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A Real-world Study on Adverse Events Related to Mirogabalin Based on the VigiAccess Database

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Abstract: *Objective:* To utilize the VigiAccess database for data mining to analyze the characteristics of adverse reactions induced by mirogabalin, providing critical information for clinical medication use. *Method:* This study analyzed data from the VigiAccess database, filtering out adverse reaction reports where mirogabalin was identified as the Primary Suspect Drug (PS). Reporting Odds Ratio (ROR), Proportional Reporting Ratio (PRR), Bayesian Confidence Propagation Neural Network (BCPNN), and Empirical Bayes Geometric Mean (EBGM) methods were employed as data mining algorithms for pharmacovigilance and adverse event monitoring. These methods identify potential drug-adverse event association signals by analyzing the relationship between drug use and adverse event reporting. ROR and PRR focus on calculating reporting ratios, while BCPNN and EBGM use neural networks and empirical Bayes models, respectively, to enhance the accuracy and reliability of signal detection. *Results:* A total of 734 adverse reaction reports associated with mirogabalin were obtained. The results showed that females reported the highest number of adverse reactions, accounting for 59.67%, while males accounted for 38.83%. In terms of age distribution, the highest number of reports came from individuals over 75 years old, accounting for 33.79%. Adverse reactions mainly involved the nervous system (33.45%), general diseases and reactions at the site of administration (11.62%), and gastrointestinal disorders (10.74%). The most common adverse reactions included dizziness (11.62%), somnolence (8.27%), renal dysfunction (2.90%), and edema (2.82%). Signal intensity analysis revealed that certain adverse reactions (such as renal dysfunction, rhabdomyolysis, and drug-induced liver injury) had significant signal strength, suggesting a strong association with mirogabalin. *Conclusion:* This study, through signal mining of the VigiAccess database, reveals the characteristics of mirogabalin's adverse reactions in the real world, particularly in the nervous system and renal function. These findings provide important reference information for clinicians, aiding in the optimization of the safe use of mirogabalin. Future research should further validate the causal relationships of these signals and explore individualized treatment strategies to reduce the incidence of adverse reactions and improve patient outcomes.

Keywords: Mirogabalin; VigiAccess; Adverse reactions; Signal detection; Proportional imbalance method

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1. Introduction

Mirogabalin is a novel calcium channel modulator developed by Daiichi Sankyo for the treatment of neuropathic pain. The drug was first approved in Japan in January 2019 for the treatment of peripheral neuropathic pain (PNP), including diabetic peripheral neuropathy (DPNP) and postherpetic neuralgia (PHN) [1]. On June 28, 2024, the China National Medical Products Administration approved mirogabalin for the treatment of diabetic peripheral neuropathy. Currently, mirogabalin is undergoing clinical development in other Asian countries but has not yet been approved in the United States, Europe, and other regions [2,3]. Since its market launch, mirogabalin has become an important choice in clinical treatment due to its significant efficacy and relatively good tolerability [4]. However, as its application expands, reports of adverse events (AEs) have also increased. Although mirogabalin has shown good safety in clinical trials, the real-world drug use environment is more complex, with factors such as individual patient differences, concomitant medication use, and long-term administration potentially significantly affecting its safety profile. In recent years, the rising incidence of neuropathic pain, epilepsy, and anxiety disorders has driven the widespread use of mirogabalin. However, existing research primarily focuses on its efficacy and short-term safety, with limited understanding of the characteristics of adverse reactions during long-term use [5]. Moreover, previous studies have largely relied on clinical trial data or small-sample retrospective analyses, which are limited by strict inclusion and exclusion criteria and may not fully reflect the drug's safety in the real world. For instance, clinical trials often exclude elderly patients, those with multiple comorbidities, or those using multiple medications, yet these populations represent a significant proportion in actual clinical practice, and their adverse event profiles may significantly differ from the trial populations.

To address this research gap, this study employs the WHO-VigiAccess database for data mining to analyze the characteristics of adverse reactions to mirogabalin in the real-world setting [6]. The VigiAccess database aggregates adverse reaction reports from around the globe, covering patients of different ethnicities, ages, genders, and disease statuses, thus providing a more comprehensive and authentic picture of drug safety [7]. Utilizing signal detection methods such as the Reporting Odds Ratio (ROR) and the Bayesian Confidence Propagation Neural Network (BCPNN), this study aims to identify potential adverse reaction signals associated with mirogabalin, particularly those not fully described in the product insert or insufficiently recognized in clinical trials. Additionally, this research focuses on the differences in adverse reactions to mirogabalin across various populations, to offer personalized treatment recommendations to clinicians, optimizing drug usage strategies, reducing the incidence of adverse reactions, and improving patients' treatment outcomes and quality of life. Through this study, we hope to provide a scientific basis for the safe use of mirogabalin and offer references for further research and regulatory decisions.

2. Data processing and statistical methods

2.1. Data source

Access the VigiAccess database (https://vigiaccess.org/), use Python 3.10 with the requests package to retrieve the BASENAME of all drugs from the WHO DRUG dictionary. Obtain the JSON data from the returned front-end page, visualize the JSON data using the Pandas package, and export it to Excel to complete the download of all public drug data. SAS 9.4 software is used for subsequent statistical analysis. The data retrieval date is December 29, 2024.

