doi.org/10.36721/PJPS.2026.39.1.REG.15013.1

Global large-scale real-world assessment of drug-associated galactorrhea based on FDA adverse drug reaction reports

Yulan Liu, Dandan Hu, Yi Lu, Yuanyuan Li, Yansi Li and Mei Liu*
Department of Pharmacy, The Air Force Hospital of Eastern Theater Command, Nanjing, Jiangsu, China

Abstract: **Background**: Galactorrhea, an abnormal milk secretion, is frequently triggered by medications that influence prolactin levels. **Objectives**: This study aimed to identify high-risk drugs for drug-associated galactorrhea (DAG) and explore their characteristics using data from the FDA Adverse Event Reporting System (FAERS). **Methods**: We analyzed 6,195 DAG reports by applying four disproportionality analysis algorithms (ROR, PRR, MGPS, BCPNN) to detect positive signals. **Results**: The analysis of 6,195 reports showed that DAG was most prevalent in patients aged 20-40 years, with a slight male predominance (55.52%). Oral medications were the primary cause (68.99%). A total of 32 drugs were strongly associated with DAG, with antipsychotics being the most frequently implicated class (N = 12), followed by antidepressants (N = 7) and hormone-related drugs (N = 6). Risperidone had the highest risk (ROR = 346.71) and report count (N = 3,378). **Conclusion**: This study provides a comprehensive list of high-risk drugs for DAG, offering critical data to guide safer prescribing and improve pharmacovigilance. Clinicians should be vigilant in monitoring for suggestive symptoms like galactorrhea, amenorrhea and sexual dysfunction, especially in high-risk individuals on long-term treatment with prolactin-elevating medications. These findings underscore the importance of patient safety and inform clinical practice.

Keywords: Antipsychotic drugs; Disproportionality analysis; FAERS; Galactorrhea; Pharmacovigilance

Submitted on 12-08-2025 – Revised on 18-09-2025 – Accepted on 04-10-2025

INTRODUCTION

Galactorrhea refers to the spontaneous secretion of milk from the mammary glands in non-pregnant and non-lactating individuals. While most commonly observed in women of reproductive age, it can also affect men and postmenopausal women. The prevalence of galactorrhea in the general population is estimated to be between 5% to 32%, with a higher incidence among specific high-risk groups, such as patients with hyperprolactinemia (Bruehlman *et al.*, 2022). Various physiological and pathological factors can cause galactorrhea, including pituitary adenomas, thyroid dysfunction and chronic renal failure (Bruehlman *et al*., 2022; Glezer *et al*., 2024). Importantly, drug-associated galactorrhea (DAG) constitutes a significant subset of cases. Given the rising use of long-term use medications, monitoring for DAG and identifying high-risk drugs is clinically crucial for early prevention and intervention. The implications of galactorrhea extend beyond abnormal mammary secretion, impacting both physiological and psychological health. Physiologically, it is often associated with hyperprolactinemia, which can lead to menstrual irregularities, sexual dysfunction, infertility and osteoporosis (Edinoff *et al*., 2021; Yun *et al*., 2024). Psychologically, galactorrhea can cause anxiety, depression and diminished self-esteem, especially in young women and male patients. This can result in social difficulties and a reduced quality of life (Randall *et al*., 2022). Therefore, galactorrhea should be viewed not just as a physical sign, but as a condition that affects endocrine health, psychological well-being and reproductive function.

**Corresponding author:* e-mail: lyl20141095@126.com

Previous studies have shown that different medications can trigger galactorrhea by affecting prolactin (PRL) secretion or mechanisms (van Heerden and Mabuza, 2020). Drugs acting on the central nervous system, such as antipsychotics, antidepressants, antihypertensives and hormonal agents, are closely linked to the condition (Sun *et al*., 2017; Qiao *et al*., 2016). For instance, antipsychotics like risperidone and paliperidone can induce hyperprolactinemia by blocking dopamine D2 receptors, which reduces the normal dopaminergic inhibition of prolactin secretion (Glocker *et al*., 2021). Selective serotonin reuptake inhibitors (SSRIs), such as fluoxetine and paroxetine, may indirectly elevate prolactin levels by increasing central serotonin. Elevated serotonin can inhibit dopaminergic neurons in the hypothalamus, reducing dopamine's suppression of prolactin secretion (Ercan *et al*., 2022; Krysiak *et al*., 2021). Furthermore, hormonal agents like ethinylestradiol and medroxyprogesterone acetate (DMPA) may contribute to galactorrhea through direct effects on mammary tissues or central regulatory mechanisms (Gu *et al*., 2022; Bhattacharjee *et al*., 2021).

Despite the relatively high prevalence of DAG, its underlying mechanisms are not fully understood and its symptoms may be misdiagnosed or overlooked. The results are limited to clinical awareness. While clinical assessments typically rely on serum prolactin levels, some studies suggest that certain drugs, such as fluvoxamine, can cause galactorrhea even with normal prolactin levels (Bhattacharjee *et al*., 2021). Therefore, accurately identifying high-risk drugs and evaluating their potential to cause galactorrhea is critical for optimizing pharmacotherapy and patient management.

The U.S. Food and Drug Administration (FDA) Adverse Event Reporting System (FAERS) is a key pharmacovigilance database for assessing drug-related adverse events (Potter *et al*., 2025). FAERS collects spontaneous reports of adverse drug reactions from healthcare institutions, pharmaceutical companies, physicians, pharmacists and patients worldwide, providing valuable data for evaluating drug safety. Using large-scale data mining of the FAERS database, researchers can identify high-risk drugs and analyze their incidence, potential mechanisms and contributing factors. These findings offer critical insights for regulatory agencies, clinical decision-making and personalized medicine.

