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Signal Mining and Analysis of Drug-Induced Peripheral Nerve Injury: A Drug- Adverse Reaction Report of 2732 Cases from FAERS

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1. Abstract

1.1. Introduction

During clinical treatment, researchers have found that a variety of medications can cause peripheral nerve injury. These drugs include, chemotherapy drugs, antibacterial drugs, immunosuppressants, and antiviral drugs. This study aims to investigate cases in Food and Drug Administration Adverse Events Reporting System (FAERS) to summarize the clinical characteristics of drug-induced PNI to help identify potential PNI risk drugs.

1.2. Methods

This study searched the FAERS database for drug-induced PNI information reported from 1998 to 2023 using "Nerve Injury" and "Peripheral Nerve Injury" as keywords. Sub-datasets including demographic characteristics, drug information, severity of adverse events, patient outcomes, and reporting sources were collected and analysed. Reporting odds ratio (ROR), proportional reporting ratio (PRR), and Bayesian confidence propagation neural network (BCPNN) were used as risk signal detection indicators, and corresponding threshold conditions were set to perform statistical analysis on adverse drug reaction (ADR).

1.3. Results

A total of 2,732 reports were examined, and female patients accounted for 61.90%, which was significantly higher than the 32.17% of male patients. The number of reports showed an increasing association with age. The United States had the largest number of report sources (56.33 %), followed by Canada (7.06%), the United Kingdom (4.87%), China (2.86%), and Germany (2.27%). A total of 17.09% of reports did not fill in the place of origin. Among the reports, 2397 cases were serious ADRs (87.74%), 12.26% were non-serious ADRs. Among the severe ADRs, 48.31% of the cases led to other severe ADRs. Of the ADRs, 29.29% of the cases were associated with prolonged hospital stay, and 12.39% of the cases caused disability. All reports involved 383 suspected drugs. After risk assessment, 52 drugs were found to have strong risk signals, involving 1,160 ADR reports, where PNI was mentioned in the instructions of 28 drugs, such as quinolone antibiotics and benzodiazepine antipsychotics, accounting for 62.58% of the drugs. PNI was not mentioned in the instructions of 24 drugs, such as pregabalin and letrozole, accounting for 37.42% of all drugs.

1.4. Conclusion

As the reporting rate of adverse reactions to PNI increases year by year, medical institutions should strengthen the pharmaceutical monitoring of PNI in female and elderly patients when using clinical medications. All patients need to strengthen prevention of PNI when using drugs with strong risk signals. The above work can provide an effective baseline basis for the prevention and treatment of severe drug-induced PNI.

2. Introduction

Drugs have two sides, and many commonly used drugs in clinical practice may cause adverse drug reactions (ADRs), among which, a large category is peripheral nerve injury (PNI). Drugs that cause PNI include chemotherapy drugs, antibacterial drugs, immunosuppressants, and antiviral drugs [1-4]. Clinical manifestations of PNI include movement disorders (48.4%), sensory disorders (59.5%), and spontaneous pain (12.2%), which could lead to a decline in patients' quality of life, a sharp increase

in medical costs, and increased difficulty in clinical follow-up treatment [5]. Food and Drug Administration Adverse Events Reporting System (FAERS) is a spontaneous reporting system that is an important data source for assessing the risks of drug use in the real world that has been widely used by researchers in recent years [6]. We had identified patients in the clinic who had an 82% incidence of oxaliplatin induced peripheral neuropathy in previous study [7]. We also found that 15.94% of Parkinson's patients had PNI, but we cannot exclude the possibility of medication use as cause [8]. Therefore, this study further extracted FAERS global information, which cannot only help clinical staff analyse and identify the clinical characteristics of drug-induced PNI, but also discover previously unidentified PNI risk drugs.

3. Material and Methods

2.1 Data source

The data for this study were derived from the FAERS public database and were extracted and queried using the Open Vigil 2.1 website http://openvigil.sourceforge.net [9]. The time for uploading reports was set from 1998 to 2023.