2.2. Adverse event name coding

The adverse event names in the database are encoded and corrected using MedDRA 26.1 (Medical Dictionary for Regulatory Activities, MedDRA).

2.3. Signal detection methods and calculation

The proportional imbalance method is used to detect signals of drug adverse events. The ROR, PRR, BCPNN, and EBGM methods are employed to detect adverse event signals. The specific calculation formulas and the definition of positive signals are provided in **Tables 1** and **2**.

Table 1. Two-by-two contingency table for disproportionality analysis

Item	Target adverse events reported	Other adverse events reported	Total
Target drugs	a	b	a + b
Other drugs	c	d	c + d
Total	a + c	b + d	a + b + c + d

Table 2. The principles of disproportionate measurement and the criteria for signal detection.

Method	Calculation formula	Criteria
ROR	$\mathrm{ROR} = \frac{a/c}{b/d}$ $\mathrm{SE}(\ln \mathrm{ROR}) = \sqrt{\frac{1}{a}+\frac{1}{b}+\frac{1}{c}+\frac{1}{d}}$ $95\%\mathrm{CI} = e^{\ln(\mathrm{ROR})\pm 1.96se}$	a ≥ 3; ROR ≥ 1;95%CI (lower limit) > 1
PRR	$\mathrm{PRR} = \frac{a/(a+b)}{c/(c+d)}$ $\mathrm{SE}(\ln \mathrm{PRR}) = \sqrt{\frac{1}{a}-\frac{1}{a+b}+\frac{1}{c}-\frac{1}{c+d}}$ $95\%\mathrm{CI} = e^{\ln(\mathrm{PRR})\pm 1.96se}$	a ≥ 3; PRR ≥ 2;95%CI (lower limit) > 1
	$\chi 2 = \frac{(ad-bc)^2(a+b+c+d)}{(a+b)(a+c)(c+d)(b+d)}$	a ≥ 3; PRR ≥ 2;
BCPNN	$\mathrm{IC}=\log_2\frac{p(x,y)}{p(x)p(y)}=\log_2\frac{a(a+b+c+d)}{(a+b)(a+c)}$ $\mathrm{E(IC)}=\log_2\frac{(a+\gamma 11)(a+b+c+d+\alpha)(a+b+c+d+\beta)}{(a+b+c+d+\gamma)\,(a+b+\alpha 1)(a+c+\beta 1)}$ $\mathrm{V(IC)} = \frac{1}{(\ln 2)^2}\{\left[\frac{(a+b+c+d)-a+\gamma-\gamma 11}{(a+\gamma 11)(1+a+b+c+d+\gamma)}\right] + \left[\frac{(a+b+c+d)-(a+b)+\alpha-\alpha 1}{(a+b+\alpha 1)(1+a+b+c+d+\alpha)}\right] + \left[\frac{(a+b+c+d)-(a+c)+\beta-\beta 1}{(a+c+\beta 1)(1+a+b+c+d+\beta)}\right]\}$ $\gamma = \gamma 11\frac{(a+b+c+d+\alpha)(a+b+c+d+\beta)}{(a+b+\alpha 1)(a+c+\beta 1)}$ $\mathrm{IC\text{-}2SD}=\mathrm{E(IC)}-2\sqrt{\mathrm{V(IC)}}$ $\alpha 1=\beta 1=1;\ \alpha=\beta=2;\ \gamma 11=1$	IC025 > 0
EBGM	$\mathrm{EBGM} = \frac{a(a+b+c+d)}{(a+c)(a+b)}$ $\mathrm{SE}(\ln \mathrm{EBGM}) = \sqrt{\frac{1}{a}+\frac{1}{b}+\frac{1}{c}+\frac{1}{d}}$ $95\%\mathrm{CI} = e^{\ln(\mathrm{EBGM})\pm 1.96se}$	EBGM05 ≤ 2

2.4. Objective drug

The drug names in the database are standardized using the WHODrug Global dictionary. The target drug, mirogabalin, is screened based on the standardized drug names (DRUGNAME) and active ingredients (PROD_AI).

3. Results

3.1. Basic characteristics of adverse event reports

A total of 24,156 drugs with baseline information and 24,131 drugs with adverse event information were identified, involving 117,935,336 adverse event reports from 46,535,254 patients. Among these, 734 adverse events were reported for mirogabalin. The data show that in terms of gender, the majority of adverse events were reported by females, accounting for 59.67% of the total, while males accounted for 38.83%. In terms of age distribution, the highest number of reports came from individuals over 75 years old, accounting for 33.79%; those over 45 years old accounted for 83.66%. Regional distribution indicated that all reports originated from Asia. The reporting years were mainly concentrated in 2024, accounting for 96.05%, with the first adverse reaction report appearing in 2018. Overall, the reports related to mirogabalin primarily involved females and middle-aged to older adults (**Table 3**).

