Visual Analysis of the Research Status of Active Surveillance of Drug Safety in China Based on CiteSpace

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Abstract

Objective To analyze the current research status and development trend of active surveillance of drug safety in China, and to provide reference and suggestions for future research. **Methods** Using bibliometric methods and with the help of the CiteSpace 6.1.R6, the literature on active surveillance of drug safety in CNKI from 2010 to 2022 was visualized and analyzed in terms of authors, institutions and keywords. **Results and Conclusion** The research on active surveillance of drug safety in China started late and is in a stable development period. Some Chinese scholars have done more work on active surveillance of drug safety. Additionally, a number of institutions have published some articles and surveillance objects, surveillance methods, and surveillance results are the main research content. However, the cross-institutional cooperation is not close. The traditional Chinese medicine injection, centralized surveillance, and automatic surveillance are the hot spots of research. It is the latest research frontier to use the Chinese hospital pharmacovigilance system to actively monitor drug safety. At present, the research related to active surveillance of drug safety in China is still in the early stage, and more in-depth research is needed to follow up.

Keywords: drug safety; active surveillance; CiteSpace; research status; visual analysis

Active surveillance methods for drug safety include centralized surveillance in sentinel hospitals, centralized surveillance schemes, prescription-event surveillance, and intelligent surveillance technology of hospital information system (referred to as automatic surveillance) with special software. As an important supplement to the passive surveillance based on a spontaneous reporting system, it can reduce the cases of missed reports, false reports, and incomplete information, thus facilitating early detection and control of risks [1]. The National Center for ADR Monitoring in China started to establish a nationwide active surveillance system in 2016, which developed a pharmacovigilance system in Chinese hospitals with an active surveillance model. Currently, the research on active surveillance of drug safety in China is still in an exploratory stage [2, 3].

In this study, CiteSpace was used to analyze Chinese literature on active surveillance for drug safety included in CNKI from the perspectives of authors, institutions and keywords, so as to explore the development trend and research hotspots, which could provide reference for related work in the future.

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1 Data and methods

1.1 Data sources and exclusion criteria

The Chinese core database, Chinese social science citation index database and Chinese science citation database of CNKI were used as data sources, and the topics were set as "active surveillance, centralized surveillance, registration, prescription events, automatic surveillance, sentinel surveillance, key surveillance, or Chinese hospital pharmacovigilance system" and "adverse reactions, adverse events, safety, incidence, or re-evaluation" after multiple pre-searches. Then, the literature classification catalog was limited to medicine and health science and technology, and all relevant Chinese literature from the date of database construction to October 15, 2022 was searched. Literature exclusion criteria: (1) Information, notices, news reports, policy interpretation, and call for papers; (2) Literature on medical devices, vaccines, and food-borne; (3) Literature without authors/keywords; (4) Duplicate literature and literature unrelated to the topic of active drug safety surveillance. Since the content of the dissertations was partially duplicated with journal papers, and there were fewer conference papers, this study only counted the information of publication time and institutions of the dissertations.

After removing the duplicates, manuscript invitations, conference announcements, and documents unrelated to the subject manually, the remaining documents were exported in full record text format. Document information such as author, institution, title, journal name, abstract, keywords, and other identification numbers were extracted. The downloaded data file was named "download_*. txt".

1.2 Research tools and data cleaning

CiteSpace is a freely available Java application for visualizing and analyzing trend and patterns in a certain academic field. As to medicine, some scholars have utilized CiteSpace to analyze the current status and hotspots of research in Pharmacoeconomics, comprehensive drug evaluation, and pharmacovigilance, with better results [4-6]. For this study, version 6.1.R6 was utilized to analyze the literature obtained from the search. However, during the analysis of keywords and research institutions, it was observed that there were duplicate keywords (e.g., adverse drug reaction and ADR) and different names of the same research institution (e.g., Center for Drug Evaluation of the National Medical Products Administration (NMPA) and the Drug Evaluation Center of the NMPA), which had an impact on keyword co-occurrence, cluster analysis, and cooperative network analysis of research institutions. Therefore, the core keywords and research institutions were combined with similar items separately before the visual analysis was performed.

