E-StOIC study: prescribed and non-prescribed management of OIC

Prof Andrew Davies[1,2,3], Dr Wendy Oldenmenger[4], Prof Marieke van den Beuken – van Everdingen[5], Dr Craig Gouldthorpe[1,3], Norah Fagan[3]
[1] Trinity College Dublin, [2] University College Dublin, [3]Our Lady's Hospice (Dublin), [4]Erasmus MC (Rotterdam), [5]Maastricht UMC

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 2.013.

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 – prescribed / non-prescribed); a single question "are you constipated?"; the Rome Foundation diagnostic criteria for OIC; and the Bowel Function Index / BFI (see below).

Bowel Function Index

1. During the last 7 days, how would you rate your ease of defecation on a scale from 0 to 100, where 0 = easy or no difficulty and 100 = severe difficulty?
2. During the last 7 days, how would you rate your feeling of incomplete bowel evacuation on a scale from 0 to 100, where 0 = no feeling of incomplete evacuation and 100 = a very strong feeling of incomplete evacuation?
3. During the last 7 days, how would you rate your constipation on a scale from 0 to 100, where 0 = not at all and 100 = very strong?

BFI score = mean score (for three items)

BFI score >28 = inadequate management

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 1, 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%).
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").
188 (78.5%) patients were prescribed laxatives: one drug - 121; two drugs - 56; three drugs - 9; four drugs - 2. The most common laxatives were macrogol (65%), senna (34.5%), and lactulose (20%). 10 patients were prescribed a PAMORA, although another 15 patients were prescribed an oxycodone / naloxone combination.
122 (65%) took prescribed laxatives every day, whilst 23 (12%) took them regularly (but not every day), 17 (9%) took them when bowel movements were less than normal, and 20 (11%) when they were "constipated" (with 6 patients "unsure" or no data).

Other strategies for managing constipation included:
❖Change in diet – 29%
❖Increase in fluid intake – 46.5%
❖Increase in exercise – 12%

RESULTS

❖Over the counter preparations – 15%
❖Complementary therapies – 6%
❖Opioid dose reduction – 6%
❖Opioid discontinuation – 4.5%

❖Suppositories – 21.5%
❖Enemas – 24.5%
❖Manual evacuation – 5.5%
126 (52.5%) patients had a BFI > 28 (which is indicative of inadequate management of constipation): 88 (80%) patients that reported constipation had a BFI > 28 (median – 50; range 0-100), whilst 38 (30%) patients that reported on constipation had a BFI > 28 (median 13; range 0-92).

CONCLUSIONS

OIC appears to be sub-optimally managed in this cohort of patients, with many patients resorting to non-prescribed interventions, and many patients requiring invasive interventions (i.e. suppositories, enemas, manual evacuation). Importantly, patients are adopting strategies which are relatively ineffective in managing OIC, and which may be difficult to maintain (i.e. change in diet / increase in fibre intake, increase in fluid intake, increase in exercise).

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