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Investigating the link between Japanese Anticholinergic Risk Scale and laxative prescription in older adults: A cross-sectional study of 9,838 patients using dispensing claims from community pharmacies

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Abstract: Anticholinergic medications can cause constipation in older adults. The Japanese Anticholinergic Risk Scale (JARS), released in May 2024, is not yet sufficiently validated clinically. We examined the association between total anticholinergic burden based on JARS and laxative prescriptions. This cross-sectional study utilized community pharmacy dispensing claims for outpatients aged ≥ 65 years who were registered with a family pharmacist between November 1 and December 31, 2024. Chronic medication use was defined as prescriptions totaling ≥ 28 days during the study period. The primary analysis focused on patients receiving 5–9 concomitant chronic medications. Among the 9,838 patients (mean age 81.1 ± 7.3 years; 61.1% female), 39.4%, 33.2%, 14.7%, 7.0%, 3.1%, and 2.5% demonstrated JARS scores of 0, 1, 2, 3, 4, and ≥ 5, respectively. Compared with JARS = 0, adjusted odds ratios (aORs) for laxative prescriptions were 0.85 (95% confidence interval [CI]: 0.76–0.94, $p = 0.003$) for JARS = 1; 0.79 (0.69–0.91, $p = 0.001$) for JARS = 2; 0.94 (0.79–1.13, $p = 0.537$) for JARS = 3; 1.20 (0.93–1.55, $p = 0.153$) for JARS = 4; and 1.64 (1.24–2.16, $p < 0.001$) for JARS ≥ 5. This indicated a stepwise pattern with positive association at the highest burden. Furthermore, use of a drug rated 3 on the JARS revealed association with higher odds of laxative prescription (aOR: 1.71, 95% CI: 1.38–2.12, $p < 0.001$). Both a total JARS burden ≥ 5 and drugs rated 3 on the JARS were significantly associated with laxative prescribing.

***Keywords*:** anticholinergic burden, community pharmacists, constipation, JARS, chronic medication

1. Introduction

Anticholinergic medications have a major safety implication in older adults because of their association with cognitive impairment, urinary retention, dry mouth, and constipation. Additionally, age-related pharmacokinetic changes and polypharmacy may further exacerbate these risks (*1,2*).

Constipation is common among older adults, and it negatively affects their quality of life (*3,4*). Reduced intestinal motility due to anticholinergic effects is a key mechanism (*5*). A systematic review showed that nine out of 11 studies reported a significant association between anticholinergic burden (ACB) and constipation (*6*). However, the majority of these studies were Western research, using non-Japanese tools such as the ACB Scale, Anticholinergic Risk Scale, and Drug Burden Index.

Released in May 2024, the Japanese Anticholinergic Risk Scale (JARS, 2nd edition) assigns a score of 0–3 to individual drugs, reflecting commonly used domestic medications (*7*). Nonetheless, the clinical utility of the JARS, particularly its associations with specific adverse outcomes such as constipation, requires validation in real-world settings.

Healthcare utilization databases enable large pharmacoepidemiologic evaluations (*8,9*). Despite being smaller than national databases, pharmacy chain–level datasets provide detailed longitudinal prescription data and integrate dispensing records across outlets (*10*). Utilizing such data, this study aimed to quantify the total JARS burden and examine its association with laxative prescription to explore the clinical utility of JARS in routine care.

2. Patients and Methods

2.1. Study design and population

This cross-sectional study used dispensing claims from community pharmacies operated by Qol Co., Ltd. (Tokyo, Japan). Eligible participants included outpatients aged ≥

