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On behalf of the

### E-STOIC Study Group

## BACKGROUND

E-StOIC study is an observational study of diagnostic criteria, clinical features, and management of opioid-induced constipation (OIC) in cancer patients from 10 European countries (Ireland, Denmark, Finland, France, Germany, Italy, Netherlands, Norway, Spain, UK).

This abstract describes the clinical features of opioid induced constipation in cancer patients from the 10 European countries.

Further results from the study are presented in poster P2474.

## METHODS

Cancer patients receiving opioid analgesics for at least a week were recruited, and asked to complete a questionnaire including background information, single question (Are you constipated?), Rome IV diagnostic criteria for OIC, Bowel Function Index (BFI), and Patient Assessment of Constipation Quality of Life questionnaire (PAC-QOL).

### 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:
  - a) Straining during more than one-fourth (25%) of defecations
  - b) Lumpy or hard stools (Bristol Stool Form Scale 1-2) more than one-fourth (25%) of defecations
  - c) Sensation of incomplete evacuation more than one-fourth (25%) of defecations
  - d) Sensation of anorectal obstruction / blockage more than one-fourth (25%) of defecations
  - e) Manual manoeuvres to facilitate more than one-fourth (25%) of defecations (e.g. digital evacuation, support of pelvic floor)
  - f) Fewer than 3 spontaneous bowel movements per week

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

## RESULTS

1200 patients completed the study: median age 65yr (range 23-96yr), 51% female; 25.5% GI cancer, 19% lung cancer, 14% urological cancer; 30% ECOG PS 1, 32.5% ECOG PS 2, 27.5% ECOG PS 3. The median morphine equivalent daily dose (MEDD) was 70mg / day; 30% morphine, 29.5% oxycodone, 22% fentanyl.

In answer to the question "Are you constipated?", 549 (45.5%) participants replied "yes", 588 (49%) replied "no" and 59 (5%) were "unsure" (with missing data in four cases - 0.5%). However, 713 (59.5%) participants met the Rome IV diagnostic criteria for OIC: only 61.5% (439) participants that met these criteria self reported, i.e. 439 patients reporting they were constipated, 230 patients reporting they were not constipated, 41 patients that were "unsure" if they were constipated (with three missing responses).

Figure 1 shows data on patient self-reported constipation versus individual Rome IV diagnostic criteria for opioid-induced constipation.