2 Results and analysis

2.1 Analysis of the number of annual publications

The titles and abstracts of all papers were read one by one, and the full texts were read when necessary. Finally, 315 Chinese journal articles were finally included, with publication time spanning from 1994 to October 2022. The number of annual publications of 315 Chinese papers was counted (Fig. 1), and the earliest papers on active monitoring of drug safety were published in 1994. Overall, the number of publications has been increasing. From 1994 to 2009, the number of articles was less than 5, and the research on active surveillance of drug safety was still in its initial stage. From 2010, the number of articles began to rise, reaching a maximum of 43 in 2016. In recent years, the research enthusiasm has decreased, but it remains high.

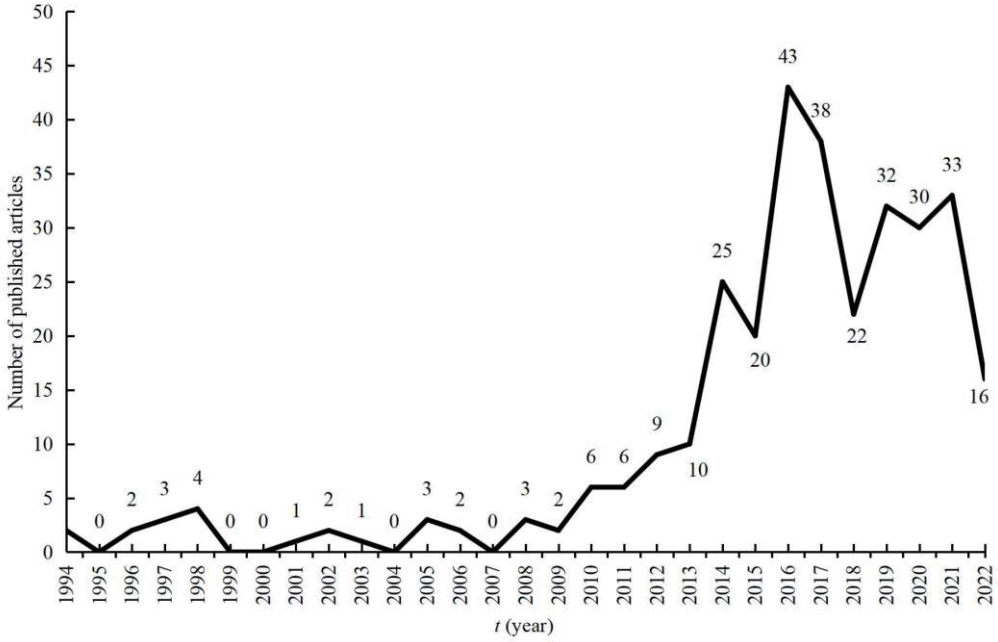

Fig. 1 Annual trend of Chinese journal publications

Thirty-five master's/doctoral dissertations were retrieved on active surveillance of drug safety, with continuous research starting in 2011 and peaking around 2016 (Fig. 2). Chongqing Medical University and Chinese People's Liberation Army Medical Hospital (Chinese PLA Medical School) had the highest number of research publications (Table 1). To obtain a more reliable and stable analysis, this study focused on analyzing the relevant literature from 2010 to October 2022 using software visualization based on the number of literature and publication year trends.