3.2. Data Address

Relevant drug ADRs were collected using "Neurological injury" as the keyword. Based on the Standard MedDRA Query (SMQ) Entry Guide Version 26.1, the preferred term (PT) was used to describe ADRs, and all PTs related to PNI are queried, so that the corresponding drugs can be described and located more accurately [10]. After obtaining non-repetitive PNI-related target reports, important information such as gender, age, reporting country, year, severity of the disease, and drugs involved in the reports were collected. The flow chart was shown in Figure 1. Risk signal detection of suspicious drugs used the proportionality imbalance method [11]. It also included reporting odds ratio (ROR), proportional reporting ratio (PRR) and Bayesian confidence propagation neural network (BCPNN) method [12]. Judgment condition setting as ADR report number $a \geq 3$, 95% CI lower limit > 1 indicates that a signal has been generated [13-14]. The size of the ROR and PRR values reflects the strength of the correlation between the drug and ADR. The larger the value, the stronger the correlation [15]; the detection standard of BCPNN method was IC025>0 [16]. When all three methods showed positive signals, it was more likely that the report was positive (Table 1 and Table 2).

3.3. Statistical Analyses

SPSS 22.0 was used for data processing, and GraphPad Prism 9.00 software was used for analysis and graphing. The measurement data were expressed as mean ± standard deviation (SD). One-way ANOVA was performed for multiple group comparisons and the LSD test for the difference between two groups. A P-value <0.05 was statistically significant.

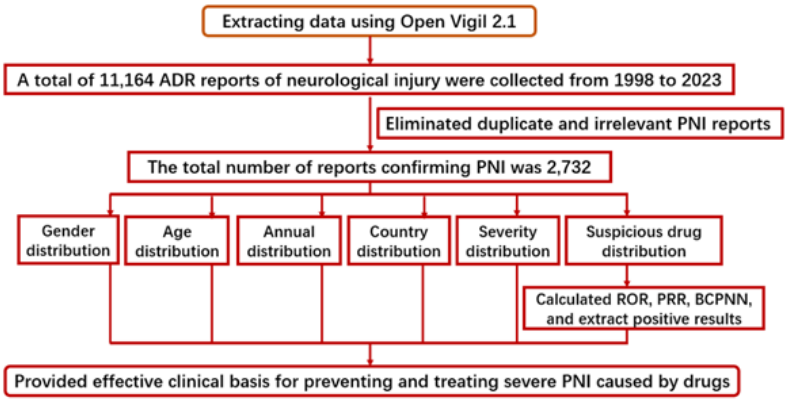

Figure 1: Data Collection Flowchart.

Table 1: A two-by-two contingency table for disproportionality analysis.

	Target adverse drug event	Other adverse drug event	Sums
Targeted drugs	*a*	*b*	*a+b*
Other drugs	*c*	*d*	*c+d*
Sums	*a+c*	*b+d*	*a+b+c+d*

Table 2: Three algorithms used to assess potential associations between drugs and PNI-ADRs.

Algorithms	Equation	Criteria
ROR	ROR= (ad/bc)	Lower limit of 95% CI>1
	95%CI= eln (ROR)±1.96(1/a+1/b+1/c+1/d)^0.5	
PRR	PRR= a(c+d)/c/(a+b)	N≥3,PRR≥2,χ^2≥4
	χ^2= [(ad-bc) ^2] (a+b+c+d)/[(a+b) (c+d) (a+c) (b+d)]	
BCPNN	IC=log2a(a+b+c+d)/(a+c) (a+b)	IC025＞0
	IC025=$e^{\ln(IC)-1.96(1/a+1/b+1/c+1/d)^0.5}$	

Note: ROR, Number of reports that contain both targeted drug and targeted drug adverse reactions; PRR, Number of reports of other drug adverse reactions that contain the targeted drug; BCPNN, Number of reports of targeted drug adverse reactions that contain other drugs. 95% CI, 95% confidence interval; N, the number of reports; χ2, chi-squared; IC, information component; IC025, the lower limit of 95% CI of the IC; E (IC), the IC expectations; V(IC), the variance of IC.