In this study, we used the FAERS database and applied data mining and disproportionality analysis to systematically assess the risk of galactorrhea associated with various pharmacological agents. Our results provide empirical evidence for identifying high-risk medications and offer valuable guidance for clinicians to mitigate the adverse effects of DAG and improve patient quality of life.

MATERIALS AND METHODS

Data source

This study collected adverse drug event data from the FDA Adverse Event Reporting System (FAERS) database, covering reports from January 1, 2004, to September 30, 2024 (https://fis.fda.gov/extensions/FPD-QDE-FAERS/FPD-QDE-FAERS.html). The FAERS database is a crucial resource for pharmacovigilance, containing seven key datasets, including demographic information, drug details and adverse events. The data was accessed through the FAERS Public Dashboard, which provides the necessary datasets and accession numbers.

The original number of reports was 21,838,627; after removing duplicate records, 19,541,994 valid reports remained. By screening for galactorrhea-related records in the adverse event reports, we identified 6,195 adverse events associated with galactorrhea. Further analysis revealed that these reports involved 6,144 patients and 565 drugs. To ensure the uniqueness of drug names and eliminate duplicate drug information, we queried the generic names of drugs in the Drug Bank database, consolidating data for drugs with the same generic name but different brand names. Ultimately, 147 drugs associated with galactorrhea were identified, each reported more than three times in the FAERS database.

These drug categories include antipsychotics, antidepressants, hormonal agents, among others. The data processing procedure in this study involved information extraction, data cleaning and standardization through the open FDA interface provided by the FAERS database. During data cleaning, we excluded records with incomplete drug names, missing basic patient information, or incomplete report details to ensure the reliability of the analysis results. The data cleaning process is illustrated in Fig. 1. The datasets used in this study can be found in online data repositories: FAERS Public Dashboard (U.S. FDA, 2023). Available at: https://www.fda.gov/drugs/questions-and-answers-fdas-adverse-event-reporting-system-faers/fda-adverse-event-reporting-system-faers-public-dashboard (Accessed 31 December 2013).

Adverse drug reactions (AEs) and drug definition of DAG

In this study, DAG is defined as an abnormal secretion of breast milk caused by medication, typically occurring in non-lactating individuals. According to the Medical Dictionary for Regulatory Activities (MedDRA®) standard terminology, "galactorrhea" is designated as the Preferred Term (PT) for identifying all relevant adverse drug reaction reports. DAG is commonly associated with elevated prolactin levels due to medication use, particularly drugs that affect dopamine receptors. These drugs inhibit dopamine's suppressive effect on prolactin secretion, leading to increased prolactin levels and subsequent galactorrhea.

In the FAERS database, DAG was identified through a screening process in which all cases reporting "galactorrhea" as a PT were included in the study. To ensure accurate identification of galactorrhea-related adverse events, all drug names in the reports were standardized using generic names, with data sourced from the DrugBank database (Knox *et al*., 2024), thereby minimizing bias due to brand name inconsistencies. Through the FAERS database screening, the study focused on all reported drugs associated with galactorrhea and further analyzed them according to drug classification.

Statistical analysis

Disproportionality analysis for positive signal detection utilized four disproportionality analysis methods: Reporting Odds Ratio (ROR) (Kerr *et al*., 2023), Proportional Reporting Ratio (PRR) (Dou *et al*., 2024), Bayesian Confidence Propagation Neural Network (BCPNN) (Lin *et al*., 2024) and Multi-item Gamma Poisson Shrinker (MGPS) (Li *et al*., 2024). These methods compare the ratio of the target event with the target drug to the ratio of all other events and drugs, using a four-cell table calculation method to mine potential true signals. The specific methods and criteria are detailed in table 1 and Supplementary Table S1. In the statistical analysis process, the core software used includes R (version 4.3.2), Microsoft Excel (2019) and GraphPad Prism (10.1.3). Key R packages used for data processing and visualization include dplyr (version 1.1.4), data table (version 1.14.10), ggplot2 (version 3.5.1) and survival (version 3.5-7).

RESULTS

Baseline patient information

In this study, we identified a total of 6,195 adverse drug reaction reports related to DAG. These reports involved 6,144 patients and 565 drugs. The patients' average age was 28.36 ± 13.27 years, showing that DAG occurs across various age groups.

Regarding gender distribution, males accounted for 55.52% of the reports (3,256 cases), while females accounted for 44.48% (2,609 cases) (Table S2). This result indicates that, contrary to common belief, the proportion of reported male patients was slightly higher. Based on the reported age distribution, DAG cases were most common in the 20-40 age group (Fig. 2A). Patients in this age group may be more susceptible to galactorrhea symptoms from prolactin-elevating drugs. Fig 2B shows the annual reporting counts of DAG by gender. The chart reveals how the incidence of DAG has varied over the years, with notable peaks observed in certain years.

Analysis of the route of drug administration revealed that oral medications were the primary cause of galactorrhea, accounting for 68.99% of cases. Intramuscular injections were the second most common route at 10.45%. Other routes (such as intrauterine, subcutaneous, transdermal, etc.) accounted for a smaller proportion (Fig. 2C). The United States submitted the most reports, with 77.02% of cases (4,732 cases), followed by the United Kingdom (2.96%), Germany (2.31%) and France (2.07%) (Fig. 2D).