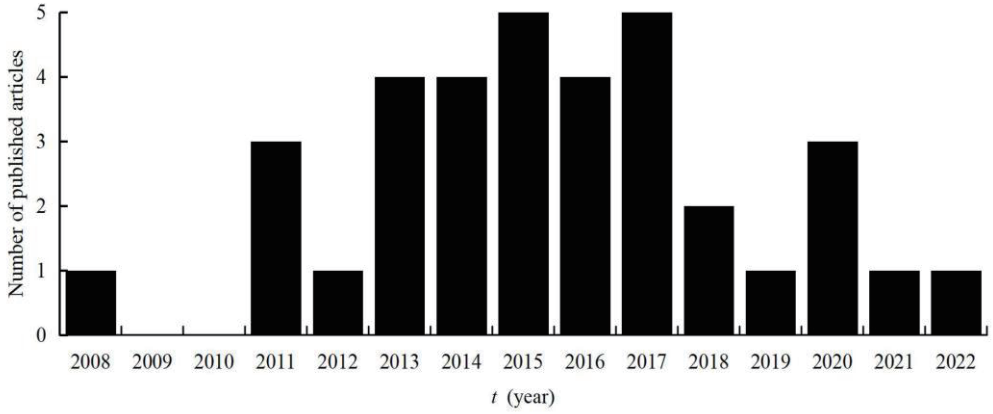

Fig. 2 Annual trend of master's/doctoral dissertation publication

Table 1 Master's/PhD thesis publishing institutions

Institution name	Number of articles
Chongqing Medical University	5
Chinese PLA Medical School	5
China Academy of Chinese Medical Sciences	4
Beijing University of Chinese Medicine	3
Guangzhou University of Chinese Medicine	3
Shanxi Medical University	3
Zhengzhou University	3
Other universities (8)	9

2.2 Analysis of published journals

Each of 6 Chinese journals had more than10 articles, all of which were core journals in the field of pharmacy research, accounting for 51.72% of the total number of articles published. The journals with the largest number of articles were "Chinese Journal of Pharmacovigilance" and "Chinese Journal of Pharmacoepidemiology", both with 36 articles, followed by the "Chinese Journal of Drug Application and Monitoring" "China Journal of Chinese Materia Medica" "Chinese Journal of Hospital Pharmacy" and "China Pharmacy". The above journals included different fields such as pharmacy, traditional Chinese medicine, law, economics, and management, reflecting the professional and cross-cutting characteristics of research. Accordingly, scholars in this field were provided with access to literature sources for active drug safety surveillance research in China and journals which they could publish relevant research papers.

2.3 Analysis of authors and institutions

The author collaboration and institutional collaboration networks were obtained by slicing the data in every year using CiteSpace 6.1.R6, which is shown in Fig. 3 and Fig. 4, respectively. In the author collaboration and institutional collaboration network diagram, each node represented 1 author/institution, the color of the node represented the publication time, the link between the nodes indicated the author/institution collaboration relationship, and the thickness of the link represented the collaboration intensity between the authors/institutions. The color of the connecting line represented the time of the first collaboration between authors/institutions. The larger the radius of the node, the greater the number of the author/institution's publications. The higher the centrality of the node (≥ 0.1), the greater the influence (same below). The density of the author cooperation network graph was 0.012 9 and the institutional cooperation network graph was 0.015 3, which were small values. Therefore, the connection and cooperation among all authors and between research institutions were not close.