Table 3. Characteristics of AEs reports

Characteristics	***n* (%)**
Sex	
Female	438 (59.67)
Male	285 (38.83)
Unknown	11 (1.5)
Age	
18–44 years	56 (7.63)
45–64 years	176 (23.98)
65–74 years	190 (25.89)
>75 years	248 (33.79)
Unknown	64 (8.72)
Continent	
Asia	734 (100)
Report year	
2018	1 (0.14)
2019	14 (1.91)
2020	2 (0.27)
2021	2 (0.27)
2022	2 (0.27)
2023	8 (1.09)
2024	705 (96.05)

3.2. Proportion of adverse events by System Organ Class (SOC)

As can be seen from the chart, the adverse events related to mirogabalin are mainly concentrated in the nervous system, general disorders and administration site conditions, and gastrointestinal diseases. Among these, adverse events related to nervous system disorders have the highest proportion, accounting for 33.45%, with a total of 380 cases. This indicates that nervous system disorders are the most common type of adverse reactions associated with mirogabalin. Following this, general disorders and administration site conditions account for 11.62%, with 132 cases; gastrointestinal diseases account for 10.74%, with 122 cases. Other common adverse events include renal and urinary disorders (5.55%, 63 cases), investigations (5.28%, 60 cases), and injuries, poisoning, and procedural complications (4.67%, 53 cases). Relatively less frequent adverse events such as psychological disorders, infections and infestations, ear and labyrinth disorders, etc., are all below 3% in proportion. Additionally, there are some system organ classes with a very low incidence of adverse events, such as endocrine disorders and immune system disorders, each accounting for only 0.18%, with only 2 cases. Some categories, like congenital, genetic, and familial diseases, as well as product issues, have not reported any adverse events. These data suggest that the use of mirogabalin may lead to a higher proportion of adverse events related to the nervous system and gastrointestinal tract, but the overall range of systems and organs involved in adverse events is broad, which should be of concern and vigilance to healthcare professionals (**Figure 1**).

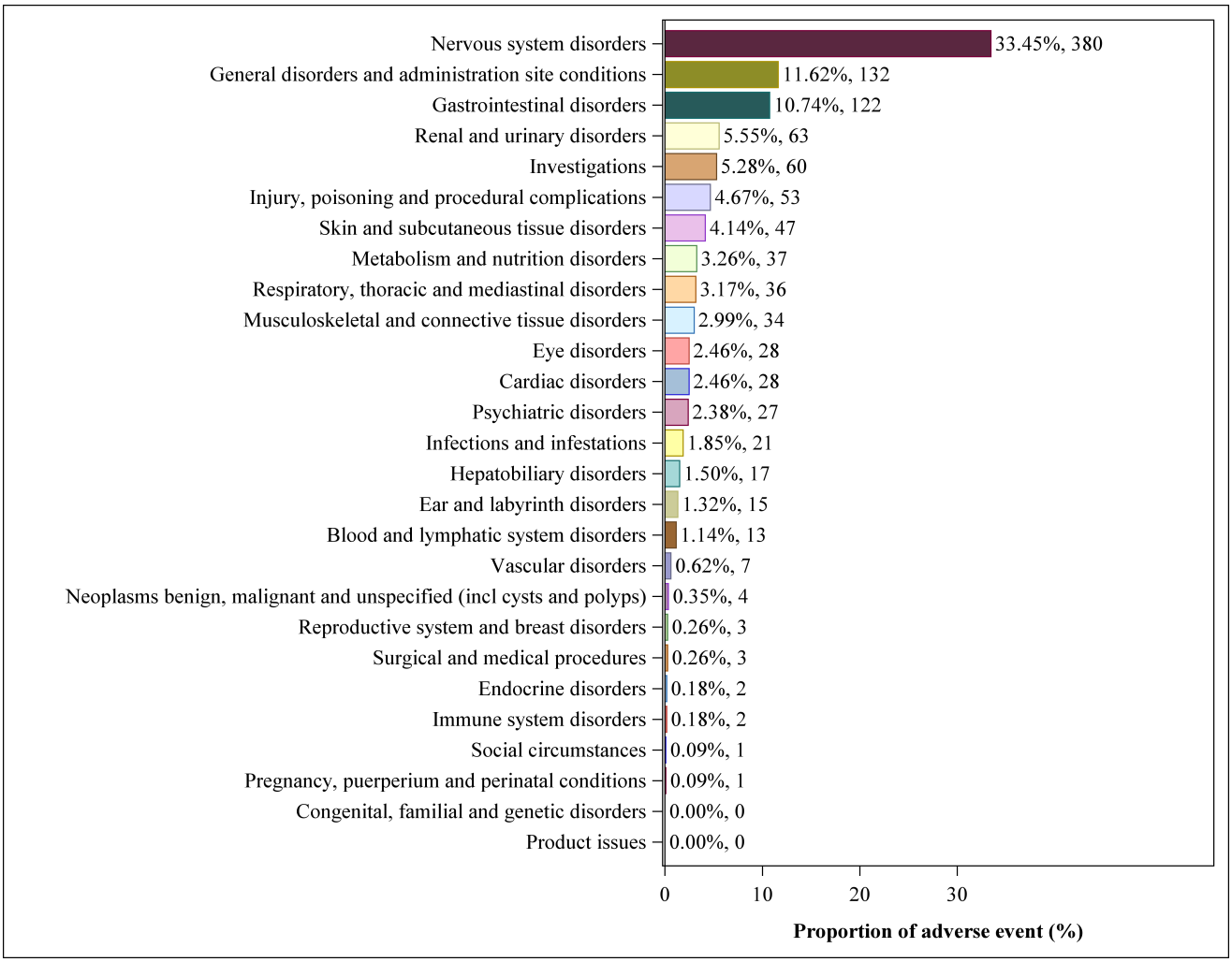


Figure 1. Proportion of adverse events by SOCs

3.3. Top 50 PTs (Preferred Terms) by frequency for adverse events

Based on the chart, the adverse events related to mirogabalin analyzed in the VigiAccess database mainly

