Real-world-data analysis of Patient-Reported Outcomes collected through the H2O consortium from patients with inflammatory bowel disease

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INTRODUCTION

The collection of **patient-reported outcomes** (PROs) in clinical practise is becoming increasingly important. However, lack of standardisation limits their usefulness. The **Health Outcomes Observatory** (H2O) project aims to standardise and facilitate the collection of PROs and clinical outcomes by developing multi-stakeholder agreed Core Outcome Sets (COS), including one for patients with inflammatory bowel diseases (IBD). This study describes preliminary data from three centres implementing the H2O-COS for IBD.

OBJECTIVE

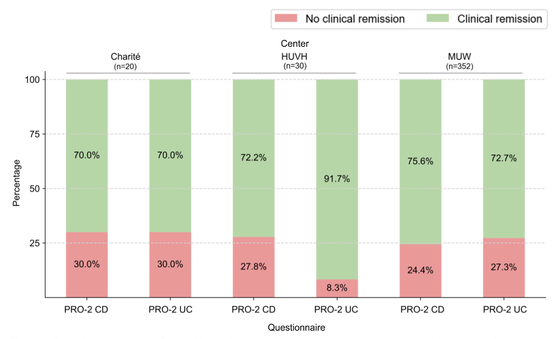
To implement and describe the collection of patient-reported outcomes (PROs) using the H2O Core Outcome Set (COS) for IBD, focusing on the assessment of symptom control, quality of life and treatment satisfaction, and to evaluate the comparability of outcomes and feasibility of joint analysis between centers.

METHOD

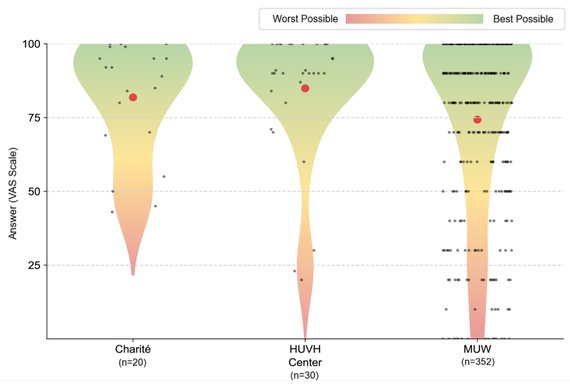
Three university hospitals - Vall d'Hebron, Barcelona (HUVH), Charité, Berlin and MedUni, Vienna (MUW) – implemented the H2O-COS for IBD, using **PRO-2** for Crohn's disease (CD) and ulcerative colitis (UC) symptoms and **IBD-Control** for quality of life and treatment satisfaction. Data were collected from December 2023 to June 2024.