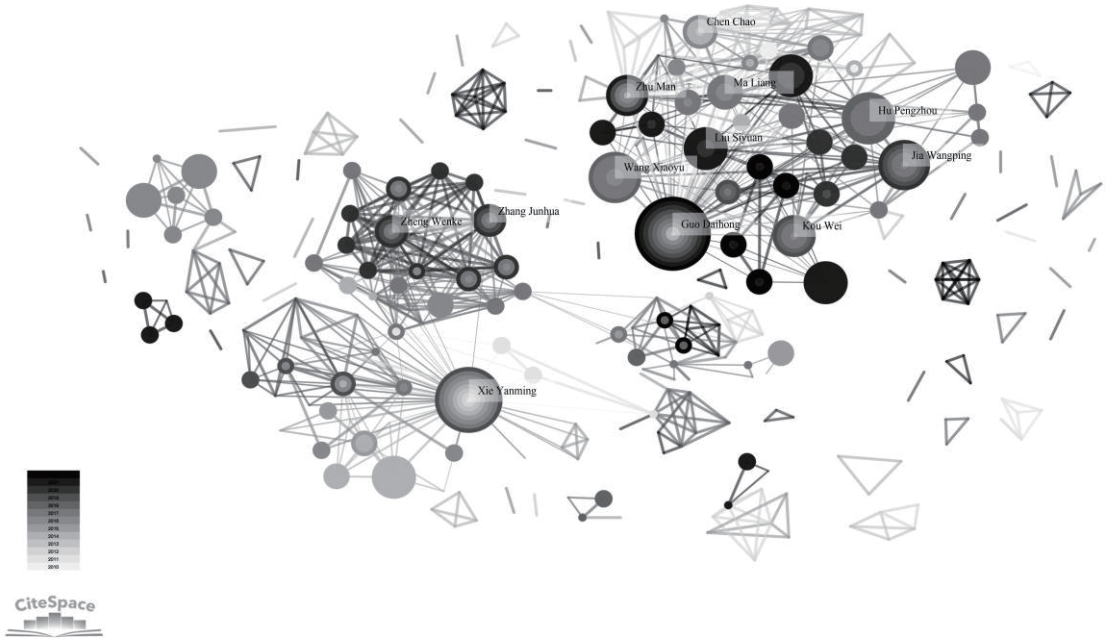

Fig. 3 Author collaboration network

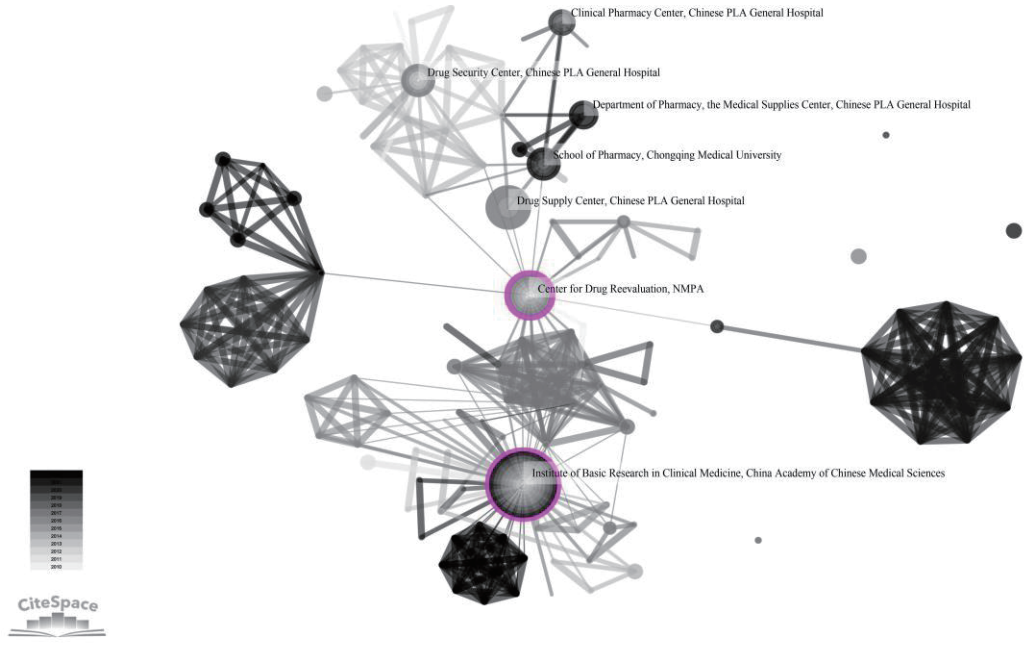

Fig. 4 Institutional cooperation network

2.3.1 Author collaboration network analysis

The 290 Chinese papers included in this study contained 357 authors, among whom 12 authors had more than 10 papers (Table 2). Guo Daihong who was from the Department of Pharmacy and Medical Supplies Center of PLA General Hospital had the highest cumulative publication volume of 64. Additionally, there were 29 authors and each of them had 5 to 9 publications, while the remaining authors had less than 5 publications.

Table 2 Authors of ≥ 10 articles on active surveillance of drug safety

Author	Number of articles issued	Author	Number of articles issued
Guo Daihong	64	Kou Wei	17
Xie Yanming	31	Zhang Junhua	12
Wang Xiaoyu	23	Liu Siyuan	12
Jia Wangping	21	Chen Chao	11
Zhu Man	19	Ma Liang	10
Hu Pengzhou	17	Zheng Wenke	10

The authors of Chinese literature on active surveillance of drug safety research in China were analyzed by visualizing the cooperation network, as shown in Fig. 3. The network consisted of 357 nodes and 817 connected lines. According to the authors' cooperative network mapping, we found that there were three major research teams. The authors within the teams cooperated closely over a long time. However, the cooperation between the teams was less, and the centrality of all the authors was lower than 0.1. This indicates that a few scholars in China have established a close cooperation, and there is a mature and unified academic community. However, the overall characteristics are small concentration and large dispersion. Further summarizing the specific research content of each team with the literature, we found that this was related to the different content and research methods of active surveillance of drug safety.