focus on symptoms such as dizziness and somnolence. Dizziness is the most common adverse reaction, with an incidence rate of 11.62%, totaling 132 cases reported; Somnolence follows closely, with an incidence rate of 8.27%, reporting 94 cases. This indicates that mirogabalin has a significant impact on the central nervous system. Additionally, the incidence rates of renal impairment and oedema are also relatively high, at 2.90% (32 cases) and 2.82% (31 cases), respectively. Other common adverse reactions include nausea (2.73%, 31 cases), altered state of consciousness (2.38%, 27 cases), peripheral oedema (1.76%, 20 cases), and headache (1.67%, 19 cases). Further analysis reveals that adverse reactions related to various systems and organs have also been reported, such as constipation (1.58%, 18 cases), vomiting (1.58%, 18 cases), and increased weight (1.32%, 15 cases). Beyond the nervous system, important adverse reactions also include cardiac failure (0.97%, 11 cases), rhabdomyolysis (0.97%, 11 cases), as well as various skin and musculoskeletal system diseases. Overall, the adverse reactions of mirogabalin mainly concentrate on the nervous system and renal function, but also involve multiple systems and organs. This suggests that clinicians should pay particular attention to monitoring patients' nervous system symptoms and renal function when using this drug, while also being vigilant for other potential adverse events (**Figure 2**).