4. Results

4.1. Distribution of Demographic Characteristics of PNI-Related ADR Reports

Through extraction and screening of the FAERS database, 2732 PNI-related ADR reports were finally obtained. The demographic characteristics mainly involved the following aspects: 1) Gender, 1691 cases were female (61.90%), 879 cases were male (32.17%), and 162 cases (5.93%) had unmarked gender. Female patients account for higher proportion than male patients, P=0.000. Stratified by different age groups: 25 cases (0.92%) aged 0-17 years old, 402 cases (14.71%) aged 18-45 years old, 570 cases (20.86%) aged 46-60 years old, 710 cases (25.99%) aged ≥60 years old, there were 1025 cases (37.52%) whose age was not marked. The incidence of PNI increased with age, P=0.000. According to the identity of the reporter, consumers have a strong awareness of independent reporting (60.94%) and 33.75% of the cases were followed by the medical staff, P=0.000. As for reporting countries, the United States has the largest number of reported cases (56.33%), followed by Canada (7.06%), the United Kingdom (4.87%), China (2.86%), and Germany (2.27%). Reports with the place of origin accounted for 17.09% of all cases, P=0.000. Importantly, there were 2397 serious reports among all reports, accounting for 87.74%, P=0.000. See Table 3 for details.

4.2. Annual Trends in The Number of PNI-Related ADR Reports

The 2,732 ADR reports reflected that using the FAERS platform to timely discover and warn of PNI-related ADRs had become a hot topic for consumers and medical staff year by year. Between 1998 and 2009, the number of reports of drug-induced PNI was relatively stable, but in the past decade it has shown a clear upward trend (Figure 2).

Table 3: Demographic characteristics of PNI-related ADRs (n=2732).

Characteristics	Case number (n)	Proportion (%)	χ^2/Z	*P*
Gender			1285.239	0.000
Female	1691	61.90%		
Male	879	32.17%		
Unknown	162	5.93%		
Age(years)			1004.922	0.000
＜18	25	0.92%		
18-45	402	14.71%		
46-60	570	20.86%		
≥60	710	25.99%		
Unknown	1025	37.52%		
Reported person			1268.733	0.000
Consumer	1665	60.94%		
Health professional	922	33.75%		
Unknown	145	5.31%		
Reported countries (top 5)			32.96	0.000
America	1539	56.33%		
Canada	193	7.06%		
England	133	4.87%		
China	78	2.86%		
Germany	62	2.27%		
Serious outcomes			19.537	0.000
Serious	2397	87.74%		
Non- serious	335	12.26%		

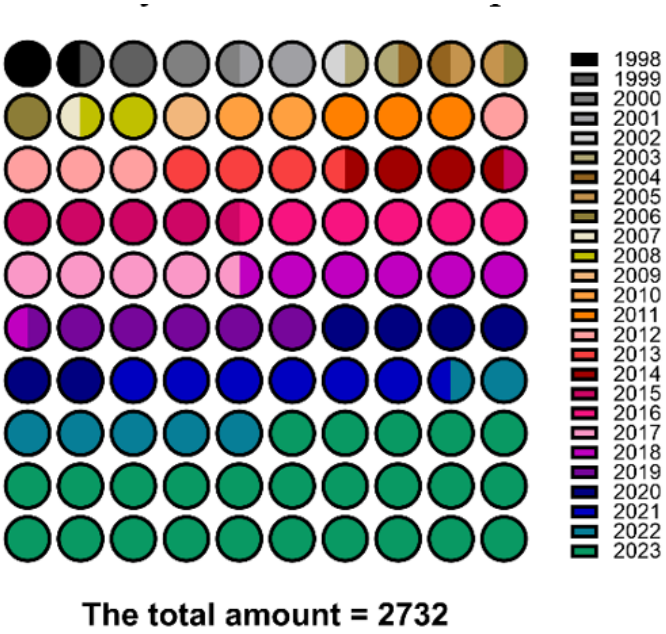

Figure 2: Annual distribution of PNI reports amount.

