



E-StOIC study: single question versus Rome IV diagnostic criteria for diagnosis of opioid-induced constipation

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BACKGROUND

The European Study of Opioid Induced Constipation (“E-StOIC”) study is an observational study investigating the diagnostic criteria, clinical features and management of opioid-induced constipation (OIC) in cancer patients from 10 European countries.

The study will involve 120 participants from Ireland, Denmark, Finland, France, Germany, Italy, Netherlands, Norway, Spain, and the United Kingdom (i.e. 1200 participants in total). The study is ongoing, with recruitment completed in Ireland and Netherlands.

This abstract describes the results of the Irish and Dutch cohort of participants (recruited from inpatients and outpatients / home care patients).

Further results from the study are presented in poster P 2.094.

METHODS

Cancer patients receiving any opioid analgesic for pain for at least a week were recruited. Participants were asked to complete a one-off questionnaire, including background information (demographics, ECOG performance status / PS, analgesic usage, laxative usage); a single question “are you constipated?”; a question relating to the EAPC definition of constipation (“the passage of small, hard faeces infrequently and with difficulty”); the Rome Foundation diagnostic criteria for OIC (see below); and the Bowel Function Index (BFI).

ROME IV Diagnostic Criteria for OIC

1. New or worsening symptoms of constipation when initiating, changing, or increasing opioid therapy that must include 2 or more of the following:

- Straining during more than one-fourth (25%) of defecations
- Lumpy or hard stools (Bristol Stool Form Scale 1-2) more than one-fourth (25%) of defecations
- Sensation of incomplete evacuation more than one-fourth (25%) of defecations

METHODS

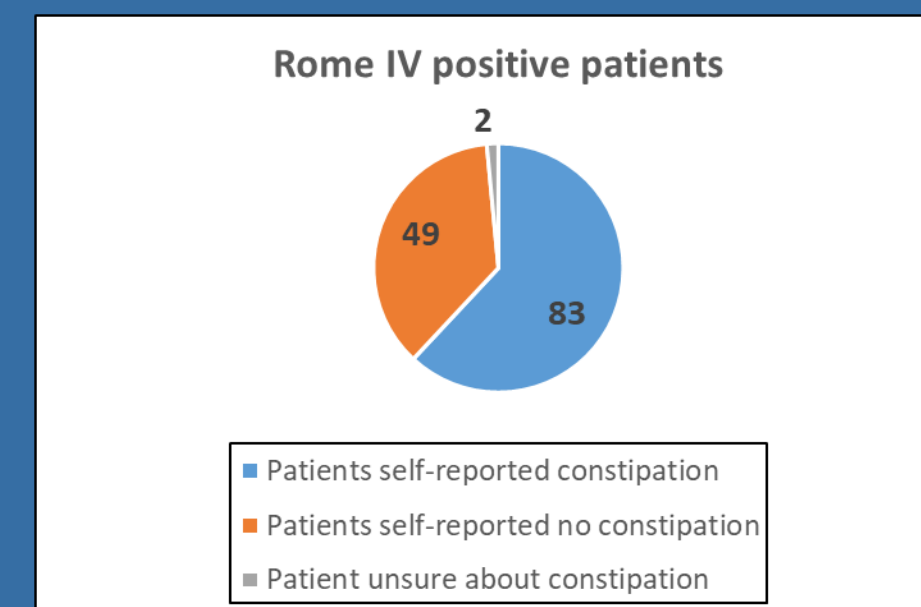
- Sensation of anorectal obstruction / blockage more than one-fourth (25%) of defecations
- Manual maneuvers to facilitate more than one-fourth (25%) of defecations (e.g. digital evacuation, support of pelvic floor)
- Fewer than 3 spontaneous bowel movements per week