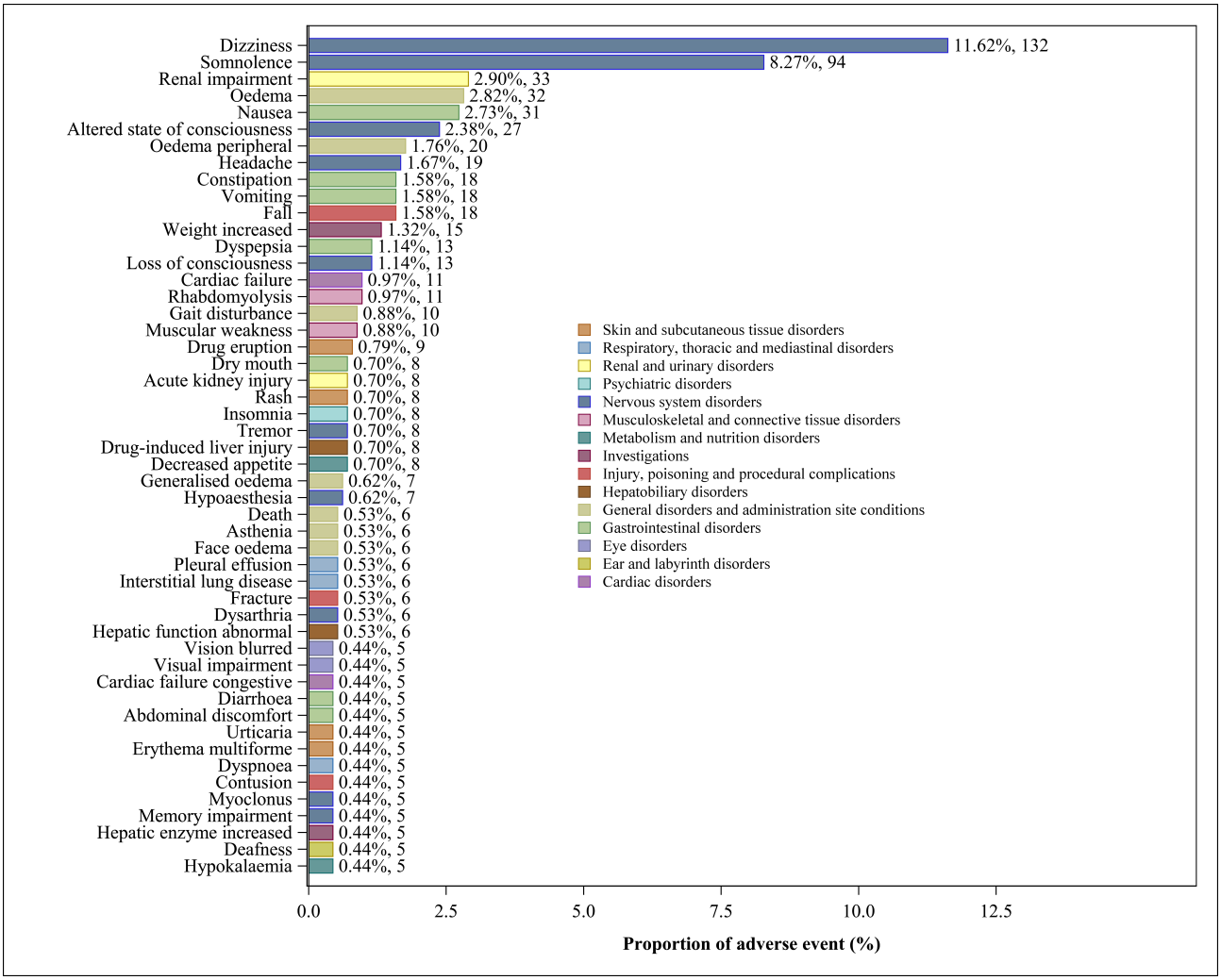


Figure 2. Top 50 PTs by frequency for adverse events

3.4. Frequency forest plot of the top 50 with simultaneous positive signals in four methods

Four algorithms all indicate that the top 50 adverse reaction PTs with positive signals are those with a high frequency of occurrence. A high frequency of adverse reactions suggests that they are more commonly reported in the database, which may indicate that these reactions are more common in actual use. The chart shows that the adverse reactions of mirogabalin mainly concentrate on the nervous system and renal function. The most common adverse reactions include dizziness (132 cases, ROR=8.44), somnolence (94 cases, ROR=19.00), renal impairment (32 cases, ROR=27.43), oedema (32 cases, ROR=9.15), and altered state of consciousness (27 cases, ROR=26.89). These adverse reactions all show a high Relative Reporting Rate (ROR), suggesting that mirogabalin may significantly increase the risk of these symptoms. Additionally, symptoms such as peripheral oedema (18 cases, ROR=7.29), constipation (18 cases, ROR=4.59), increased weight (15 cases, ROR=5.31), and rhabdomyolysis (11 cases, ROR=18.96) also exhibit high ROR values, indicating a strong correlation with mirogabalin. Less frequent reports include cardiac failure (11 cases, ROR=12.45), drug-induced liver injury (8 cases, ROR=26.12), and generalized oedema (7 cases, ROR=19.49). Although the number of reports for these adverse reactions is relatively low, their high ROR values also suggest potential risks. Moreover, serious adverse events such as amnesia (memory impairment), hypokalemia, and death, although reported in small numbers, also require attention (**Figure 3**).

System Organ Class(SOC)	Preferred Term(PT)	Case Reports	ROR (95% CI)
Nervous system disorders	Dizziness	132	8.44(7.04,10.12)
Nervous system disorders	Somnolence	94	19.01(15.39,23.47)
Renal and urinary disorders	Renal impairment	33	27.43(19.40,38.78)
General disorders and administration site conditions	Oedema	32	18.29(12.87,25.99)
Nervous system disorders	Altered state of consciousness	27	96.83(66.09,141.87)
General disorders and administration site conditions	Oedema peripheral	20	7.29(4.69,11.35)
Injury, poisoning and procedural complications	Fall	18	5.50(3.45,8.76)
Gastrointestinal disorders	Constipation	18	4.59(2.88,7.30)
Investigations	Weight increased	15	5.31(3.19,8.84)
Gastrointestinal disorders	Dyspepsia	13	4.65(2.69,8.03)
Nervous system disorders	Loss of consciousness	13	6.70(3.88,11.57)
Musculoskeletal and connective tissue disorders	Rhabdomyolysis	11	18.96(10.47,34.33)
Cardiac disorders	Cardiac failure	11	12.45(6.87,22.54)
Musculoskeletal and connective tissue disorders	Muscular weakness	10	5.10(2.73,9.50)
General disorders and administration site conditions	Gait disturbance	10	3.93(2.11,7.32)
Skin and subcutaneous tissue disorders	Drug eruption	9	18.12(9.40,34.91)
Hepatobiliary disorders	Drug-induced liver injury	8	26.12(13.03,52.37)
General disorders and administration site conditions	Generalised oedema	7	19.49(9.27,40.98)
Injury, poisoning and procedural complications	Fracture	6	31.54(14.14,70.37)
Nervous system disorders	Dysarthria	6	10.65(4.77,23.76)
Respiratory, thoracic and mediastinal disorders	Pleural effusion	6	8.88(3.98,19.81)
Respiratory, thoracic and mediastinal disorders	Interstitial lung disease	6	8.09(3.63,18.05)
Ear and labyrinth disorders	Deafness	5	12.44(5.17,29.95)
Cardiac disorders	Cardiac failure congestive	5	5.48(2.28,13.19)
Skin and subcutaneous tissue disorders	Erythema multiforme	5	10.68(4.44,25.71)
Nervous system disorders	Myoclonus	5	27.55(11.44,66.33)
Injury, poisoning and procedural complications	Prescribed overdose	4	22.50(8.43,60.06)
Skin and subcutaneous tissue disorders	Stevens-Johnson syndrome	4	5.56(2.08,14.85)
Nervous system disorders	Dreamy state	4	492.58(184.13,1317.78)
Nervous system disorders	Toxic encephalopathy	4	71.04(26.61,189.67)
Nervous system disorders	Dyslalia	3	408.19(131.16,1270.37)
Nervous system disorders	Dysstasia	3	7.98(2.57,24.77)
Investigations	Glycosylated haemoglobin increased	3	9.86(3.18,30.63)
Injury, poisoning and procedural complications	Road traffic accident	3	6.91(2.23,21.47)
Eye disorders	Diplopia	3	6.91(2.22,21.46)
Metabolism and nutrition disorders	Diabetes mellitus inadequate control	3	12.90(4.15,40.05)
Metabolism and nutrition disorders	Increased appetite	3	10.08(3.25,31.30)