The majority of patient outcomes were classified as "other serious (important medical events)" at 74.16%. About 21.49% of patients requiring hospitalization, including initial or prolonged stays. While the fatality rate for DAG was low, 0.78% of cases resulted in death (Fig. 2E). For report sources, consumers provided the most reports at 60.12% (3,624 cases), followed by doctors (19.06%, 1,149 cases) and other healthcare professionals (Supplementary Table S2).

Adverse reaction distribution of DAG

From the 147 drugs reported to cause galactorrhea, we conducted a disproportionality analysis. We identified 49 drugs that met positive signal criteria for all four algorithms: ROR, PRR, MGPS and BCPNN. We then excluded certain drugs, such as dopamine agonists like bromocriptine, which are often prescribed for conditions involving galactorrhea or hyperprolactinemia. These drugs were excluded because their limited effectiveness or inconsistent pharmacodynamics could lead to reported cases of galactorrhea despite their intended use.

However, we chose to retain aripiprazole in the final analysis. Although it is sometimes used to treat antipsychotic-induced hyperprolactinemia, pharmacovigilance data and published case reports show that aripiprazole can paradoxically cause galactorrhea in certain clinical contexts. Ultimately, we identified 32 drugs associated with DAG, including both psychiatric and non-psychiatric agents. Fig. 3 presents a forest plot illustrating the reporting odds ratios (RORs) and corresponding 95% confidence intervals (CIs) for 32 drugs. Risperidone had the strongest association with DAG, with the highest number of reports (N=3,378) and the highest ROR [346.71 (95% CI: 329.73-364.57)]. Paliperidone followed, with 1,214 reports and an ROR of 98.04 (95% CI: 92.06-104.41). Other antipsychotics such as aripiprazole, quetiapine and olanzapine also showed significant associations, with lower ROR values ranging from 3.92 to 5.22.

Among antidepressants, escitalopram (ROR:9.84) and venlafaxine (ROR:5.81) were the most notable. Several SSRIs, including fluoxetine, citalopram, sertraline and paroxetine, also showed elevated risks. Furthermore, several hormonal agents were strongly linked to DAG, including ethinylestradiol (ROR: 33.77), medroxyprogesterone acetate (ROR: 7.06) and estradiol (ROR: 7.75). Other drugs such as fluvoxamine (ROR: 25.17), iloperidone (ROR: 24.72) and cabergoline (ROR: 15.35) also exhibited high signal strength despite having fewer reports. Overall, the results indicate that a variety of psychotropic and hormone-related drugs are associated with a significantly increased risk of galactorrhea, highlighting the need for careful prolactin monitoring in clinical settings.

The detailed data in Supplementary Table S3 provide more specific information for DAG risk assessment. Risperidone, for example, had a PRR of 340.49 (95% CI: 340.44-340.54), an MGPS of 155.37 (95% CI: 148.98-162.04) and a BCPNN of 7.28 (95% CI: 5.61-8.95), all indicating an extremely high risk of DAG ($P < 0.001$). Other drugs, like Paliperidone, Quetiapine and Olanzapine, also had high-risk values, though they were lower compared to risperidone. These results provide important data to support the clinical management and risk assessment of DAG, especially in evaluating risks across different drug categories.

Drug risk of DAG

We assessed the potential risk of DAG for each drug based on the BCPNN value and further evaluated the number of adverse events related to DAG for each drug. In the risk assessment of DAG, the top five drugs with the highest risk were: Risperidone (BCPNN value = 7.28), Paliperidone (BCPNN value = 6.29), Ethinylestradiol (BCPNN value = 5.07), Fluvoxamine (BCPNN value = 4.65) and Iloperidone (BCPNN value = 4.62) (Fig. 4A).

Regarding the number of occurrences of DAG, the top five drugs were: Risperidone (N = 3378), Paliperidone (N = 1214), Aripiprazole (N = 198), Quetiapine (N = 147) and Olanzapine (N = 134), ranked from highest to lowest in terms of the number of occurrences (Fig. 4B).

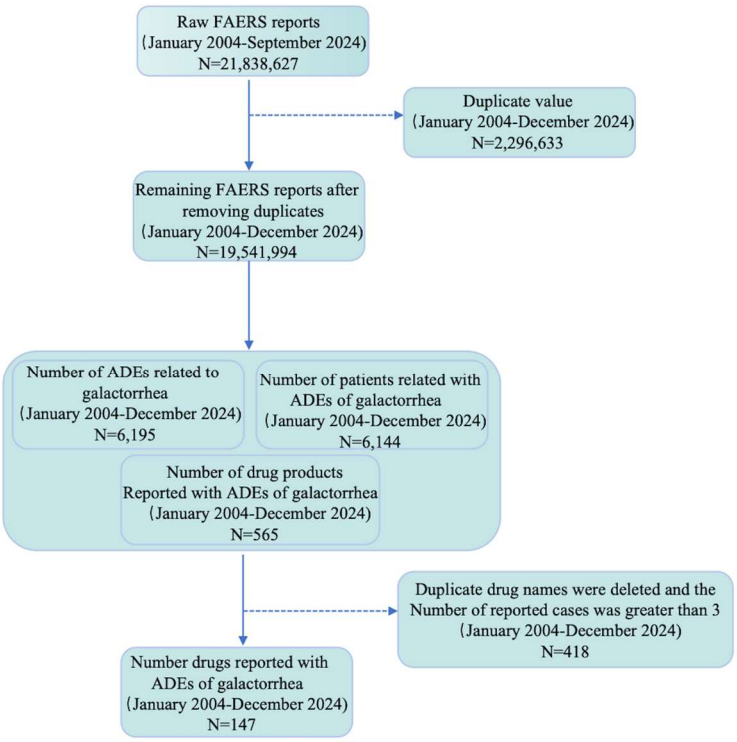

Fig. 1: Data cleaning process for DAG in the FAERS database.

