# The incidence and time to presentation of Capecitabine induced cardiovascular toxicity in rectal cancer patients receiving concurrent chemo-radiotherapy.

**Descriptor:**

To evaluate critically the incidence of and time to presentation of Capecitabine induced CVT in rectal cancer patients receiving concurrent chemo-radiotherapy. Aims:

1. To quantify the incidence of Capecitabine induced CVT within this patient cohort

2. To quantify the time to presentation of Capecitabine induced CVT within this patient cohort

**Background:**

Chemo-radiotherapy with Capecitabine is standard treatment for locally advanced rectal cancer. Within this treatment regime, Capecitabine is prescribed at 825mg/m2 twice daily (BD), days 1 – 35 of treatment. Coronary vasospasm is a recognised toxicity of Capecitabine. Risk factors for the development of cardiovascular toxicities (CVT) include a previous history of cardiovascular disease (CVD) and obesity. The presentation and incidence of Capecitabine induced CVT (across all malignancies) are poorly defined, with no literature identifying the incidence within patients receiving Capecitabine with radiotherapy treatment at the dose of 825mg/m2 /BD. Patients receiving treatment for metastatic disease commonly receive a Capecitabine dose of 1250mg/m2/BD1, 7, with a common CVT incidence of 5% (ranges of 3-9%). However, extremes of 1.2-34.6% have been reported. CVT specifically reported in patients with rectal cancer range from 10.7 - 14%.

## The Cycle

**The standard:**

Currently, there are no international or national standards regarding the incidence of Capecitabine induced CVT in patients receiving chemo-radiotherapy for rectal cancer. Following a literature review and based on clinical practice, the following objective was defined:

• The local incidence of Capecitabine induced CVT will be = 5%

**Target:**

The audit was carried out to provide baseline data to facilitate discussion around the local incidence of Capecitabine induced CVT and to provide evidence for target setting in future policy/audits.

## Assess local practice

**Indicators:**

• This audit was undertaken between September 2012 – March 2013 for rectal cancer patients treated between March 2008 - March 2012

   1. Rectal cancer diagnosis

   2. Referred for concurrent radiotherapy with oral Capecitabine

   3. No previous chemotherapy or radiotherapy treatment for rectal cancer diagnosis

   4. Complete clinical history recorded within clinical case notes

   5. CVT were defined as a positive clinical history with or without ischaemic ECG changes or a raised Troponin

**Data items to be collected:**

• Gender

• Age at diagnosis

• T stage, N stage, M stage

• Tumour location in relation to bowel anatomy

• Height, weight, BMI calculation, BMI status

• WHO P/S

• Previous medical history

• Smoking status

• Alcohol status/intake

• Allergy status

• Current medication/s

• Defunctioned prior to treatment

• Surgical status – pre/post-operative

• Chemotherapy dose prescribed

• Rational of chemotherapy dose reduction (if applicable)

• Incidence of CVT – yes/no

• Nature and type of symptoms

• Radiotherapy # number at CVT presentation

• Chemotherapy stopped or re-challenged

• Outcome of CVT

**Suggested number:**

N=500

With an average reported incidence of 5% of CVT due to Capecitabine, a study size of 500 patients produced a standard error of 1.0%. This was felt to be an acceptable level of statistical significance, power and a feasible study within the authors time scale. It is recognised that a larger study sample size would have reduced the standard error rate; however this would not have been practical due to time pressures.

**Suggestions for change if target not met:**

Review of local policy regarding the patient inclusion and exclusion criteria for receiving Capecitabine with concurrent radiotherapy.

**Resources:**

• Access to patient notes electronic / paper

• Set up Excel spreadsheet for collection and analysis of data

**References:**

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**Editor's comments:**

It is recognised that this clinical audit excludes a large amount of patients due to the extensive amount of data collected and analysed. Not all data has been reported within this audit. For other centres to undertake this audit, not all data items require collection. The clinical team are happy to be contacted if further information or support is required.

**Submitted by:**

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**Published Date:**

Thursday 1 May 2014

**Last Reviewed:**

Thursday 1 May 2014