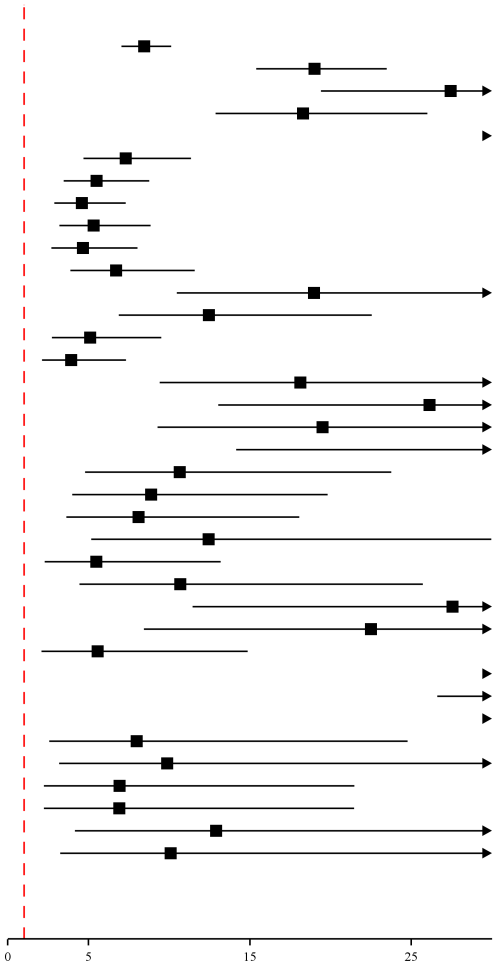


Figure 3. Frequency forest plot of the top 50 with simultaneous positive signals in four methods

3.5. Four methods with simultaneous positive signals

Four types of algorithms all indicate a positive signal, with the top 50 adverse reaction preferred terms listed by ROR signal strength. A strong signal strength suggests a significantly higher association between a particular drug and an adverse reaction than other drugs, which may imply a causal relationship between the drug and the adverse reaction. First, the chart shows that the signal strength for nervous system-related adverse reactions is most significant. For example, “Dreamy state” has the highest ROR value at 492.58 (95% CI: 184.13, 1317.78), followed by “Dyslalia” with an ROR value of 408.19 (95% CI: 131.16, 1270.37). Additionally, “Altered state of consciousness” (96.86, 95% CI: 60.19, 141.87) and “Toxic encephalopathy” (71.04, 95% CI: 26.61, 189.67) also exhibit very high signal strength. Adverse reactions related to the kidneys and liver, such as “Renal impairment” (ROR=27.43, 95% CI: 19.40, 38.78) and “Drug-induced liver injury” (ROR=26.12, 95% CI: 13.03, 52.37), also show significant signal strength. Other systemic adverse reactions, such as “Rhabdomyolysis” (ROR=18.96, 95% CI: 10.47, 34.33), “Generalized oedema” (ROR=19.49, 95% CI: 9.27, 40.99), and “Drug eruption” (ROR=18.12, 95% CI: 10.49, 34.01) also demonstrate higher ROR values. This underscores the need for close monitoring of these potential high-risk adverse reactions when using mirogabalin, particularly for the symptoms with high signal strength mentioned above, and to take appropriate preventive and therapeutic measures promptly to ensure patient safety (**Figure 4**).

System Organ Class(SOC)	Preferred Term(PT)	Case Reports	ROR (95% CI)
Nervous system disorders	Dreamy state	4	492.58(184.13,1317.78)
Nervous system disorders	Dyslalia	3	408.19(131.16,1270.37)
Nervous system disorders	Altered state of consciousness	27	96.83(66.09,141.87)
Nervous system disorders	Toxic encephalopathy	4	71.04(26.61,189.67)
Injury, poisoning and procedural complications	Fracture	6	31.54(14.14,70.37)
Nervous system disorders	Myoclonus	5	27.55(11.44,66.33)
Renal and urinary disorders	Renal impairment	33	27.43(19.40,38.78)
Hepatobiliary disorders	Drug-induced liver injury	8	26.12(13.03,52.37)
Injury, poisoning and procedural complications	Prescribed overdose	4	22.50(8.43,60.06)
General disorders and administration site conditions	Generalised oedema	7	19.49(9.27,40.98)
Nervous system disorders	Somnolence	94	19.01(15.39,23.47)
Musculoskeletal and connective tissue disorders	Rhabdomyolysis	11	18.96(10.47,34.33)
General disorders and administration site conditions	Oedema	32	18.29(12.87,25.99)
Skin and subcutaneous tissue disorders	Drug eruption	9	18.12(9.40,34.91)
Metabolism and nutrition disorders	Diabetes mellitus inadequate control	3	12.90(4.15,40.05)
Cardiac disorders	Cardiac failure	11	12.45(6.87,22.54)
Ear and labyrinth disorders	Deafness	5	12.44(5.17,29.95)
Skin and subcutaneous tissue disorders	Erythema multiforme	5	10.68(4.44,25.71)
Nervous system disorders	Dysarthria	6	10.65(4.77,23.76)
Metabolism and nutrition disorders	Increased appetite	3	10.08(3.25,31.30)
Investigations	Glycosylated haemoglobin increased	3	9.86(3.18,30.63)
Respiratory, thoracic and mediastinal disorders	Pleural effusion	6	8.88(3.98,19.81)
Nervous system disorders	Dizziness	132	8.44(7.04,10.12)
Respiratory, thoracic and mediastinal disorders	Interstitial lung disease	6	8.09(3.63,18.05)
Nervous system disorders	Dysstasia	3	7.98(2.57,24.77)
General disorders and administration site conditions	Oedema peripheral	20	7.29(4.69,11.35)
Injury, poisoning and procedural complications	Road traffic accident	3	6.91(2.23,21.47)
Eye disorders	Diplopia	3	6.91(2.22,21.46)
Nervous system disorders	Loss of consciousness	13	6.70(3.88,11.57)
Skin and subcutaneous tissue disorders	Stevens-Johnson syndrome	4	5.56(2.08,14.85)
Injury, poisoning and procedural complications	Fall	18	5.50(3.45,8.76)
Cardiac disorders	Cardiac failure congestive	5	5.48(2.28,13.19)
Investigations	Weight increased	15	5.31(3.19,8.84)
Musculoskeletal and connective tissue disorders	Muscular weakness	10	5.10(2.73,9.50)
Gastrointestinal disorders	Dyspepsia	13	4.65(2.69,8.03)
Gastrointestinal disorders	Constipation	18	4.59(2.88,7.30)
General disorders and administration site conditions	Gait disturbance	10	3.93(2.11,7.32)