2. Loose stools are rarely present without the use of laxatives

RESULTS

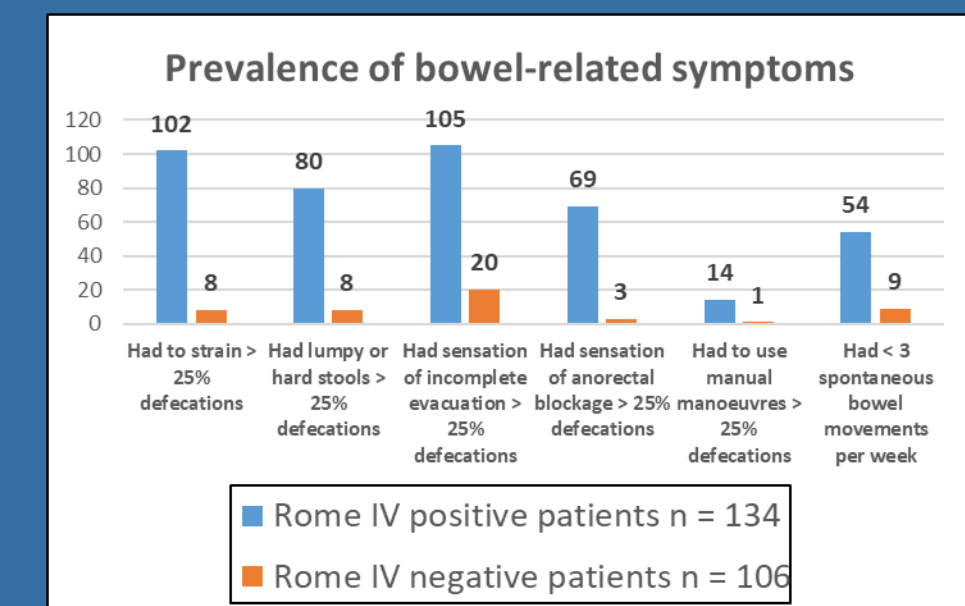
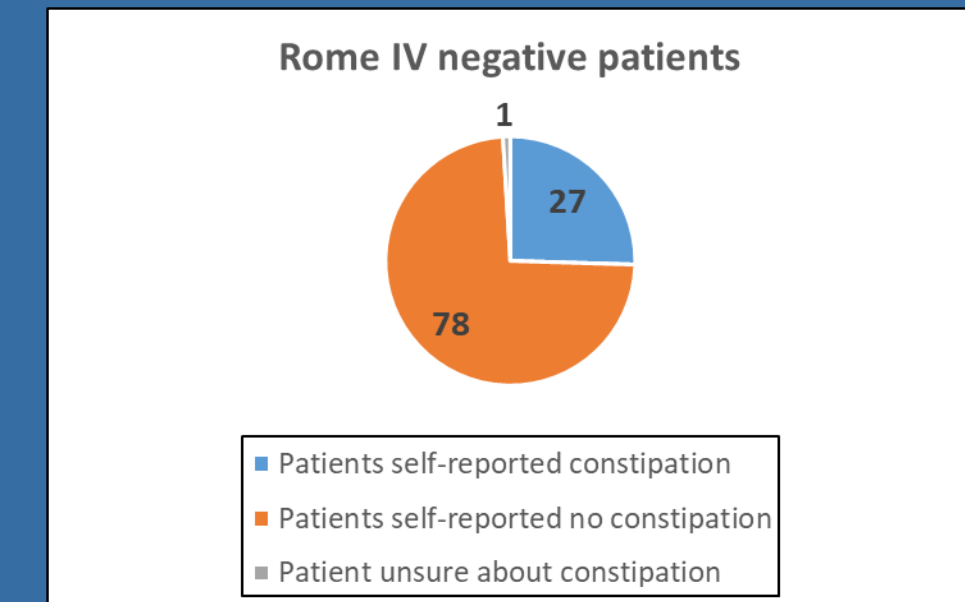
242 patients were recruited, and 240 completed study: the median age was 66yr (range 23-96yr), and 52% were male. The most common diagnoses were GI cancer (22.5%), lung cancer (21%), breast cancer (13%), and urological cancer (11.5%). 30.5% had ECOG PS 2, 36% ECOG PS 2, and 24% ECOG PS 3. The most common opioid analgesics were oxycodone (41%), fentanyl (24%), morphine (18%), oxycodone / naloxone combination (6.5%).

46% (110) patients self-reported constipation (i.e. single question), although 56% (134) patients met the Rome IV criteria for OIC. Of the patients that met the Rome IV criteria, only 83 (62%) reported being constipated, whilst 49 (36.5%) reported being not constipated (with 2 patients “unsure”).



Of the patients that self-reported constipation, only 46 (42%) agreed that “the passage of small, hard faeces infrequently and with difficulty” described their bowel habit (i.e. EAPC definition).

RESULTS



126 (52.5%) had a BFI >28 (which is indicative of inadequate management of constipation), including 38 (30%) patients that self-reported no constipation.

CONCLUSIONS

Many patients with OIC (diagnosed using the Rome IV criteria) do not consider themselves constipated, and the use of a simple yes / no question to assess OIC is insufficient in this cohort of patients.

This study is an investigator initiated study, which has received unrestricted funding from Kyowa Kirin International.

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