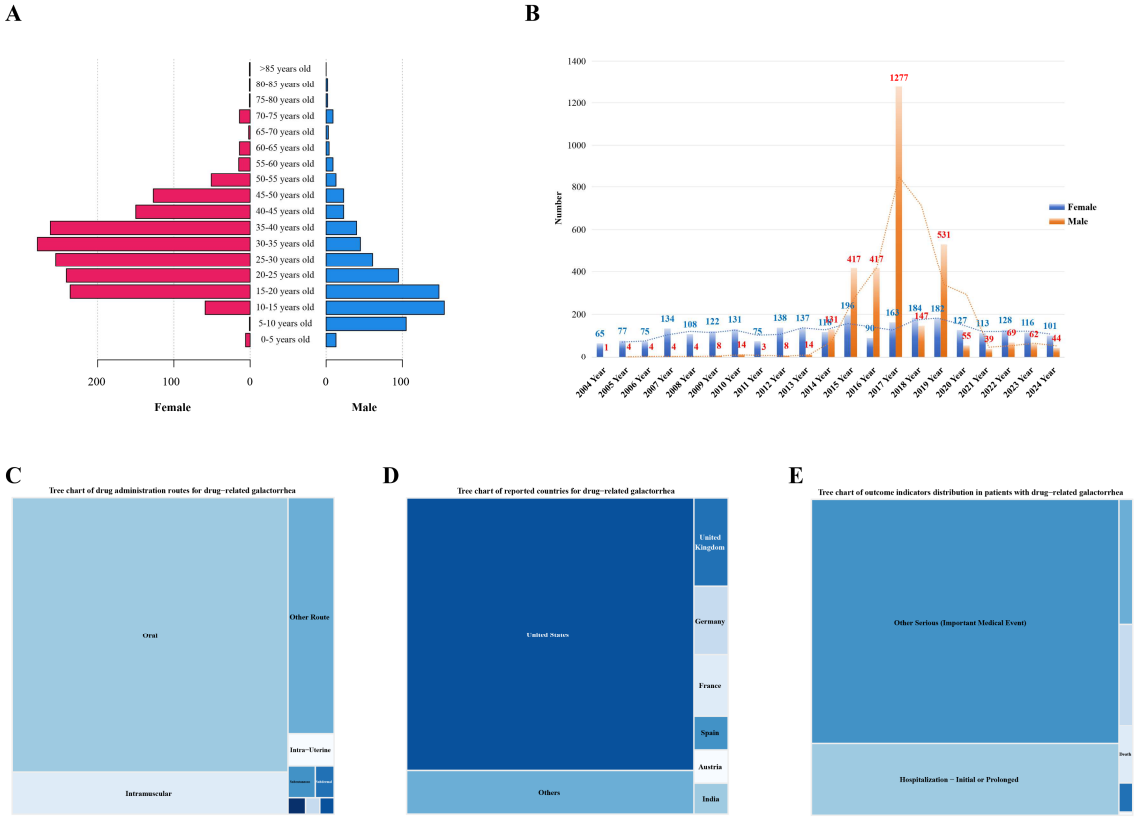

Fig. 2: Distribution of demographic data for DAG.
(A) Population pyramid of subjects with DAG categorized by gender and age. (B) Bar chart showing the annual reporting counts of DAG by gender. (C) Distribution of modes of drug administration among subjects. (D) Distribution of reporting countries. (E) Distribution of outcomes among subjects

Table 1: Four-grid table of disproportionality analysis method.

Item	Target adverse events	All other adverse events	Total
Target drugs	a	b	a+b
All other drugs	c	d	c + d
Total	a+c	b+d	a+b + c + d

Notes: A contingency table for the calculation formula of the proportion imbalance analysis.