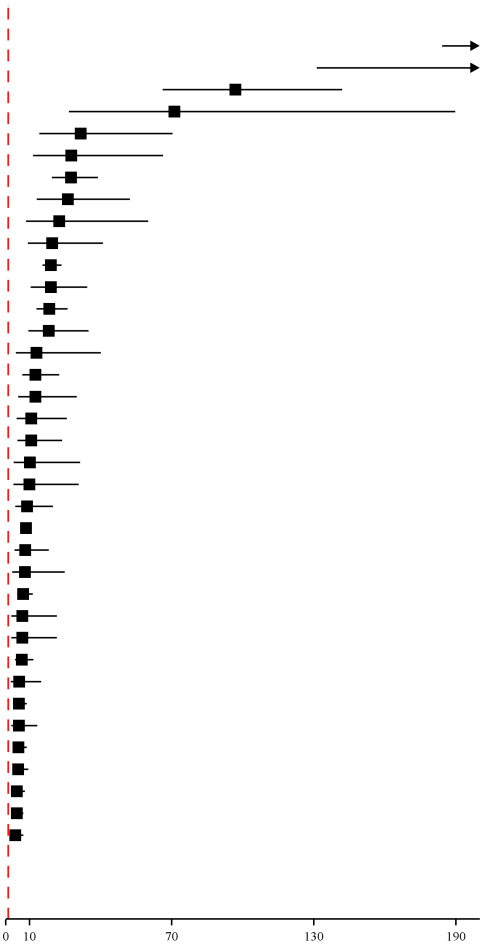


Figure 4. Four methods with simultaneous positive signals

4. Discussion

This study conducted a comprehensive analysis of the adverse reactions of mirogabalin using the WHO-VigiAccess database. The results revealed that the adverse reactions of mirogabalin primarily involve the nervous system and renal function. Dizziness and somnolence are the most common adverse reactions, accounting for 11.62% and 8.27%, respectively. These findings are closely related to the mechanism of action of mirogabalin, which affects central nervous system activity by regulating calcium channels, potentially leading to neurological symptoms such as dizziness and somnolence [8,9]. Additionally, the incidence of renal impairment and oedema is also relatively high, at 2.90% and 2.82% respectively, which may be associated with the drug's metabolic pathway and renal excretion function [10].

Compared with the existing literature, the results of this study are consistent in some aspects. Previous studies have also reported that mirogabalin can cause adverse reactions such as dizziness, somnolence, and renal impairment. However, this study also identified some less commonly mentioned adverse reactions, such as rhabdomyolysis and drug-induced liver injury, which have not been detailed in other studies. This indicates that the VigiAccess database can provide more comprehensive information on drug safety, especially in real-world settings [6,7].

The molecular structure and mechanism of action of mirogabalin may explain the characteristics of its adverse reactions. As a calcium channel modulator, mirogabalin exerts its therapeutic effect by inhibiting the α2δ subunit of voltage-gated calcium channels, thereby reducing the release of neurotransmitters [11]. However, this mechanism of action may also lead to adverse reactions in the central nervous system, such as dizziness and somnolence. Moreover, since mirogabalin is primarily excreted through the kidneys, the occurrence of renal impairment and oedema may be related to reduced drug excretion [12].

The findings of this study have significant implications for clinical practice. Firstly, clinicians should closely monitor patients for neurological symptoms and renal function when prescribing mirogabalin, especially in high-risk populations such as the elderly and patients with impaired renal function [13]. Secondly, for patients reporting adverse reactions such as dizziness and somnolence, adjustments to the drug dosage or a change in treatment regimen may be necessary [14]. Additionally, less commonly mentioned but potentially serious adverse reactions, such as rhabdomyolysis and drug-induced liver injury, should also be given sufficient attention for timely prevention and treatment measures [15].