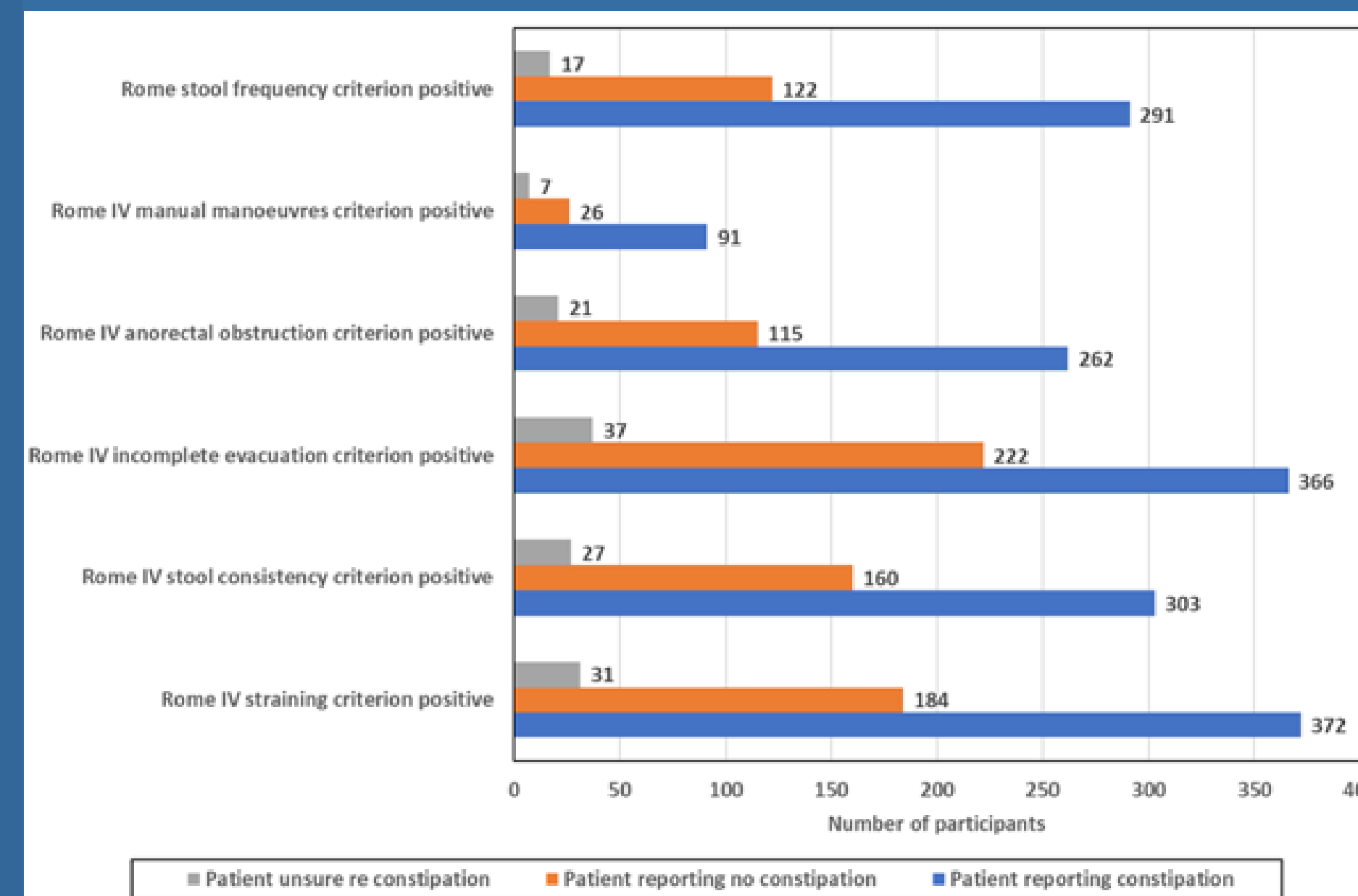
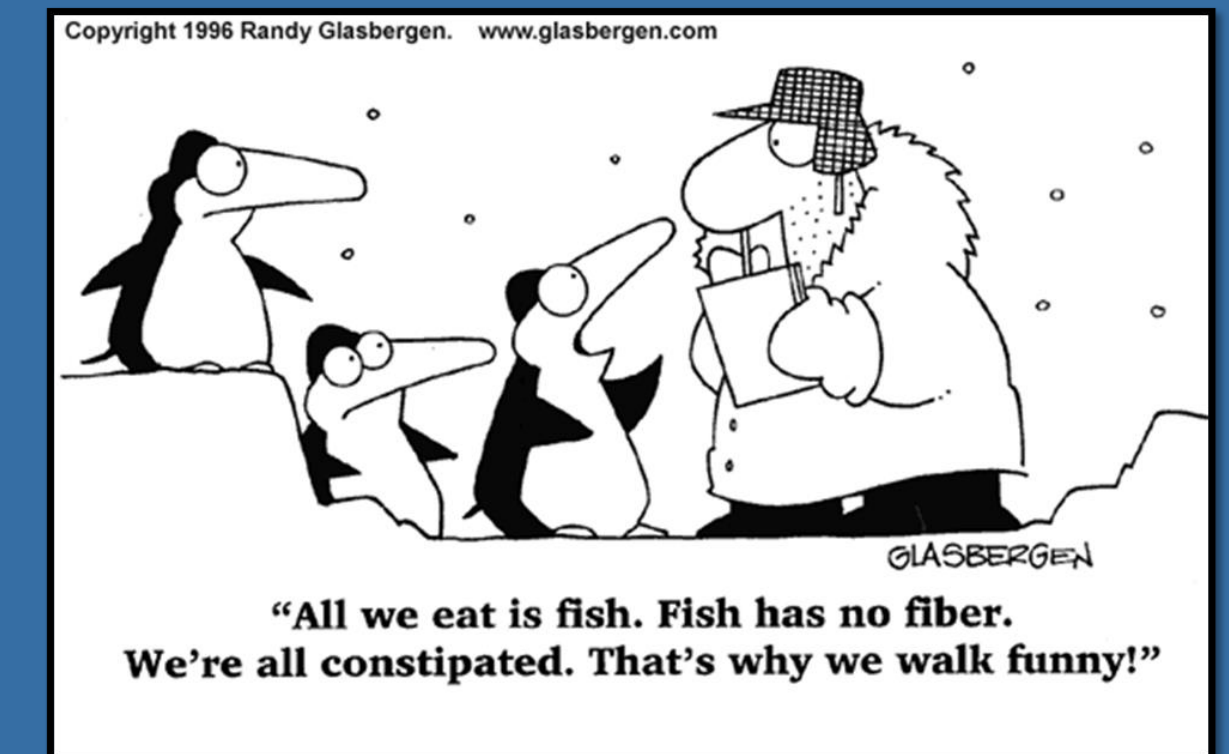


Figure 1 - Patient self-reported constipation versus individual Rome IV diagnostic criteria for opioid-induced constipation.

## RESULTS



Rome IV diagnostic criteria positivity was associated with younger age (Mann-Whitney U-test:  $p = 0.003$ ), and certain cancer diagnoses (Chi-square test:  $\chi^2 = 31.12$ ;  $p = 0.001$ ). Thus, OIC was more frequent in patients with breast cancer, lung cancer, skin cancer (melanoma), and urological / male genital cancer. However, it was not associated with sex (Chi-square test:  $p = 0.950$ ), or ECOG performance status (Chi-square test:  $p = 0.754$ ). Rome IV diagnostic positivity was associated with higher MEDD (Mann-Whitney U-test:  $p = 0.018$ ), and was less frequent in patients receiving transdermal buprenorphine as their background opioid analgesic (Chi-square test:  $\chi^2 = 4.32$ ;  $p = 0.038$ ).

## CONCLUSIONS

OIC remains a common problem in European cancer patients. 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 not adequate enough.

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