



Observational study

## Opioid-induced constipation, use of laxatives, and health-related quality of life



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### H I G H L I G H T S

- We studied laxative use and quality of life in persons with opioid-induced constipation (OIC).
- 417 opioid treated patients with OIC self-administered a cross-sectional online survey.
- Abdominal pain and bloating were frequent as was laxative self-management of OIC.
- Quality of life was low among those using several laxatives and those using laxatives daily.

### A R T I C L E I N F O

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### A B S T R A C T

**Background and aims:** Real-life data on laxative use in patients suffering from opioid-induced constipation (OIC) are very limited, and many OIC patients are only using over the counter laxatives to resolve their constipation. Our aim was to describe laxative utilization and quality of life in participants in Norway who ever experienced OIC.

**Methods:** This was a cross-sectional online survey conducted between 27th of June and 3rd of July 2014 among participants above 18 years with self-reported OIC and who had agreed to receive information from the pharmacy chain (Boots A/S, Norway). The questionnaire comprised a series of multiple choice, close-ended, and free text questions on abdominal symptoms, laxative use and health-related quality of life.

**Results:** A total of 417 participants met the study eligibility criteria: (1) treated with opioid for a minimum of 4 weeks, (2) actively accepted participation, and (3) confirmed ever experiencing OIC and in addition completed the survey. Among the eligible participants, 86% were females, 85% were younger than 60 years of age, and 57% were currently suffering OIC. More than half of the currently constipated participants were experiencing moderate to very severe abdominal bloating (63%), abdominal pain (55%) and/or pain during bowel movement (50%). Less than every fourth participant (23%) had consulted health care professionals (HCPs) about their constipation. Up to 39% reported that they handled their OIC by self-management, e.g., bought laxative, reduced the dose and/or changed opioid without consulting HCP or pharmacy. Less than half (48%) of the laxative users were satisfied with the laxative they were using to relieve their constipation. The EQ-5D health-related quality of life score was mean (SD): 0.587 (0.272). Although not statistically significant ( $p=0.067$ ), there was a tendency of lower quality of life among the participants who were currently constipated compared with those not currently constipated (difference of mean EQ-5D:  $0.629-0.555=0.074$ ). A significantly lower ( $p=0.001$ ) quality of life was found among participants who were dissatisfied with their laxative [mean (SD): 0.424 (0.350)] than among those who were satisfied or neither satisfied nor dissatisfied [mean (SD): 0.628 (0.235) and 0.673 (0.155), respectively].

**Conclusions:** The results suggest a high degree of moderate to very severe abdominal symptoms, a high degree of self-management of opioid-induced constipation, a low degree of satisfaction with laxative, and low health-related quality of life of patients suffering from chronic pain necessitating long-term opioid treatment, subsequent constipation and laxatives use.

**Implications:** Patients suffering from OIC with low quality of life and remaining symptoms despite use of two or more laxatives are a vulnerable patient group in need of optimized healthcare management, who also might benefit from more specific and innovative therapy.

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**Table 1**  
Study eligibility criteria.

Opioid therapy $\geq 4$ weeks with the expectation to continue for at last 3 months (target population)	Participants who confirmed used of one or more of the specified opioid therapies:  Tramadol hydrochloride, tramadol hydrochloride/paracetamol Oxycodone hydrochloride Oxycodone hydrochloride, naloxone Morphine, hydromorphone hydrochloride, morphine sulphate, morphine sulphate pentahydrate Buprenorphine Methadone hydrochloride Codein/paracetamol Ketobemidone Pethidine hydrochloride Fentanyl
OIC (criteria for confirmation of study eligibility)	Participants who respond “yes” to the question “have you ever experienced constipations while on opioid therapy such as less than three BM pr. week, bloating or pain in abdomen, BM too hard or straining/squeezing BM”

OIC: opioid induced constipation; BM: bowel movements.

## 1. Introduction

Constipation is a well-known and common side-effect of opioid treatment in patients with moderate-to-severe pain. Between 40 and 70% of chronic opioid users suffer from opioid induced constipation (OIC) [1–5].

