Series Manual

Dressings for Malignant Cutaneous Wounds - Series 38

What is this series about?

It is estimated that fungating wounds present in 5-14% of advanced cancer patients, often occurring in the last 6 months of life and most commonly associated with breast or head and neck cancers. Malignant cutaneous wounds are caused by direct infiltration of the skin, tissues, mucosa, blood or lymph vessels by a tumour or metastatic deposit. Patients find these wounds extremely distressing and uncomfortable as they can be painful, become infected, produce high levels of exudate, cause bleeding and be malodourous. In particular, wound malodour is an overwhelming concern for the patient, their family, and carers, at times preventing people being in the same room as the patient. The physiological, psychological and sociological consequences of living with a malodorous wound have a dramatic impact on the comfort, the overall pain experience and the quality of life for individuals and those around them, in the face of terminal disease. The holistic management of these wounds is challenging as there is no robust evidence for which of the current treatment options are the most effective at improving quality of life or managing symptoms.
The aims of this Rapid Program series are to identify what wound management procedures clinicians use for malignant cutaneous wounds, how clinicians decide on what course of management they will take for the wound and which management/s achieve the goals of care.
We thank you for your time and valuable expertise in participating in this series.

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

a) 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 3 digit number

ii) Medication number

The medication number for the Dressings for cutaneous malignant wounds series is **38**

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/**38**/001

Time points

There are 3 main time points where data is required;

1. Commencement of the intervention (baseline) (T0)
2. 3 days post baseline (T1)
3. 7 days post baseline (T2)

Other data collection points are:

Date of death – at the beginning of each timepoint there is the ability to enter date of death if patient has died.

- 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.