4.3. Analysis of Drug Risk Signals Involved In PNI-Related ADR Reports

Among the 2,732 reports, we focused on assessing the risk signals of drugs to provide early warning tips for clinical application. The results showed that all reports involved a total of 383 different drugs. As a result, 52 drugs were determined to have significant risk signals, with 1160 related reports. Among the high-risk drugs, the instructions for 28 drugs (726 reports) clearly mentioned the risk of PNI, accounting for 62.58% of the reports; the remaining 24 drugs (434 reports) did not explicitly indicate PNI as potential ADRs in their instructions, accounting for 37.42% of the reports. This result alerted drug users not only to be wary of drugs that had been reminded of PNI in the instructions, but also to pay attention to drugs whose instructions had not updated the PNI and whose risk signals had not reached a strong level. When we analysed these ADRs whether they were warned or not, the incidence rate was determined according to the Common Terminology Criteria for Adverse Events (CTCAE) Version 5.0. The incidence rates of quinolones and adalimumab were greater than 10% which were “very common”. The incidence rates of pregabalin, statins, insulin and lenalidomide were greater than 5%, as we had known that ADRs ≥1% were “common”. Therefore, drugs with a frequency ≥1% in this study deserve higher clinical attention. See Table 4 for details.

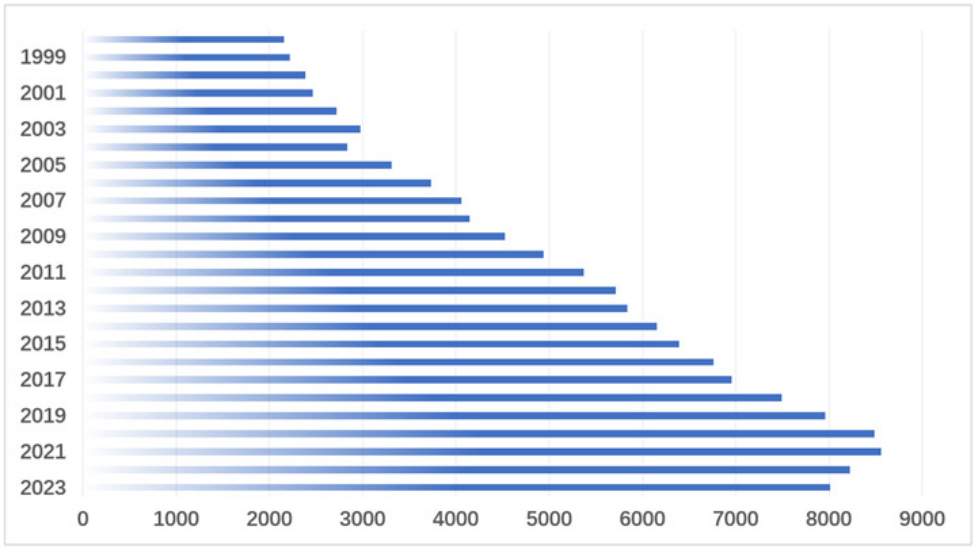

Figure 3: The amount of ADRs on PubMed from 1998 to 2023.

Table 4: Drugs with strong risk signals of PNI-related ADRs and warning information in instructions for use(n=1160).