A majority of patients experiencing symptoms of OIC, report that the OIC has negative impact on their general quality of life and every day activities [6–8]. In a recent study, more than 70% of the patients who receive opioids due to musculoskeletal pain, reported that they had not been informed about the risk of experiencing/developing OIC as a treatment side-effect [9]. Additionally, one-third of the patients had skipped doses, reduced or stopped their use of opioid therapy in order to resolve their gastrointestinal side effects, resulting in increased experience of pain for more than 90% of these patients [6].

Real-life data on laxative utilization among patients suffering from OIC are very limited, and many patients suffering from OIC are only using over the counter laxatives to resolve their constipation.

In this cross-sectional survey study, the aim was to describe laxative utilization and quality of life in participants who ever experienced OIC.

## 2. Method

### 2.1. Study design and sample

This is a cross-sectional survey study among participants experiencing self-reported OIC. The online survey was conducted in collaboration with a pharmacy chain (Boots A/S, Norway), administering the survey via e-mail to more than 82,000 individuals who had indicated an interest in receiving general information from the pharmacy. Participants had to (1) confirm that they had been on opioid therapy for a minimum of 4 weeks with an expectation to continue for at last 3 months (to ensure participants were consistently treated with opioid e.g. not acute injury or post-surgical use), (2) actively accept participation in the study to get online access to the self-reported questionnaire, and (3) the participants had to confirm ever experiencing constipation while on opioid therapy. The study eligibility criteria are presented in Table 1.

### 2.2. Data collection

All participants were informed that participation was voluntary and anonymous, and they gave consent to the collection, use, and disclosure of their online response. No data were collected that potentially could identify a person such as date of birth, name or personal identification number. The online survey took approximately 10 min to complete and comprised a series of multiple choice, close-ended, and free text questions which was divided in two parts, symptoms and treatment and health related quality of life. Data were collected between 27th of June 2014 and 3rd of July 2014.

Initially, eligible participants were asked if they were currently experiencing constipation while on opioid therapy, those who confirmed current constipation were then asked to evaluate the severity (no, mild, moderate, severe or very severe) of the following three common symptoms of OIC: abdominal pain, abdominal bloating, and pain on/during bowel movements.

Eligible participants were asked about management of their OIC, and their responses were categorized into: consulted health care professional (HCP; e.g., physician or nurse); consulted pharmacy without contacting HCP; self-management (e.g., bought over-the-counter laxative, reduced dose of opioid, changed opioid, or other) without contacting a HCP or pharmacy; or other/did nothing.

Participants who reported that they consulted a HCP or a pharmacy were then asked if they were advised to buy laxative with or without a prescription.

- Prescribed laxative users were defined as those who were advised by a HCP or pharmacy to buy prescribed laxative.
- Non-prescribed laxative users were defined as those who were advised by HCP or pharmacy to buy laxative without prescription and those who bought laxative without contacting a HCP or a pharmacy.

Both prescribed and non-prescribed laxative users were asked to specify what type of laxatives they bought: macrogol 3350/potassium chloride/sodium bicarbonate/sodium chloride, lactulose, bisacodyl, senna, ispaghula, other. Further, all laxative users were categorized according to number of different brands of laxatives used (one laxative, two or more laxatives), frequency of laxative use (daily; 6–3 days/week; 1–2 days/week; <1 day/week), and self-rated satisfaction with laxative on a 5-point scale from very satisfied to very dissatisfied.

Health related quality of life was assessed by means of the Euro-QOL 5 Dimensions (EQ-5D) [10] which is a validated 5-item health state descriptive system where full health is one, and zero is equivalent to death (EQ-5D index) and a visual analogue scale (EQ-5D VAS, range 0–100 from worst to best imaginable health state).

### 2.3. Statistical methods

Continuous variables are presented as means and standard deviations and categorical variables as absolute and relative frequencies. Statistical comparisons were made using analysis of variance (ANOVA) for continuous variables and chi-square test for categorical variables. The significance level is set at 5% but as no adjustment for multiplicity has been performed the *p*-values should be considered as exploratory.

### 2.4. Ethical conduct

An opinion was obtained from Regional Committees for Medical and Health Research Ethics (REC) in writing (reference number:

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