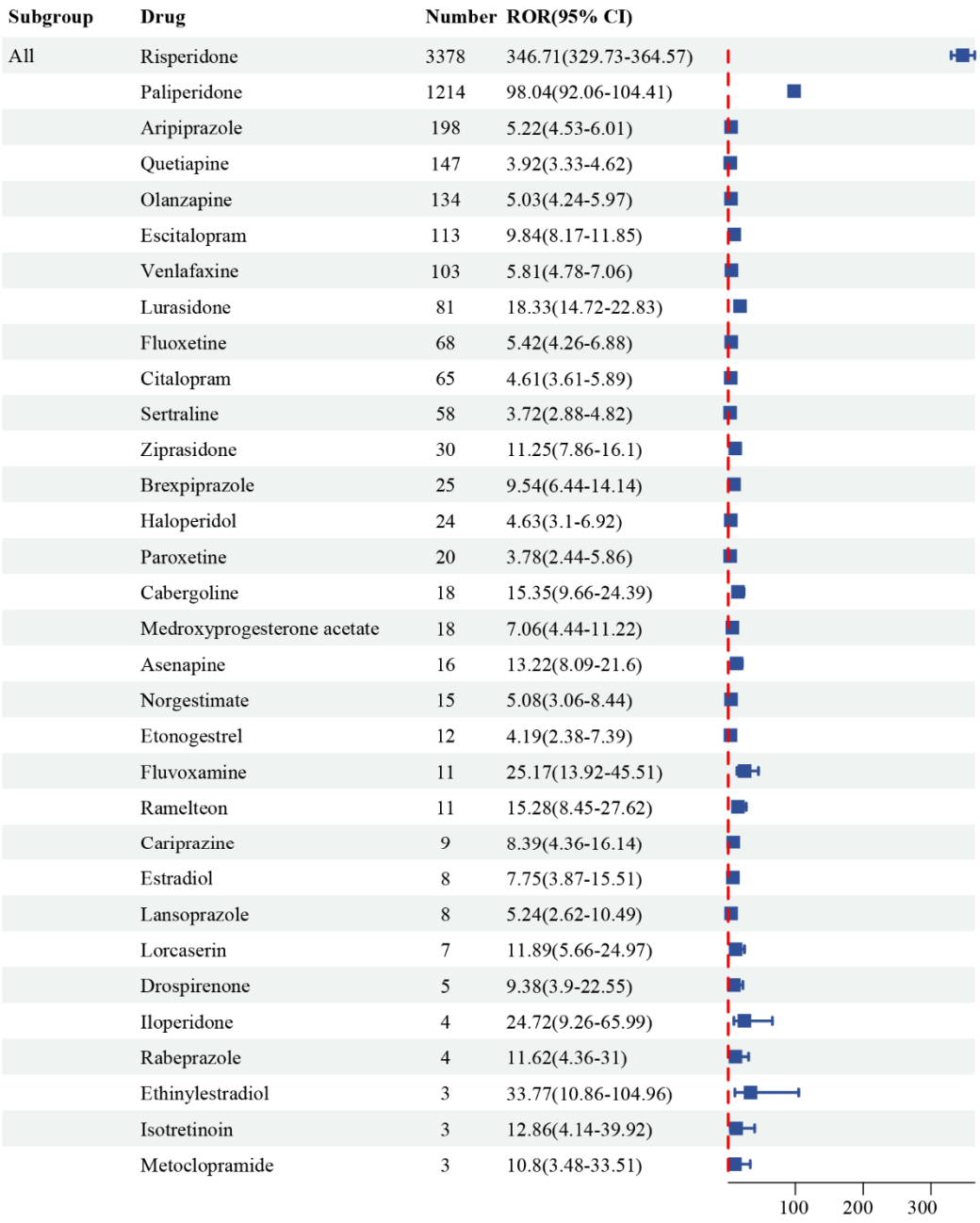

Fig. 3: Distribution of drugs causing DAG.