Warning Information	PT name	Frequency (%)	ROR (95%CI)	PRR (χ^2)	IC (IC025)
PNI information included in the drug instruction	Toradol	3(0.26%)	7.88(61.58-1.01)	7.88(5.46)	0.70(0.09)
	Nitrofurantoin	4(0.34%)	6.70(29.01-1.55)	6.70(8.68)	0.68(0.16)
	Cordarone	6(0.52%)	5.64(12.44-2.56)	5.63(23.40)	0.65(0.29)
	Eloxatin	15(1.29%)	4.67(8.84-2.46)	4.66(27.06)	0.61(0.32)
	Methylprednisolone Acetate	3(0.27%)	4.34(12.59-1.49)	4.33(8.68)	0.60(0.21)
	Cipro	3(0.26%)	4.30(8.75-2.11)	4.29(19.21)	0.59(0.29)
	Sensorcaine	7(0.60%)	3.78(9.92-1.44)	3.78(8.47)	0.57(0.22)
	Paxil	5(0.43%)	2.92(4.63-1.84)	2.91(22.78)	0.49(0.31)
	Lidocaine Hydrochloride	4(0.34%)	2.89(7.13-1.17)	2.89(5.83)	0.49(0.20)
	Amitriptyline	10(0.86%)	2.85(4.27-1.90)	2.84(28.01)	0.48(0.32)
	benzodiazepines	3(0.26%)	2.82(6.51-1.22)	2.81(6.40)	0.48(0.21)
	Thalomid	18(1.55%)	2.73(4.39-1.70)	2.72(18.63)	0.47(0.29)
	Chantix	6(0.52%)	2.61(4.85-1.40)	2.61(9.89)	0.46(0.25)
	Norvasc	9(0.78%)	2.56(4.90-1.34)	2.56(8.74)	0.45(0.24)
	Oxybutynin	4(0.34%)	1.97(3.52-1.10)	1.97(5.46)	0.35(0.20)
	Velcade	12(1.03%)	1.82(3.28-1.01)	1.82(4.15)	0.32(0.18)
	Avonex	41(3.53%)	1.75(2.17-1.41)	1.74(26.93)	0.30(0.24)
	Metformin	10(0.86%)	1.73(2.75-1.09)	1.73(5.48)	0.30(0.19)
	Singulair	8(0.69%)	1.71(2.66-1.10)	1.71(5.89)	0.29(0.19)
	Yaz	9(0.78%)	1.66(2.40-1.14)	1.65(7.18)	0.28(0.19)
	Quinolones	217(18.71%)	1.59(1.72-1.47)	1.53(136.24)	0.24(0.22)
	Celebrex	9(0.78%)	1.55(2.36-1.02)	1.55(4.31)	0.25(0.16)
	Revlimid	62(5.34%)	1.54(1.92-1.24)	1.54(15.42)	0.24(0.19)
	Botox	15(1.29%)	1.48(1.92-1.13)	1.47(8.49)	0.22(0.17)
	Flagyl	9(0.78%)	1.47(2.12-1.02)	1.47(4.29)	0.22(0.15)
	Forteo	19(1.64%)	1.30(1.70-1.00)	1.30(3.89)	0.16(0.12)
	Topamax	17(1.47%)	1.28(1.60-1.02)	1.27(4.56)	0.14(0.11)
	Humira	198(17.07%)	1.12(1.22-1.03)	1.11(6.48)	0.06(0.06)
No PNI information included in the drug instruction	Femara	3(0.26%)	11.04(83.94-1.45)	11.03(8.52)	0.74(0.10)
	Kybella	10(0.86%)	4.26(11.06-1.64)	4.25(10.51)	0.59(0.23)
	Glucotrol Xl	4(0.35%)	4.20(14.43-1.22)	4.20(6.17)	0.59(0.17)
	Kesimpta	5(0.43%)	3.16(5.56-1.79)	3.15(17.66)	0.52(0.29)
	Soliris	7(0.60%)	2.49(4.64-1.33)	2.48(8.77)	0.44(0.24)
	Kisqali	3(0.26%)	2.37(5.03-1.11)	2.36(5.31)	0.42(0.20)
	Tysabri	19(1.64%)	2.29(3.27-1.61)	2.29(22.17)	0.41(0.29)
	Ultomiris	4(0.35%)	2.23(4.32-1.16)	2.23(6.04)	0.40(0.21)
	Oxycodone	4(0.35%)	2.23(3.87-1.28)	2.22(8.48)	0.40(0.23)
	Repatha	7(0.60%)	2.10(3.62-1.22)	2.10(7.57)	0.38(0.22)
	Venlafaxine	7(0.60%)	2.07(3.68-1.16)	2.07(6.40)	0.37(0.21)
	Voltaren	10(0.86%)	1.63(2.57-1.04)	1.63(4.63)	0.27(0.17)
	Dilaudid	5(0.43%)	1.60(2.30-1.11)	1.59(6.39)	0.26(0.18)
	Eliquis	15(1.29%)	1.59(2.11-1.20)	1.59(10.50)	0.26(0.19)
	Neurontin	21(1.81%)	1.58(2.12-1.17)	1.58(9.30)	0.25(0.19)
	Gilenya	10(0.86%)	1.53(2.09-1.12)	1.52(7.14)	0.24(0.17)
	Adrenalin	14(1.21%)	1.50(2.19-1.03)	1.50(4.48)	0.23(0.16)
	Pomalyst	19(1.64%)	1.50(2.20-1.02)	1.50(4.34)	0.23(0.16)
	Insulin	66(5.69%)	1.41(1.66-1.19)	1.40(16.38)	0.19(0.16)
	Baclofen	7(0.60%)	1.35(1.74-1.05)	1.35(5.67)	0.18(0.14)
	Lyrica	100(8.62%)	1.34(1.52-1.18)	1.33(19.56)	0.17(0.15)
	Quetiapine Fumarate	3(0.26%)	1.33(1.71-1.03)	1.32(4.71)	0.16(0.13)
	Cosentyx	15(1.29%)	1.30(1.66-1.02)	1.30(4.62)	0.15(0.12)
	Statins	76(6.55%)	1.19(1.37-1.03)	1.18(5.47)	0.10(0.09)