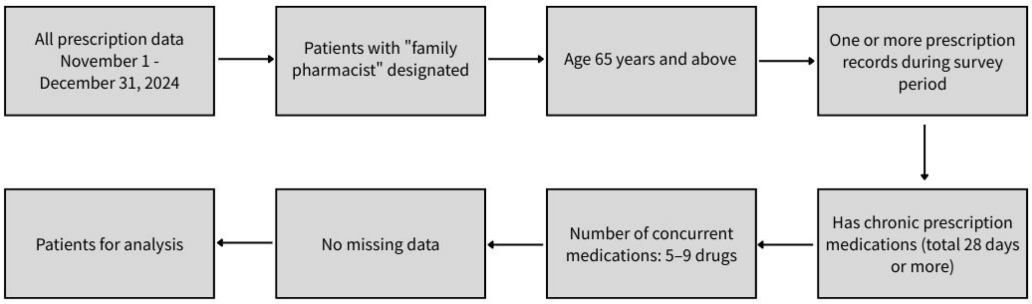

Figure 1. Patient selection flowchart. The inclusion criteria were as follows: outpatients aged ≥ 65 years who were registered with a family pharmacist, with at least one dispensing record between November 1 and December 31, 2024, and at least one chronic prescription (≥ 28 total days). The analytic cohort was restricted to patients receiving 5–9 concomitant chronic medications. Records with missing data were excluded.

65 years who were registered with a family pharmacist ("kakaritsuke pharmacist") between November 1 and December 31, 2024. Introduced in 2016, the family pharmacist system allows designated pharmacists to manage patients' medication information with their consent across institutions (*11,12*).

Chronic medication use was defined as prescriptions totaling ≥ 28 days within the two-month study window, which is consistent with previous studies and Japanese pharmacy claims research (*13,14*). The two-month observation window was selected because it highlights the consistent prescription patterns across various dispensing records while aligning with the definition of chronic use (≥ 28 days). The study period (November–December) was chosen because this pragmatic timeframe was close to implementation and avoided extreme seasonal temperatures.

To ensure internal consistency and sufficient exposure groups, the primary analysis was restricted to patients with 5–9 concomitant chronic medication prescriptions. This criterion aligns with the widely accepted polypharmacy definition (≥ 5 drugs) (*15*). Additionally, sensitivity under other thresholds requires future studies (*8,16*). Patients with ≥ 1 dispensing record and at least one chronic medication were included in the analysis, whereas those with missing data were excluded (Figure 1).

2.2. ACB assessment

For each patient, days of chronic medication use were aggregated using national reimbursement codes, while the total burden was estimated using the JARS scores (0–3). Total JARS burden was categorized as 0, 1, 2, 3, 4, or ≥ 5 points to enable detailed assessment of stepwise increase in medication burden. This categorization was guided by a recent pharmacovigilance study reporting a mean total anticholinergic load of 4.20 ± 3.09 in anticholinergic syndrome-related adverse events (*17*), suggesting potential clinical relevance at higher burden levels. Weekly formulations or topicals with systemic effects (*e.g.*, transdermal systems, corticosteroid topicals) were included in the assessment when used for chronic conditions.

Table 1. Classes of laxatives and representative generic drugs

Class	Generic names
Saline laxatives	Magnesium oxide, magnesium hydroxide
Stimulant laxatives	Sennosides (senna), sodium picosulfate, bisacodyl
Osmotic laxatives	Macrogol (polyethylene glycol, PEG) 4000, lactulose, sorbitol
Intestinal epithelial function modifiers (secretagogues)	Linaclotide, lubiprostone
IBAT inhibitor	Elobixibat
Kampo formula	Daiokanzoto
Agents for opioid-induced constipation	Naldemedine

Abbreviation: IBAT, ileal bile acid transporter.

2.3. Definition and classification of laxatives

The primary endpoint was chronic laxative use. A laxative was defined as *i*) a drug indicated for chronic constipation, *ii*) a stimulant laxative, or *iii*) a saline laxative prescribed for ≥ 28 days during the study window. Classes and representative generic names are listed in Table 1.

2.4. Covariates and medication counts

A set of covariates, including age, sex, and number of concomitant chronic medications (considering only drugs supplied for ≥ 28 days), were incorporated in the analysis. Weekly formulations or topicals with

systemic effects were included. Opioid use was initially considered a confounder; however, it was not included in the covariate adjustments because of sparse data (opioids were used in only 7 patients [0.07%]).

2.5. Statistical analysis

Patient characteristics were summarized descriptively. The association between JARS burden and laxative prescription was modeled using multivariable logistic regression, with JARS = 0 serving as the reference; adjustment was made for age, sex, and medication count. A secondary analysis with the same covariate adjustments was conducted using any drug rated 3 on the JARS as the exposure. Analyses were performed using the JMP software (SAS Institute Inc., Cary, NC, USA), with a two-sided $\alpha = 0.05$.

