Characteristics of Patients Prescribed Naldemedine in United Kingdom Primary Care: an Observational Retrospective Cohort Study

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Background

- Opioid-induced constipation (OIC) is a common problem for patients receiving opioid-based pain management.[1]
- Conventional laxatives often fail to adequately manage OIC, highlighting the need for targeted treatments [2,3]
- Peripherally-acting mu-opioid receptor antagonists (PAMORAs) counteract the constipating impact of opioid therapies by blocking mu-opioid receptors in the gut.[4]
- Naldemedine is recommended, within its marketing authorisation, as an option for treating opioid-induced constipation in adults who have had laxative treatment.[5]
- This study aimed to profile the demographic and clinical characteristics of patients prescribed naldemedine for OIC in UK primary care.

Methods

- Data for this observational, retrospective cohort study were sourced from the Clinical Practice Research Datalink (CPRD) Aurum database, a comprehensive, longitudinal dataset collected from general practices in England and known for its extensive coverage and representativeness.[6,7]
- Patients prescribed naldemedine between 1st September 2020 and 20th October 2023 were selected using therapy codes. Index date was defined as the date of first naldemedine prescription.
- Naldemedine episodes were defined by overlapping prescriptions, with discontinuation defined as a gap of more than 56 days without renewal.
- Baseline characteristics were described, and patterns of naldemedine use were assessed.
- Time to discontinuation was explored using a Kaplan-Meier estimate.
- Adherence was examined using the Medical Possession Ratio (MPR), defined as distinct days' supply prescribed over an episode divided by the duration.

Results

- A total of 171 patients were prescribed naldemedine during the study period (Table 1).
- Mean age at index date was 63 years and 62.0% of the cohort were female (62.0) (Table 1).
- Mean Charlson Comorbidity Index was 2.7 (Table 1).
- In the year preceding index date, 50.3% of patients had a cancer diagnosis, while 29.8% underwent surgery in the month prior (Table 1).
- Opioid use was common, with 98.2% of patients having an opioid prescription in the six months before treatment, and 90.6% having one in the month before (Figure 1).
- 61.4% of patients had a laxative prescription in the month before index (Table 1).
- More than half of the patients discontinued naldemedine after a median of 56 days of treatment (Figure 2).

Table 1. Baseline demographic and clinical characteristics of patients prescribed naldemedine in the Clinical Practice Research Datalink Aurum database

Baseline characteristics	
Total patients	171
Age at index	
Mean (SD)	63.2 (16.1)
Median (IQR)	65.8 (50.1 – 74.6)
Gender	
Male (%)	65 (38.0)
Female (%)	106 (62.0)
Charlson comorbidity index	
Mean (SD)	2.7 (2.7)
Median (IQR)	2.0 (0.0 – 4.0)
Prior cancer (within one year of naldemedine prescription)	
Yes (%)	86 (50.3)
Prior surgery (within 28 days of naldemedine prescription)	
Yes (%)	51 (29.8)
Prior laxative use (within 28 days of naldemedine prescription)	
Yes (%)	105 (61.4)
Total naldemedine prescriptions during follow-up	
Median (IQR)	2 (1-5)
Medical possession ratio (%)	
Mean	104.0
Median (IQR)	100.0 (98.5 – 100.5)