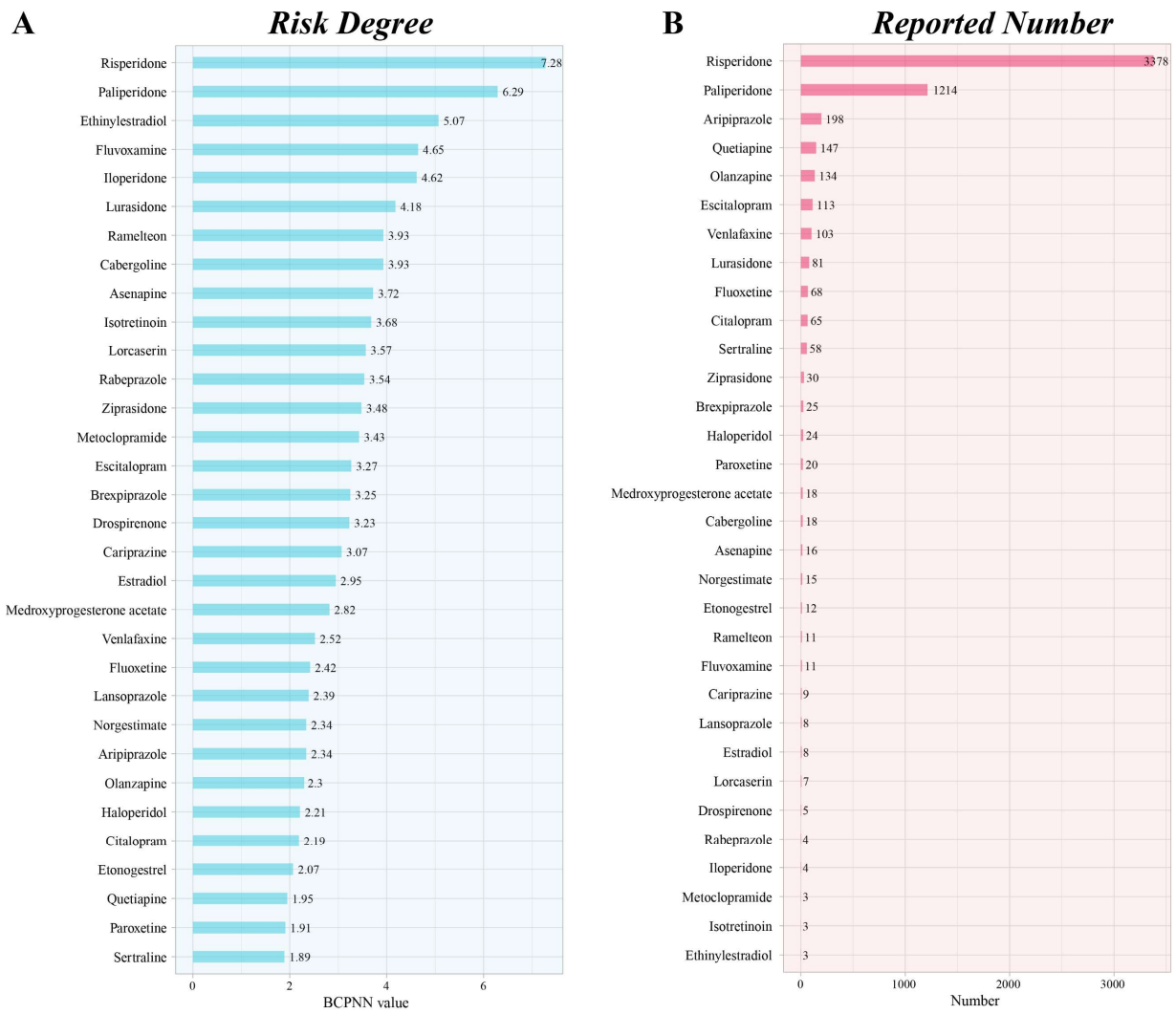

Fig. 4: Distribution of risks and drug induction number for DAG arranged in descending order based on drug risk (A) and drug induction number (B).

DISCUSSION

DAG is a known adverse effect triggered by medications that affect prolactin secretion or action. Our study systematically assessed the risk of DAG using the FAERS database, identifying 32 high-risk drugs. The top three drug categories were antipsychotics (12 drugs), antidepressants (7 drugs) and hormonal medications (6 drugs). We found that risperidone and paliperidone had the highest number of reported cases, with 3,378 and 1,214 reports, respectively.

Interestingly, our analysis revealed a slightly higher proportion of reports from male patients (55.52%) compared to females (44.48%). This highlights that clinicians should consider gender-specific factors when managing DAG to reduce its side effects, particularly in male patients who might be at an elevated risk or whose symptoms are often overlooked. Consistent with previous research, our findings showed antipsychotic drugs, such as risperidone, paliperidone and aripiprazole, ranked high in DAG risk assessment. These drugs are known to cause hyperprolactinemia by blocking dopamine receptors, which reduces the inhibitory effect of dopamine on prolactin secretion. Hyperprolactinemia and its associated adverse effects caused by antipsychotic drugs have been confirmed in multiple studies (Jiang *et al.*, 2024; Rusgis *et al.*, 2021). Some reports also indicate that the combination of risperidone and fluvoxamine can lead to male lactation-related gynecomastia and mammary gland hyperplasia (Pratheesh *et al.*, 2011). A systematic review and meta-analysis previously confirmed the strong association between antipsychotics (especially risperidone) and galactorrhea and the mechanism may be related to increased prolactin levels (Trinchieri *et al.*, 2021). A clinical study on adolescent patients demonstrated that risperidone and olanzapine significantly increased prolactin levels, with risperidone showing the most prominent hyperprolactinemia, making it significantly correlated with galactorrhea (Afzal *et al.*, 2007). Our

study's high-risk signal for risperidone aligns with these findings, reinforcing the drug's significant role as a cause of DAG.

In addition to antipsychotic drugs, our study also found that selective serotonin reuptake inhibitors (SSRIs) may increase the risk of DAG. Most antidepressants increase serotonin (5-HT) levels, which can indirectly affect prolactin secretion, leading to hyperprolactinemia and galactorrhea (Krysiak *et al*., 2021; Ruiz-Santiago *et al*., 2024; Camkurt *et al*., 2017). A case report showed that venlafaxine caused dose-dependent galactorrhea, with symptom relief upon dose reduction (Aggarwal *et al*., 2010). A case study reported a 25-year-old woman who developed abnormal milk secretion during escitalopram treatment (Chatterjee *et al*., 2015). Additionally, a case report described a patient on a stable dose of fluoxetine who developed hyperprolactinemia-induced galactorrhea, with symptoms improving after switching to sertraline (Damsa *et al*., 2004). Another study further reported three cases of galactorrhea caused by SSRIs, with one patient using paroxetine alone and two patients using fluvoxamine. All cases were accompanied by elevated serum prolactin levels. It is worth noting that while SSRIs share similar mechanisms, their effects on prolactin may vary individually and galactorrhea risk may be linked to dosage and treatment duration (Bhattacharjee *et al*., 2021).

Due to the lack of a clear diagnostic gold standard, it can be challenging to differentiate DAG from galactorrhea caused by pre-existing endocrine conditions. Therefore, clinicians should consider the DAG as a potential cause when a patient presents with galactorrhea to avoid misdiagnosis and unnecessary treatments. For patients on long-term antipsychotic, antidepressant, or hormonal medications, it is prudent to evaluate prolactin levels if suggestive symptoms like galactorrhea, amenorrhea, or sexual dysfunction appear. Given the risk of subclinical complications like osteoporosis, infertility and sexual dysfunction, periodic assessments may be considered for high-risk individuals, particularly those on long-term treatment with prolactin-elevating drugs like risperidone or paliperidone.

Limitation

The limitations of this study lie in the fact that the FAERS database relies on voluntary reports, which may introduce reporting and selection bias. Additionally, the administration routes and specific formulations for some drugs are often unclear, requiring further research to supplement these details. Furthermore, disproportionality analysis is a statistical method that can only show associations between drugs and adverse reactions, not a direct causal relationship. Therefore, our findings reflect a correlation with DAG, but do not establish causality. Finally, external data validation and multi-database integration are needed to fully assess the accuracy of our findings. Future research should aim to validate our results using more precise clinical data and cohort studies. This would help further investigate the galactorrhea risk associated with different drugs in various populations and aid in developing more appropriate risk management strategies.

