chart

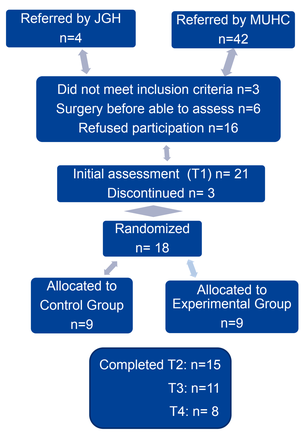


TABLE 1
Baseline Descriptives

Number of Participants	n=18
Gender	Female
Median Age (range)	56 (36-80)
Median BMI (range)	28.63(23.4-33.7)
Full time employment	n=10
Part time employment	n=3
Grade 2 or 3 endometrial cancer	n=11
Stage 1b1 or 2a cervical cancer	n=4
Stage 1 vulvar cancer	n=3
Patients having received radiotherapy	n=8

PATIENT IMPACT

Knowledge of early strategies that may reduce the risk of developing lymphedema in this population will help inform clinical practice recommendations and direct future research in this area. Upon completion of the study, we will conduct appropriate data analyses and disseminate our findings in peer-reviewed journal publications and at relevant conferences.

Based on information obtained from this trial, we will develop and adapt appropriate educational materials (seminars, website and pamphlets) as part of the existing Education Program of the MUHC Lymphedema Support Centre in collaboration with the Lymphedema Association of Quebec. These resources will be targeted to nurses, surgeons, oncologists, physiotherapists and lymphedema therapists within and beyond the Quebec region. We will also integrate these recommendations into our current educational programs targeted to patients diagnosed or at risk of lymphedema (Lymphedema 101 workshop, Exercise for Lymphedema workshop, information brochures on risk reduction and living with lymphedema, website).

CONCLUSION

This pilot randomized controlled trial will result in an improved understanding on the prevention and enhanced management of lower limb lymphedema in patients with gynecological cancer and contribute to the development of post-operative recommendations for this population. It will also permit us to evaluate the feasibility of the study design, patient recruitment, assessment methods and intervention and thus prepare for a robust, fully powered randomized controlled trial in the future.

REFERENCE

1. Casley-Smith, J. R. (1997). Modern Treatment for Lymphoedema, 5th edition. *The Lymphedema Association of Australia*

McGill

Centre universitaire de santé McGill — McGill University Health Centre

Hôpital général juif — Jewish General Hospital

Centre hospitalier de St. Mary — St. Mary's Hospital Center