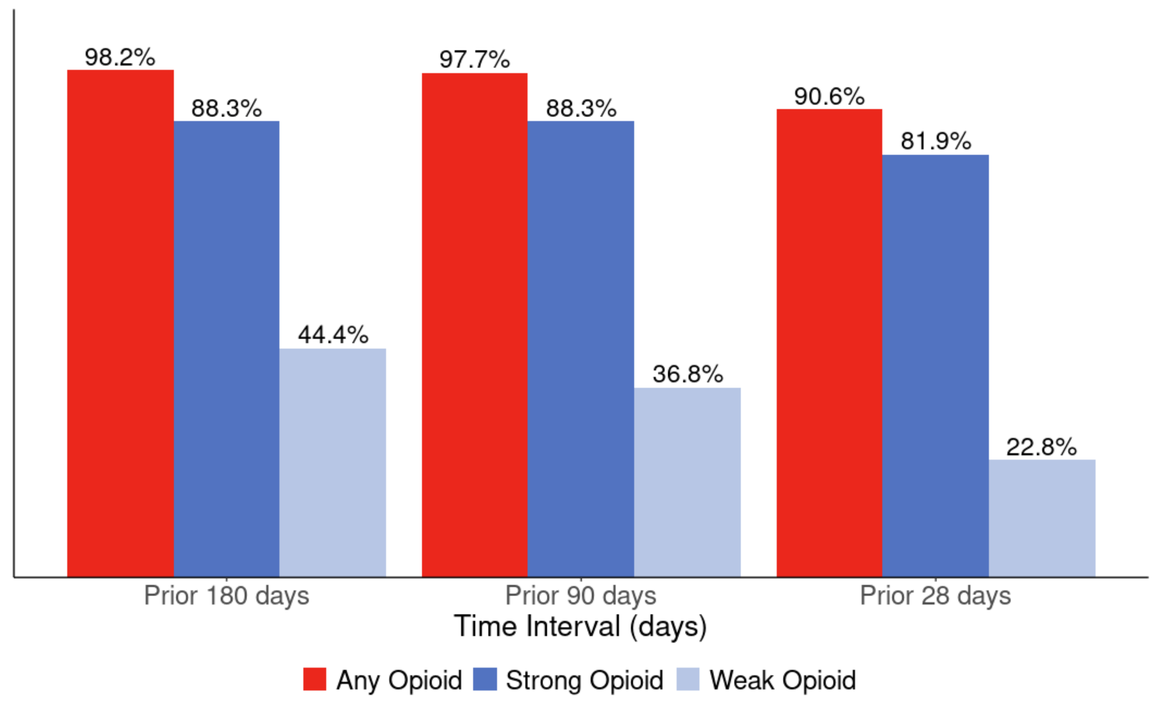

Figure 1. Prior opioid use by strength in patients prescribed naldemedine in the Clinical Practice Research Datalink Aurum database

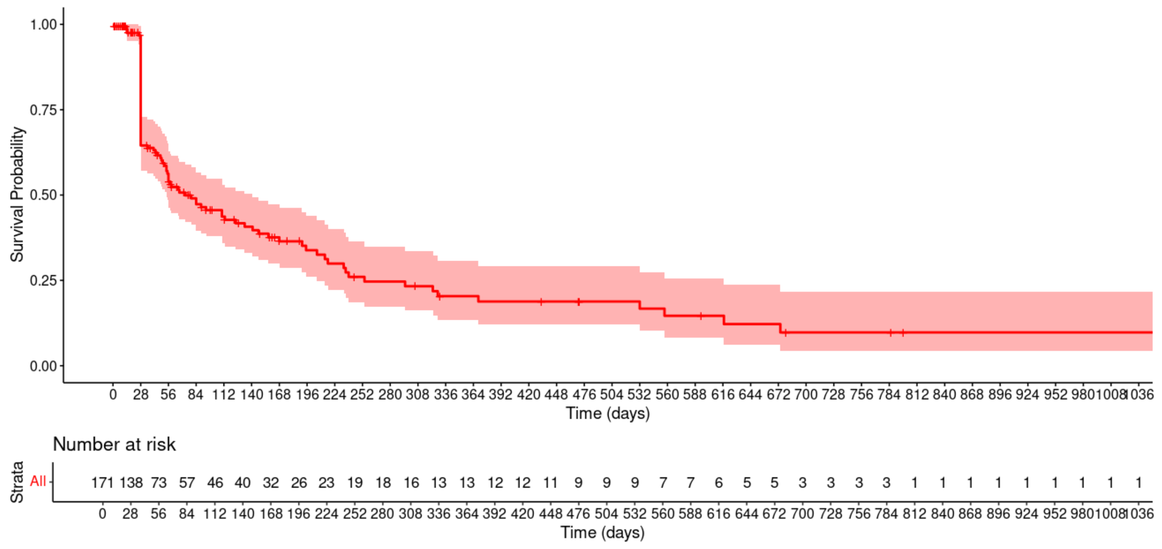

Figure 2. Kaplan-Meier plot of time to naldemedine treatment discontinuation in the Clinical Practice Research Datalink Aurum database

Conclusion

- This study profiles naldemedine use in UK primary care.
- Over half had a record of cancer in the previous 12 months, and almost a third had a code indicative of surgery in the previous month.
- Median prescriptions prescribed were 2, and median exposure was 56 days.

References

1. Kalso E, Edwards JE, Moore RA, et al. Opioid-induced adverse effects: a systematic review and meta-analysis of randomized trials of the efficacy of laxatives. Pain Med. 2012 Mar;13(3):216-29.
2. Candy B, Jones L, Goodman ML, et al. Laxatives for the management of constipation in people receiving palliative care. Cochrane Database Syst Rev. 2015 May 13;(5).
3. Abramowitz L, Béziaud N, Labreze L, et al. Prevalence and impact of constipation and bowel dysfunction induced by strong opioids: a cross-sectional survey of 520 patients with cancer pain: DYONISOS study. J Med Econ. 2013 Dec;16(12):1423-33.
4. Webster L, Brenner DM, Paterson C, et al. PAMORAs for opioid-induced constipation: Efficacy, safety, and future directions. Pain Med. 2020 Nov;21(11):3224-35.
5. National Institute for Health and Care Excellence (NICE). Naldemedine for treating opioid-induced constipation [Internet]. Technology appraisal guidance [TA651]. 2020 Sep 30. Available from: https://www.nice.org.uk/guidance/ta651/resources/naldemedine-for-treating-opioidinduced-constipation-pdf-82609193616325
6. Herrett E, Gallagher AM, Bhaskaran K, et al. Data Resource Profile: Clinical Practice Research Datalink (CPRD). Int J Epidemiol. 2015;44(3):827-36. doi:10.1093/ije/dyv098.
7. Wolf A, Dedman D, Campbell J, et al. Data resource profile: Clinical practice research datalink (CPRD) Aurum. Int J Epidemiol. 2019 Dec;48:1740-1740G.

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