CONCLUSION

In conclusion, the mechanisms underlying DAG are complex, involving multiple drug categories such as antipsychotics, antidepressants, hormonal medications and gastrointestinal motility drugs. In clinical practice, when prescribing these drugs to high-risk patients, doctors should consider the prolactin effects of the medication and regularly monitor the patients' prolactin levels to reduce related adverse reactions such as galactorrhea. Additionally, our study is the first to find that there are significant differences in the onset time of DAG among different drug types, with antipsychotic drugs inducing galactorrhea more quickly, while antidepressants and hormonal medications induce it over a longer period. This finding may be related to the pharmacological mechanisms and pharmacokinetic properties of these drugs. Future research should further investigate the long-term effects of different medications on prolactin levels and develop more precise clinical management strategies to improve the safety of drug use and the quality of life of patients.

Overall, this study reveals potential high-risk drugs associated with DAG through systematic data analysis, particularly antipsychotic drugs and some antidepressants. Our findings highlight the importance of clinical management of DAG, especially in patients who use high-risk medications long-term. Therefore, clinicians should be vigilant, regularly check patients' prolactin levels, especially when using known high-risk drugs, to reduce the occurrence of drug-related adverse reactions.

Acknowledgements

Not applicable

Authors' contributions

Yulan Liu and Dandan Hu contributed equally to the study design and manuscript preparation. Yulan Liu and Dandan Hu drafted the original manuscript. Yulan Liu, Dandan Hu, Lu Yi, Yuanyuan Li and Yansi Li collected the data and handled the statistical analysis. Yulan Liu, Dandan Hu and Mei Liu designed the study. All authors approved the final version of this manuscript.

Funding

Nanjing Pharmaceutical Society-Hangzhou Four Medicine Hospital Pharmaceutical Research Fund **(**Grant No. 2022YX026**)** provided funding for this study.

Data availability statement

The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request.

Ethical approval and consent to participate

The data for this study were obtained from the publicly available dataset, the U.S. Food and Drug Administration Adverse Event Reporting System (FAERS) Database. The FAERS data are thoroughly de-identified and contain no personally identifiable information. Therefore, according to FDA guidelines and established ethical standards, secondary analyses of these anonymized data are exempt from Institutional Review Board (IRB) review.

Conflict of interest

The authors declared no conflict of interest.

Supplementary data

https://www.pjps.pk/uploads/2025/12/SUP1764827970.pdf

REFERENCES

Afzal KI, Briones DF and DeVargas C (2007). Risperidone-induced polydipsia and polyphagia associated with galactorrhea, abdominal pain and rapid weight gain in an adolescent Hispanic female. *CNS Spectrums*, **12**(11): 818-820.

Aggarwal A, Kumar R, Sharma RC and Sharma DD (2010). Escitalopram induced galactorrhoea: A case report. *Prog. Neuro-Psychoph.*, **34**(3): 557-558.

Bhattacharjee S, Biswas R and Mandal N (2021). Selective serotonin reuptake inhibitor-induced galactorrhea with hyperprolactinemia. *Indian J. Psychiat*, **63**(6): 613-616.

Bruehlman RD, Winters S and McKittrick C (2022). Galactorrhea: Rapid evidence review. *Am. Fam. Physician*, **106**(6): 695-700.

Camkurt MA, Gulpamuk G, Findikli E and Elve R (2017). Dose dependent course of hyperprolactinemic and normoprolactinemic galactorrhea induced by venlafaxine. *Clin. Psychopharm. Neu.*, **15**(2): 181-183.

Chatterjee SS, Mitra S and Mallik N (2015). Emerging hyperprolactinemic galactorrhea in obsessive compulsive disorder with a stable dose of fluoxetine. *Clin. Psychopharm. Neu.*, **13**(3): 316-318.

Damsa C, Bumb A, Bianchi-Demicheli F, Vidailhet P, Sterck R andreoli A and Beyenburg S (2004). "Dopamine-dependent" side effects of selective serotonin reuptake inhibitors: A clinical review. *J. Clin. Psychiat.*, **65**(8): 1064-1068.

Dou W, Liu X, An P, Zuo W and Zhang B (2024). Real-world safety profile of tetracyclines in children younger than 8 years old: An analysis of FAERS database and review of case report. *Expert Opin. Drug Saf.*, **23**(7): 885-892.

Edinoff AN, Silverblatt NS, Vervaeke HE, Horton CC, Girma E, Kaye AD, Kaye A, Kaye JS, Garcia AJ, Neuchat EE, Eubanks TN, Varrassi G, Viswanath O and Urits I (2021). Hyperprolactinemia, clinical considerations and infertility in women on antipsychotic medications. *Psychopharmacol. Bull*, **51**(2): 131-148.

Ercan Z, Dogru MS, Ertugrul NU, Yardimci A and Canpolat S (2022). Beneficial effects of irisin in experimental paroxetine-induced hyperprolactinemia. *Endocrine*, **76**(2): 419-425.

Glezer A, Garmes HM, Kasuki L, Martins M, Elias PCL, Nogueira VDSN, Rosa-E-Silva ACJD, Maciel GAR, Benetti-Pinto CL and Nacul AP (2024). Hyperprolactinemia in women: Diagnostic approach. *Rev Bras Ginecol Obs*, **46**: e-FPS04.

Glocker C, Grohmann R, Engel R, Seifert J, Bleich S, Stubner S, Toto S and Schule C (2021). Galactorrhea during antipsychotic treatment: Results from AMSP, a drug surveillance program, between 1993 and 2015. *Eur. Arch. Psy. Clin. N.*, **271**(8): 1425-1435.