2.6. Ethical considerations

This study was conducted in accordance with the principles embodied in the Declaration of Helsinki (2013 revision) and the Ethical Guidelines for Medical and Biological Research Involving Human Subjects (Japan, 2021; revised 2023). Ethical approval was obtained from the Qol Institutional Review Board (approval no. QOL-091). Existing dispensing records were utilized using an opt-out consent approach *via* the facility's website, and data were anonymized prior to analysis.

Table 2. Baseline characteristics of the study population (*n* = 9,838)

Characteristic	Total
Age, years, mean ± SD	81.1 ± 7.3
65–74 years, *n* (%)	1,885 (19.1%)
75–84 years, *n* (%)	4,601 (46.8%)
≥ 85 years, *n* (%)	3,352 (34.1%)
Sex, *n* (%)	
Men	3,830 (38.9%)
Women	6,008 (61.1%)
Number of concomitant chronic medications, mean ± SD	6.6 ± 1.4
Medication count categories, *n* (%)	
5 drugs	2,596 (26.4%)
6 drugs	2,387 (24.3%)
7 drugs	2,007 (20.4%)
8 drugs	1,634 (16.6%)
9 drugs	1,214 (12.3%)
Total JARS score, *n* (%)	
0	3,878 (39.4%)
1	3,268 (33.2%)
2	1,447 (14.7%)
3	692 (7.0%)
4	305 (3.1%)
≥ 5	248 (2.5%)
Laxative prescription, *n* (%)	2,807 (28.5%)
Opioid use, *n* (%)	7 (0.07%)

Abbreviation: JARS, Japanese Anticholinergic Risk Scale.

3. Results

3.1. Patient characteristics

A total of 9,838 patients (mean age, 81.1 ± 7.3 years) were included in this study. Among the participants, men and women accounted for 38.9% and 61.1%, respectively. The mean number of chronic medications prescribed was 6.6 ± 1.4. Opioids were rarely used (*n* = 7, 0.07%) (Table 2).

3.2. Distribution of total JARS burden

Total JARS burden was categorized as 0 in 39.4% (*n* = 3,878) of the patients, 1 in 33.2% (*n* = 3,268), 2 in 14.7% (*n* = 1,447), 3 in 7.0% (*n* = 692), 4 in 3.1% (*n* = 305), and ≥ 5 in 2.5% (*n* = 248). With higher JARS scores, the proportion of women (JARS = 0: 61.2%, JARS = 1: 60.0%, JARS = 2: 61.1%, JARS = 3: 63.0%, JARS = 4: 68.2%, and JARS ≥ 5: 58.5%) and medication count (JARS = 0: 6.4 ± 1.3, JARS = 1: 6.6 ± 1.3, JARS = 2: 7.0 ± 1.4, JARS = 3: 7.1 ± 1.4, JARS = 4: 7.2 ± 1.4, and JARS ≥ 5: 7.2 ± 1.4) increased (Table 3).

3.3. Laxative prescription

Overall, 2,807 (28.5%) patients were treated with laxatives. Descriptions on laxative classes and usage patterns are presented in Table 4.

3.4. Association between the total JARS burden and laxative prescription

Crude laxative-prescription rates were 29.3% for JARS = 0, 26.5% for JARS = 1, 27.0% for JARS = 2, 30.5% for JARS = 3, 35.4% for JARS = 4, and 37.9% for JARS

Table 3. Patient characteristics by total JARS score category

Characteristic	0 point	1 point	2 points	3 points	4 points	≥ 5 points
n	3,878	3,268	1,447	692	305	248
Age, years, mean ± SD	81.8 ± 7.0	81.0 ± 7.3	81.1 ± 7.6	80.8 ± 7.5	80.2 ± 7.9	76.4 ± 7.9
Women, %	61.2	60.0	61.1	63.0	68.2	58.5
Number of concomitant chronic medications, mean ± SD	6.4 ± 1.3	6.6 ± 1.3	7.0 ± 1.4	7.1 ± 1.4	7.2 ± 1.4	7.2 ± 1.4
Laxative prescription, %	29.3	26.5	27.0	30.5	35.4	37.9

Abbreviation: JARS, Japanese Anticholinergic Risk Scale.