4.4. Severity Analysis of PNI-Related ADR Reports

In total, 84.34% of the 2732 reports were demonstrated as serious adverse reactions, of which the highest proportion (48.31%) was further leading to other serious ADRs, followed by hospitalization (29.29%), and disability (12.39%). This result suggested that the ADR manifestations of PNI were very serious and were worthy of attention from patients and doctors. See Table 5 for details.

Table 5: Specific manifestations of serious ADRs in drug-induced PNI (n=2732).

Serious manifestation	Case number (n)	Proportion (%)	χ^2	P
Causes other serious ADRs	1158	48.31%	37.022	0.000
Hospitalized	702	29.29%		
Disabled	297	12.39%		
Other Outcomes	90	3.75%		
Life Threatening	84	3.50%		
Dead	63	2.63%		
lead to deformity	3	0.13%		
Sums	2397	100.00%		

5. Discussion

5.1. PNI-Related Adrs Varied Among Patients of Different Genders and Age Groups

According to the ADR monitoring data of international drug self-reporting, the proportion of female reports (60.10%) is higher than that of male reports (39.90%). But there is a higher proportion of serious outcomes among male reports [17]. One explanation may be that women are more likely to pay attention to and participate in voluntary reporting of ADRs [18]. When only considering Swedish national border database or the relevant study in central Portugal, the proportion of women reporting ADR are also significantly higher than that of men [19-20]. However, the gender difference in specific incidence should also be related to the type of medication taken, disease characteristics, and the weight, body fat mass and pharmacokinetics of patients. This could also explain the differences among different age groups.

ADR is a common drug-related problem in the elderly. Older patients are more sensitive to certain drug classes: antipsychotics, warfarin, antiplatelet agents, hypoglycaemics, insulin, antidepressants, and sedative-hypnotics [21]. Decline in brain function as people age can be caused by a variety of factors, including changes in neurotransmitters, the nerve cells themselves, accumulation of toxic substances, and changes in blood flow to the brain. Therefore, this study can also be further stratified according to gender and age, respectively.

5.2. PNI-Related ADRs Gained More Attention Year by Year

By searching for ADR-related studies from 1998 to 2023 on PubMed, we can see how much attention the academic community pays to drug-related adverse reactions (Figure 3). Therefore, the gradually gaining attention about PNI-related ADRs in this study is also related to the trend of large base numbers.