Gu W, Mitsuhashi A, Kobayashi T and Shozu M (2022). Metformin attenuates the production and proliferative effects of prolactin induced by medroxyprogesterone acetate during fertility-sparing treatment for endometrial cancer. *Bmc Cancer*, **22**(1): 753.

Jiang T, Su H, Xu J, Li C, Zhang N, Li Y, Wu Y, Ni R, Ming Y, Li Z, Li L and Liu Y (2024). Drug-induced interstitial lung disease: A real-world pharmacovigilance study of the FDA adverse event reporting system from 2004 to 2021. *Ther Adv Drug Saf*, **15**: 20420986231224227.

Kerr S, Greenland S, Jeffrey K, Millington T, Bedston S, Ritchie L, Simpson CR, Fagbamigbe AF, Kurdi A, Robertson C, Sheikh A and Rudan I (2023). Understanding and reporting odds ratios as rate-ratio estimates in case-control studies. *J. Glob Health*, **13**: 4101.

Knox C, Wilson M, Klinger CM, Franklin M, Oler E, Wilson A, Pon A, Cox J, Chin N, Strawbridge SA, Garcia-Patino M, Kruger R, Sivakumaran A, Sanford S, Doshi R, Khetarpal N, Fatokun O, Doucet D, Zubkowski A, Rayat DY, Jackson H, Harford K, Anjum A, Zakir M, Wang F, Tian S, Lee B, Liigand J, Peters H, Wang R, Nguyen T, So D, Sharp M, Da SR, Gabriel C, Scantlebury J, Jasinski M, Ackerman D, Jewison T, Sajed T, Gautam V and Wishart DS (2024). DrugBank 6.0: The DrugBank Knowledgebase for 2024. *Nucleic Acids Res.*, **52**(D1): D1265-D1275.

Krysiak R, Szkrobka W and Okopien B (2021). The impact of ethinyl estradiol on metformin action on prolactin levels in women with hyperprolactinemia. *Exp. Clin. Endocr. Diab.*, **129**(1): 22-28.

Li J, Wang Y, Yang X, Zhu H and Jiang Z (2024). Drug-induced hypoglycemia: A disproportionality analysis of the FAERS database. *Expert Opin Drug Saf*, **23**(8): 1061-1067.

Lin W, Zeng Y, Weng L, Yang J and Zhuang W (2024). Comparative analysis of adverse events associated with CDK4/6 inhibitors based on FDA's adverse event reporting system: A case control pharmacovigilance study. *BMC Pharmacol Toxico*, **25**(1): 47.

Potter E, Reyes M, Naples J and Dal Pan G (2025). FDA Adverse Event Reporting System (FAERS) Essentials: A guide to understanding, applying, and interpreting

adverse event data reported to FAERS. *Clin. Pharmacol. Ther.*, **118**(3): 567-582.

Pratheesh PJ, Praharaj SK and Srivastava A (2011). Euprolactinemic gynecomastia and galactorrhea with risperidone-fluvoxamine combination. *Psychopharmacol Bull*, **44**(1): 70-73.

Qiao Y, Yang F, Li C, Guo Q, Wen H, Zhu S, Ouyang Q, Shen W and Sheng J (2016). Add-on effects of a low-dose aripiprazole in resolving hyperprolactinemia induced by risperidone or paliperidone. *Psychiat. Res.*, **237**: 83-89.

Randall JA, Sutter C, Wang S, Bailey E, Raither L, Perfetti R, Shendelman S and Burbridge C (2022). Qualitative interviews with adults with classic galactosemia and their caregivers: Disease burden and challenges with daily living. *Orphanet J. Rare Dis*, **17**(1): 138.

Ruiz-Santiago C, Rodriguez-Pinacho CV, Perez-Sanchez G and Acosta-Cruz E (2024). Effects of selective serotonin reuptake inhibitors on endocrine system (Review). *Biomed Rep*, **21**(3): 128.

Rusgis MM, Alabbasi AY and Nelson LA (2021). Guidance on the treatment of antipsychotic-induced hyperprolactinemia when switching the antipsychotic is not an option. *Am. J. Health-Syst. Ph.*, **78**(10): 862-871.

Sun WW, Li LY, Huang XF, Shi YC, Yang HQ, Song ZY and Lin S (2017). The central mechanism of risperidone-induced hyperprolactinemia. *Prog. Neuro-Psychoph.*, **76**: 134-139.

Trinchieri A, Perletti G, Magri V, Stamatiou K, Trinchieri M and Montanari E (2021). Drug-induced gynecomastia: A systematic review and meta-analysis of randomized clinical trials. *Arch. Ital. Urol. Andro*, **93**(4): 489-496.

U.S. Food and Drug administration (2023). FDA Adverse Event Reporting System (FAERS) public dashboard. available at: https://www.fda.gov/drugs/fdas-adverse-event-reporting-system-faers/fda-adverse-event-reporting-system-faers-public-dashboard (Accessed 31 December 2013).

Van Heerden M and Mabuza D (2020). Galactorrhoea and hyperprolactinaemia in a non-pregnant female with burns. *EJIFCC*, **31**(4): 354-361.

Yun SJ, Sang H, Park SY and Chin SO (2024). Effect of hyperprolactinemia on bone metabolism: Focusing on osteopenia/osteoporosis. *Int. J. Mol. Sci.*, **25**(3): 1474.