RESULTS

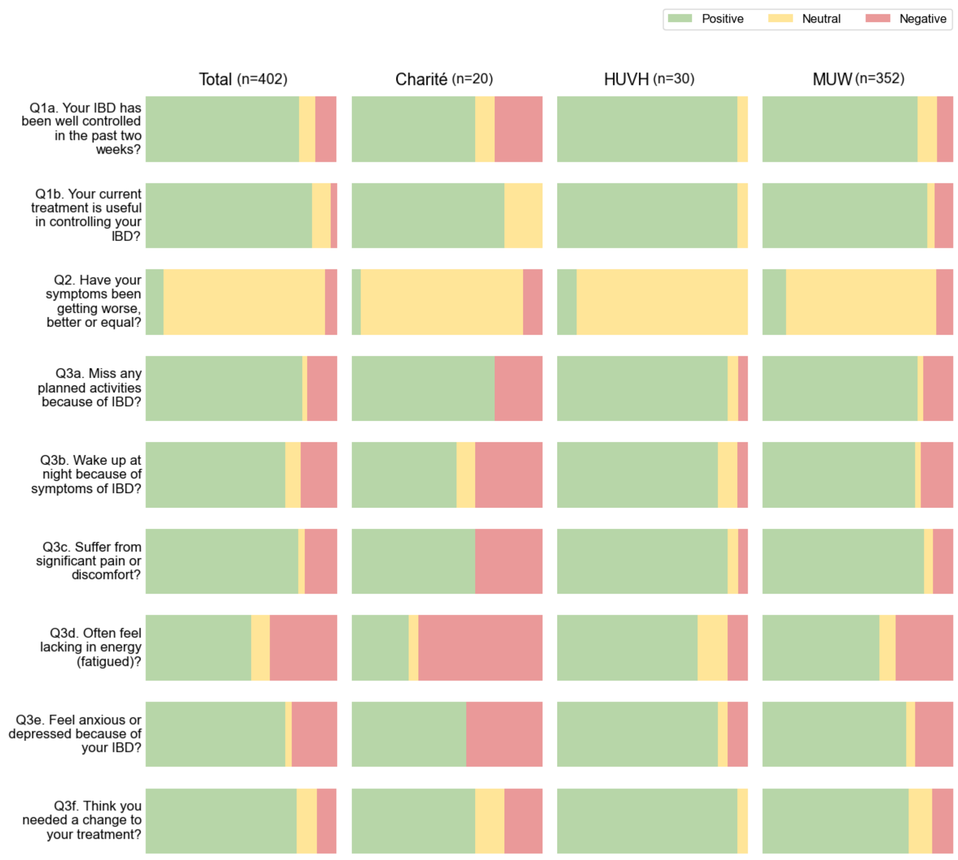
Data from 402 patients were analysed: 30 from HUVH, 20 from Charité and 352 from MUW. The substantial differences in sample sizes limit the feasibility of comparative analyses due to potential biases related to disease severity or stage in the selected populations. Therefore, the results focus on descriptive analysis, assessing the potential for comparability in this context. Symptomatic remission was present in 92% UC patients in HUVH. Rectal bleeding and increased bowel movements were reported by 10% and 50% in Charité UC patients, and 13% and 45% in MUW. CD patients reported moderate or severe abdominal pain in 30% (Charité),12% (MUW) and 9% (HUVH). In the IBD-Control questionnaire, 11%, 65% and 30% of HUVH, Charité and MUW patients reported fatigue, and 11%, 40% and 20% reported anxiety or depression associated with IBD, respectively. The most anticipated topics for upcoming visits were "side effects or difficulties with using my medication" in HUVH (47%) and "ways to adjust my own treatment" in MUW (30%). Overall, 88% of patients believed that their current treatment is useful in controlling IBD.



Remission results *displayed as percentages for each center-disease type combination. Clinical remission is defined as follows: for UC, PRO-2 ≤ 1, rectal bleeding sub-score = 0, and stool frequency score ≤ 1; for CD, the number of stools ≤ 3 and abdominal pain score ≤ 1. In the case of MUW, all patients responded to both questionnaires, thus remission was calculated for all patients in both disease types.*



Distribution of overall control rate of IBD *in the last two weeks, by center. Based on responses to IBD-Control Questionnaire item 5. The red dot shows the mean of the responses.*



Distribution of responses to IBD-Control Questionnaire Items*, overall (Total) and by center. Responses classified as "Negative" correspond to "No" for questions 1a and 1b, and "Yes" for questions 3a to 3f. "Positive" correspond to "Yes" for questions 1a and 1b, and "No" for questions 3a to 3f. "Neutral" ratings represent "Not Sure" responses to all questions.*

CONCLUSIONS

Integrating PRO collection into routine care not only improves personalized treatment and facilitates patient-physician discussions but also reveals underlying issues that might otherwise go unnoticed. The multi-center implementation of the H2O-COS was feasible, and despite patients reporting good control of their IBD, many still experienced symptoms such as anxiety, depression, and fatigue, highlighting the need for further consultation. Standardized data collection enables inter-center comparison and supports multicenter research, showing the potential of PROs to enhance care by addressing both clinical outcomes and patients' quality of life.

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