≥ 5. Multivariable logistic regression analysis (with 0 as the reference) indicated adjusted odds ratios (aORs) of 0.85 (95% confidence interval [CI]: 0.76–0.94, $p = 0.003$) for JARS = 1; 0.79 (95% CI: 0.69–0.91, $p = 0.001$) for JARS = 2; 0.94 (95% CI: 0.79–1.13, $p = 0.537$) for JARS = 3; 1.20 (95% CI: 0.93–1.55, $p = 0.153$) for JARS = 4; and 1.64 (95% CI: 1.24–2.16, $p < 0.001$) for JARS ≥ 5, revealing a stepwise increase with a significant positive association at the highest burden (Table 3, Figure 2).

3.5. Secondary analysis on drugs rated 3 on the JARS

Compared with the non-use of drugs rated 3 on the JARS, the use of such drugs was significantly linked with higher odds of laxative prescription (aOR: 1.71, 95% CI: 1.38–2.12, $p < 0.001$).

4. Discussion

This cross-sectional study assessed older outpatients to examine the association between the JARS and laxative prescriptions using community pharmacy claims. Our results revealed that total JARS burden ≥ 5 was significantly associated with laxative prescription, with the use of drugs rated 3 on the JARS showing an independent significant association. The laxative prescription rate revealed a stepwise increase across JARS categories, with rates of 29.3% for JARS = 0; 26.5% for JARS = 1; 27.0% for JARS = 2; 30.5% for JARS = 3; 35.4% for JARS = 4; and 37.9% for JARS = ≥ 5. The aOR for the ≥5 points group was 1.64 (95% CI: 1.24–2.16, $p < 0.001$), representing a clinically substantial increase. Notably, JARS = 1–2 groups showed significantly lower odds (aOR = 0.85 (95% CI: 0.76–0.94) and 0.79 (95% CI: 0.69–0.91), respectively) compared with the reference group, while the JARS = 3 group exhibited no significant difference (aOR = 0.94 , 95% CI: 0.79–1.13), and the JARS = 4 group demonstrated a trend toward increased odds that did not attain statistical significance (OR = 1.20, 95% CI: 0.93–1.55). This finding is consistent with the hypothesis that higher anticholinergic burden may be associated with constipation, with symptoms manifesting clinically primarily in the highest burden patients. These findings provide preliminary support for identifying patients more likely to be prescribed laxatives.

In the secondary analysis, the use of drugs rated 3 on the JARS showed high independent association with laxative prescription (aOR = 1.71, 95% CI: 1.38–2.12), suggesting that specific high-risk medications may be strongly associated with constipation beyond the cumulative burden score. This finding underscores the criticality of individual drug properties, apart from the total score summation. Notably, antimuscarinic agents prescribed for overactive bladder have consistently been reported to cause constipation as a major side-effect (*18,19*). In addition, drugs possessing strong anticholinergic properties are recognized for carrying elevated constipation risk.

The lower aORs for JARS = 1–2 may reflect residual

Table 4. Use of laxatives by class among patients receiving any laxative (*n* = 2,807)

Class	Patients, *n*	Share among laxative users, %
Saline laxatives	1,933	68.9
Stimulant laxatives	908	32.3
Osmotic laxatives	120	4.3
Intestinal epithelial function modifiers (secretagogues)	291	10.4
IBAT inhibitor	123	4.4
Kampo formula	13	0.5
Agents for opioid-induced constipation	7	0.2
Total laxative users	2,807 (28.5% of cohort)	—
Monotherapy	2,299	81.9
Combination therapy	508	18.1

Abbreviation: IBAT, ileal bile acid transporter.

