UTS IMPACCT Trials Coordination Centre

Series Manual 25

Compression and Related Physical Therapies for Cancer Related Lymphoedema

What is this series about?

Lymphoedema is palpable swelling of the soft tissues due to the presence of increased fluid. It is a common problem in cancer patients wherein lymphatic flow can be obstructed by the cancer itself, by a complication of the cancer such as a blood clot, or by a complication of the cancer treatment such as radiotherapy or surgery. Lymphoedema can negatively impact quality of life by causing discomfort, disfigurement and loss of function and/or mobility, and can be particularly distressing for patients towards the end of life. Compressive bandaging, manual lymphatic drainage and other related therapies are often used by physiotherapists, occupational therapists and other clinicians to reduce or control lymphoedema, however there is limited evidence supporting their use for cancer-related lymphoedema, particularly in the relatively frail population of patients receiving palliative care who may find such therapies painful or burdensome. This RAPID series aims to explore the use, efficacy, side effect and complication profile of compression and related therapies in the management of cancer-related limb lymphoedema in the palliative care patient cohort.

Patient tracking

A log or spreadsheet should be developed in order track the patient medical record number and the study ID number allocated to each patient when commenced on a medication/intervention. This spreadsheet will be the only link between the data collected and the identity of the patient and remains the property of the participating site. This information should not be shared with the Palliative Care Clinical Studies Collaborative (PaCCSC). The spreadsheet should also contain the date and time of the data entry at each time point.

Patient PID	Patient name	Patient medical record number	Date of initial data entry	Time of data entry

Allocating Patient ID number

The ID number for each set of data collected is a composite number built up using a series of three codes.

i) Site identifier.

This is the number allocated to each participating site as a two or three digit number

ii) Medication/intervention number

The medication/intervention number for the Compression & Related Therapies for Lymphoedema Series is **25**

iii) Patient number

This is usually a three digit number e.g. **001**

Therefore the full patient ID number will be; Site identifier/medication number/patient number e.g. 01/**25**/001

Time points

There are 2 main time points where data is required;

1. Commencement of the intervention (baseline) (T0)
2. Assessment at therapist's discretion when maximum benefit has been achieved (minimum 3 sessions; often coincides with time of fitting compression garment) (T1)

Other data collection points are:

1. Adverse event/harm at unexpected time points (T_1)
    - There can be up to three other times where adverse events/harms can be recorded (Adhoc A, B & C)
    - These pages can be left blank if there are no unexpected adverse events
2. Cessation of the intervention
    - Complete this page if the medication/intervention of interest is ceased at any time during the data collection period for any reason
3. Date of death
    - Enter the date of death if/when known
    - If the date of death is entered during the data collection period no further prompts will be received.

Each medication/intervention of interest will have different time points for clinical benefit and adverse events according to its profile. Time points are determined by each Series subcommittee and are based on clinical experience and published product information.

Adverse event assessment

Adverse events (or harms) are assessed using a standard scale from the National Cancer Institute Criteria for Adverse Events (NCI CTCAE). The NCI uses a scale between 1 and 5 ranging from mild to serious (resulting in death) symptoms or sequelae. The NCI criteria are provided as a reference document which is supplied separately and should be referred to for any events recorded is association with the patient's clinical course.

Each medication/intervention has a number of pre-populated expected adverse events (harms). These are listed at each time point, and the NCI grade is described and provided for easy reference. A grade should be provided for each listed adverse event.

If unexpected adverse events occur at any other time, either before or after any pre-determined time point, these should be recorded in the unexpected adverse event section of the CRF. Up to three other time points can be recorded.

Data entry

REDCap data entry link can be acquired by emailing **RAPID@uts.edu.au** and requesting the link to the series that is applicable to you.