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GI obstruction: an Italian EPCCS add-on study

Cinzia Brunelli,
National Cancer Institute-Milano
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BACKGROUND

- Malignant gastro-intestinal obstruction (MGIO) is a relatively common complication of advanced solid tumours and has direct implications on patients quality of life.
- A wide range of treatment options currently exist for MGIO, including surgical interventions, endoscopically placed stents, chemotherapy and other medical management.

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BACKGROUND

- Existing literature offers little evidence to optimal MGIO management.
- Most articles are reports from retrospective studies carried out on single institutions in selected populations over many years.
- The few prospective surveys are uncontrolled observational studies of outcomes from a single form of therapy.

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STUDY DESIGN

The MGIO is an observational multicentre longitudinal study carried out within the EPCCS study project.

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STUDY AIM

To describe the clinical management of MGIO (diagnosis, treatment and symptomatology) in patients followed by palliative care services for advanced malignant abdominal disease, not eligible for palliative surgery or for curative anti-neoplastic treatment.

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MGIO DIAGNOSIS

THE FOLLOWING ELEMENTS MUST BE PRESENT:

- presence of at least one GI symptom requiring palliative treatment (abdominal colicky pain, nausea, vomiting, abdominal distension);
- clinical evidence of GI dysfunction (reduced bowel function and reduced ability to oral intake for solid food and/or liquids);
- clinical or radiological/instrumental evidence of GI obstruction (plain RX or contrast RX, or CT scan, or US or endoscopy);
- instrumental evidence of abdominal malignant disease (intra-abdominal primary or metastatic cancer).

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MGIO STUDY ELIGIBILITY SCREENING

	YES	NO
INCLUSION CRITERIA		
Informed Consent to participation and enrolment in the EPCCS study	√	
Presence of at least one GI symptom requiring palliative treatment (abdominal colicky pain, nausea, vomiting, abdominal distension)	√	
Clinical evidence of GI dysfunction (reduced ability to oral intake for solid food and/or liquids, reduced bowel function)	√	
Instrumental evidence of abdominal malignant disease (intra-abdominal primary or metastatic cancer)	√	
Clinical or radiological/instrumental evidence of GI obstruction	√	
EXCLUSION CRITERIA		
Waiting for palliative surgery for MGIO treatment		√

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DATA COLLECTION

Data will be prospectively collected within the EPCCS study through an additional CRF made up of three parts :

- a screening CRF
- baseline and a longitudinal CRF for treatment and symptoms evaluation
- an end of study CRF

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SAMPLE SIZE

- The sample size depends on the prevalence of this complication in the population followed by centres participating in the EPCCS.
- We aim at involving at least 20 PC centres in the MGIO study for a total of 1000 patients screened.
- In the hypothesis of a 15% prevalence of MGIO in a palliative care population, 150 patients are expected to be enrolled.

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ANALYSIS

This observational descriptive study will allow to:

- Estimate MGIO prevalence in a population of advanced cancer patients
- Describe diagnostics and treatments used in the management of MGIO
- Study the association between MGIO and other clinical and demographic patient related characteristics
- Describe the main MGIO symptoms development during the first 4 weeks from diagnosis, by treatment.

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FUTURE DEVELOPMENTS

A large multicentre international observational longitudinal study

- Allows targeted hypothesis generation
- Provides data to plan future intervention studies

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ITALIAN EPCCS STUDY GROUP

- 14 Italian centers accepted to participate in EPCCS study
 - Most of them are waiting for ethical approval
 - Five are ready to start patients accrual
- 12 centres are participating in the MGIO study

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**THE PARTICIPATION TO MGIO STUDY
IS OPEN TO EUROPE**

WHO WANTS TO JOIN?

alessandra.pigni@istitutotumori.mi.it
cinzia.brunelli@istitutotumori.mi.it