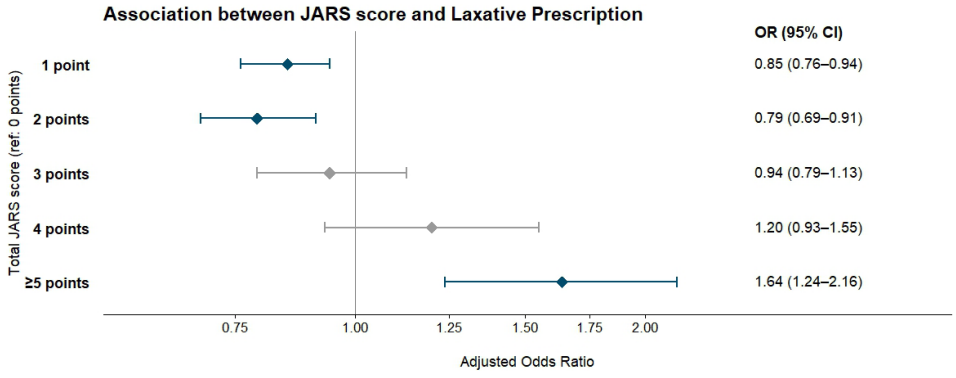

Figure 2. Association between the total JARS score and laxative prescription (forest plot). Adjustments were made for age, sex, and number of concomitant chronic medications. Squares represent point estimates, whereas horizontal bars indicate 95% confidence intervals. The dashed vertical line represents an odds ratio of 1.0 (no association). Reference category: JARS = 0. *Abbreviation*: JARS, Japanese Anticholinergic Risk Scale.

confounding from non-anticholinergic constipating drugs (*e.g.*, iron, nonsteroidal anti-inflammatory drugs, calcium channel blockers, opioids) and possible threshold effects where mild anticholinergic exposure does not induce clinically significant constipation. For instance, some calcium channel blockers and opioids are assigned 1–2 points on the JARS, implying these drugs may be dispersed across the 0–2 point categories. This broad distribution potentially contributes to confounding. Therefore, future analyses should focus on adjusting for both anticholinergic effects and constipation-inducing properties of medications, and model the JARS score as a continuous variable to evaluate nonlinear associations.

The higher proportion of females with increasing JARS burden likely reflects sex-specific disease patterns (*e.g.*, overactive bladder, depression), suggesting a higher occurrence of constipation in women (*20–23*). The prevalence of overactive bladder has been reported as 21.9% in women (*20*), while systematic reviews have revealed this rate to be approximately twice as high in women compared with men (*22*). However, given the limited information on indications and symptom severity in this study, it is difficult to fully disentangle the primary contributing factors.

Slightly younger age in higher-burden groups may indicate cautious avoidance of strong anticholinergic medications by the oldest patients. Detailed information on laxative classes and usage patterns is presented in Table 4, with saline and stimulant laxatives being the predominant treatment types, in accordance with Japanese practice (*24*).

This study has several limitations that warrant consideration. First, the cross-sectional design precludes the establishment of temporal relationships between anticholinergic exposure and laxative prescription; therefore, causal inferences cannot be drawn. Protopathic bias may also be present, as laxatives could have been prescribed before or concurrently with anticholinergic medications, rather than as a consequence of anticholinergic exposure. Second, dispensing claims lack clinical details, leaving residual confounding unaddressed. Potential confounders not captured in our data include dietary factors (*e.g.*, fiber intake, fluid consumption), physical activity, the severity of underlying diseases, and the use of non-anticholinergic constipating medications (*e.g.*, iron supplements, calcium channel blockers, non-steroidal anti-inflammatory drugs). Although we attempted to account for opioid use, the sparse data ($n = 7$) precluded meaningful adjustment. Third, laxative prescriptions were used as a surrogate marker for constipation; however, this may not fully reflect the actual occurrence or severity of constipation. Patients may have managed symptoms with over-the-counter laxatives or dietary modifications not captured in prescription claims. In addition, laxatives may have been prescribed prophylactically or for indications not directly reflecting constipation severity, which may have introduced outcome misclassification. Fourth, the restriction to patients receiving 5–9 concomitant chronic medications limits the generalizability of our findings to broader populations.

Despite these limitations, this study represents the first real-world evaluation linking the JARS to constipation-related prescriptions in Japan. The results suggest that the JARS may serve as a practical strategy for ACB assessment. The study also underscores the need for proactive constipation-risk management in patients with high JARS burden. Future research should investigate other anticholinergic outcomes (*e.g.*, cognitive impairment, falls, urinary retention) and drug-specific risk profiles to guide safer alternatives and inform better disease mitigation strategies.

In conclusion, higher ACB (total JARS burden ≥ 5) and the use of drugs rated 3 on the JARS were significantly associated with laxative prescription in older adults. These findings provide preliminary support for the potential clinical utility of the JARS. Future longitudinal studies are needed to confirm these associations and establish temporal relationships.

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