Although this study provides valuable information on the adverse reactions of mirogabalin, it also has some limitations. Firstly, the data in the VigiAccess database relies on voluntary reporting, which may be subject to reporting biases and incomplete information. Secondly, signal detection methods, such as ROR and BCPNN can identify associations between drugs and adverse reactions, but cannot establish causality. Therefore, future studies need to validate the causal relationships of these signals through more rigorous prospective studies and cohort studies.

Future research can further explore the safety and efficacy of mirogabalin in different populations, particularly the long-term safety. Additionally, combining genomics and pharmacokinetic studies can help better understand the impact of individual differences on adverse drug reactions. Finally, developing more accurate prediction models for adverse reactions can help identify high-risk patients earlier in clinical practice, thereby improving the safety of drug use.

5. Conclusion

This study, through signal detection in the WHO-VigiAccess database, has uncovered the characteristics of adverse reactions to mirogabalin in the real-world setting, particularly to the nervous system and renal function. These findings not only provide valuable reference information for clinicians but also contribute to the optimization of the safe use of mirogabalin. Future research should further validate the causal relationships of these signals and explore individualized treatment strategies to reduce the incidence of adverse reactions and improve patient outcomes.

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Disclosure statement

The authors declare no conflict of interest.

References

[1] Tang H, Lu J, Duan Y, et al., 2023, The Clinical Application and Progress of Mirogabalin on Neuropathic Pain as a Novel Selective Gabapentinoids. Mediators Inflamm, 2023: 4893436.

[2] Burgess J, Javed S, Frank B, et al., 2020, Mirogabalin Besylate in the Treatment of Neuropathic Pain. Drugs Today (Barc), 56(2): 135–149.

[3] Nakanishi K, Ota C, Yomiya K, 2020, Analgesic Effects of Mirogabalin for Cancer Pain. Gan To Kagaku Ryoho, 47(6): 927–931.

[4] Brown K, Mendell J, Ohwada S, et al., 2018, Tolerability, Pharmacokinetics, and Pharmacodynamics of Mirogabalin in Healthy Subjects: Results from Phase 1 Studies. Pharmacol Res Perspect, 6(5): e00418.

[5] Misawa S, Denda T, Kodama S, et al., 2023, Efficacy and Safety of Mirogabalin for Chemotherapy-induced Peripheral Neuropathy: A Prospective Single-arm Trial (MiroCIP Study). BMC Cancer 23, 1098.

[6] Min C, 2022, The Importance of a World Health Organization International Pharmacovigilance Database (Vigibase): Novel Methods for Safety Monitoring and Surveillance of Medical Products. Life Cycle, 2.

[7] Li M, You R, Su Y, et al., 2023, Characteristic Analysis of Adverse Reactions of Five Anti-TNFα Agents: A Descriptive Analysis from WHO-VigiAccess. Frontiers in Pharmacology, 14.

[8] Kato J, Matsui N, Kakehi Y, et al., 2019, Mirogabalin for the Management of Postherpetic Neuralgia: A Randomized, Double-blind, Placebo-controlled Phase 3 Study in Asian Patients. PAIN, 160(5): 1175–1185.

[9] Baba, M, Matsui N, Kuroha M, et al., 2019, Long-term Safety and Efficacy of Mirogabalin in Asian Patients with Diabetic Peripheral Neuropathic Pain. Journal of Diabetes Investigation, 11(3): 693–698.

[10] Brown K, Mendell J, Ohwada S, et al., 2018, Tolerability, Pharmacokinetics, and Pharmacodynamics of Mirogabalin in Healthy Subjects: Results from Phase 1 Studies. Pharmacology Research &Amp; Perspectives, 6(5): e00418.

[11] Chen EY, Beutler SS, Kaye AD, et al., 2021, Mirogabalin as a Novel Gabapentinoid for the Treatment of Chronic Pain

Conditions: An Analysis of Current Evidence. Anesth Pain Med. 11(6): e121402.

[12] Kato J, Matsui N, Kakehi Y, et al., 2020, Long-term Safety and Efficacy of Mirogabalin in Asian Patients with Postherpetic Neuralgia: Results from an Open-label Extension of a Multicenter Randomized, Double-blind, Placebo-controlled Trial. Medicine, 99(36): e21976.

[13] Ushida T, Katayama Y, Hiasa Y, et al., 2023, Long-term Safety and Efficacy of Mirogabalin for Central Neuropathic Pain: A Multinational, Phase 3, 52-week, Open-label Study in Asia. Pain and Therapy, 12(4): 963–978.

[14] Tetsunaga T, Tetsunaga T, Nishida K, et al., 2020, Short-term Outcomes of Mirogabalin in Patients with Peripheral Neuropathic Pain: A Retrospective Study. Journal of Orthopaedic Surgery and Research, 15(1): 191.

[15] Obara S, Nakano Y, Oishi R, et al., 2024, Marked Improvement in Severe Chronic Penile Pain Following the Administration of Mirogabalin: A Case Report. Cureus, 16(7): e65231.

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