5.3. Different Risk Signals of Various Drugs Provided Valuable Warnings for Clinicians

According to the analysis of risk signal intensity, drugs such as letrozole, ketorolac, nitrofurantoin, and amiodarone showed strong PNI risk indicators. The instructions for use of letrozole do not explicitly mention peripheral nerve damage, but include words such as “paraesthesia, taste disorder” in the uncommon ADR manifestations. The risk of peripheral nerve damage may also require consideration of interactions with other drugs. Ketorolac is a nonsteroidal anti-inflammatory drug commonly used in clinical practice. On the one hand, it can relieve pain and reduce inflammation. On the other hand, its peripheral neurotoxicity has been clearly pointed out. A recent case series demonstrated a 56-year-old woman with polyarteritis nodosa who developed sciatic nerve injury 5 minutes after gluteal injection of ketorolac. It manifested as a loss of strength in her right foot, and the clinical evaluation showed plegia of the tibialis anterior, peroneus longus, and extensor hallucis longus muscles (Medical Research Council grade 0); plantar flexion was also impaired (Medical Research Council grade 2); impaired leg flexion was also evident (Medical Research Council grade 3) [22]. Nitrofurantoin is a commonly used anti-epileptic drug, and its instructions clearly remind patients that long-term use or immune response may cause PNI such as tingling and numbness. More than a decade ago, the Johns Hopkins University School of Medicine used two cases of middle-aged women with small fibre neuropathy caused by nitrofurantoin to warn of this event that was neither dose-dependent nor related to renal impairment [23]. Studies had found that the incidence of amiodarone-induced neurological damage was 3% to 30% [24]. Another study demonstrated that amiodarone at high doses caused more severe optic neuropathy inducing oxidative damage in mice model [25].

From the perspective of ADR incidence in this research, PNI caused by quinolones and adalimumab should be very common.

Drugs such as pregabalin, statins, insulin, and lenalidomide were also risk targets that need to be monitored.

There were actually many cases of PNI caused by quinolones, which had attracted great attention [26-27]. Common neurological impairments seen in patients treated with quinolones included limb weakness, hearing loss, paresthesias, and even limb paralysis [28]. The PNI risk of adalimumab had been systematically analysed by scholars using the FAERS platform [29]. The same comprehensive analysis was also completed in the ADR report for lenalidomide [30]. Their research results well supported the conclusions of this study which conducted using the same method.

The interesting thing about this study was that it found drugs whose instructions did not explicitly mention the risk of PNI, which provided valuable information for updating drug instructions and clinical drug use. As with drugs such as pregabalin and gabapentin that had their own neuropathic pain-relieving properties, the information provided by the database made it clear why we need to be cautious about their dual effects. Muscle pain was a common problem with statins, and the results of this study would link myalgia and peripheral nerve damage well together. Because hypoglycaemic drugs, a hot topic in recent years may play a therapeutic role in neurodegenerative diseases, insulin is also expected to be a promising drug [31]. The increase in the dosing interval and dosage of insulin could easily lead to severe and prolonged hypoglycaemia, which in turn can cause extensive neurological damage and complications [32]. Our result might interpret this research hotspot from another direction.

In short, as more reports are submitted, the safety signal spectrum of drug-induced PNI may change over time. Countermeasure research in this area will provide more helpful data for the real world and will bring us more warning information.

5.4. Limitations

First, there was a possibility of underreporting, duplication, or incomplete reports, which might lead to inevitable bias. Second, the reports of drugs such as quinolones and benzodiazepines in this study could not be analysed by subgroup analysis only by interpreting the reports. This required us to conduct multicentre clinical studies of specific drugs based on this result to better judge which drug will have a greater risk of PNI. Although there were some limitations, it had also provided a hint for further research.

6. Conclusion

Based on the FAERS platform, we obtained valuable patient information on drug-induced PNI. We extracted data that women and middle- or elder- aged patients were more likely to suffer from drug-induced PNI. We also found that obvious identification of them were mostly serious diseases (87.74%), which more likely to cause other serious ADRs, and lead to prolonged hospitalization and even disability. Among the key information, we identified 383 suspicious drugs. And 52 drugs with strong risk signals had been listed in this study. We recommended that medical staff should be sensitive to the potential risks of PNI caused by any drugs regardless of whether the risk signal was strong or not. Medical institutions should not only increase the reporting rate of adverse reactions to PNI, but also be prepared to prevent the occurrence of PNI and prevent severe PNI in a timely manner.

7. Author Contributions

All authors contributed to the study conception and design. Yatan Li summarized the data from database and led the analysis. Reyisaimu Munireding, Yayong Wang and Xiche Qin assisted in the analysis. Ziyi Wang provided consultation and writing of the manuscript.

8. Funding

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9. Ethics Approval

This study was approved by Ethics Committee of the Second Affiliated Hospital of Xinjiang Medical University.

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