The team, represented by Guo Daihong, Wang Xiaoyu and Jia Wangping who have published the most papers and conducted some research, relied on the powerful information platform and massive electronic medical information database of the Chinese PLA General Hospital. They used the principle of trigger technology to design and develop an active surveillance and warning system for adverse drug events of inpatients (This software has obtained the copyright of the National Copyright Administration). This system realized the automatic identification and auxiliary assessment, and its positive predictive value of effect verification is as high as 69.4% [7]. In 2016, based on the existing active surveillance system, they developed an automatic surveillance module of pharmacogenetic metabolic reactions for inpatients with the help of text classification technology [8]. They also completed nearly one million cases of automatic monitoring studies of the medication population by interfacing with HIS and conducted intelligent assessment of more than 20 key drugs ADE [9, 10]. Another team, represented by Xie Yanhong, adopted a prospective, multicenter, large-sample, registry-based hospital centralized surveillance model. They completed nearly 600 000 cases involving Diemailing Kudiezi Injection, Shenfu Injection, and Yueanxin Kudiezi Dish Injection [11-13]. The third team, represented by Zhang Junhua, conducted an in-depth study on the protocol design, data management, and ethical issues of centralized hospital surveillance of the safety of Chinese medicine injections [14-16].

2.3.2 Analysis of institutional cooperation network

Each of the 7 institutions had more than 10 publications (Table 3), with a total of 116 publications (collaborative literature from different institutions was counted as 1), which accounted for 40% of the total number of publications. According to the institutional collaboration network diagram (Fig. 4), a total of 279 nodes and 594 links were obtained. The research institutions were mainly hospitals and research centers, followed by universities. Each province has research institutions that have conducted active surveillance of drug safety, but there are fewer collaborative institutional studies across geographic areas. The centers of the PLA General Hospital had the most cumulative publications and the longest publication span, and there were also collaborative relationships between some of its affiliated hospitals. Combined with the literature, we

found that their research content was systematic with high reference value for studying active surveillance of drug safety. Most institutions had a centrality of 0 or less than 0.1, which was less influential. Meanwhile, the Center for Drug Reevaluation of NMPA and the Institute of Basic Research in Clinical Medicine, China Academy of Chinese Medical Sciences both had more than 0.1 in their nodes, and they had relatively more cooperation with other institutions, indicating that these two institutions were more influential and in the leading position in active drug safety surveillance research in China.

Table 3 Highly productive institutions for active drug safety surveillance research in China

No.	Institution name	Number of articles	Centrality
1	Institute of Basic Research in Clinical Medicine, China Academy of Chinese Medical Sciences	37	0.16
2	School of Pharmacy, Chongqing Medical University	26	0.04
3	Center for Drug Reevaluation, NMPA	23	0.27
4	Drug Security Center, Chinese PLA General Hospital	17	0.05
5	Department of Pharmacy, the Medical Supplies Center, Chinese PLA General Hospital	14	0.00
6	Clinical Pharmacy Center, Chinese PLA General Hospital	13	0.01
7	Drug Supply Center, Chinese PLA General Hospital	13	0.00

2.4 Keyword analysis

2.4.1 Keyword co-occurrence analysis

The use of keywords as nodes in co-occurrence analysis provides a broad overview of the topic of the paper and it can reflect changes in hot areas, analytical perspectives, and research methods within different time sequences, thus revealing the inner connection of the discipline [17]. By using CiteSpace software to draw a visualization graph with keywords as nodes, we obtained 301 keywords and 477 connected lines (Fig. 5). High-frequency keywords (co-occurring frequency ≥ 10 times) were ranked based on the frequency of keywords, as shown in Table 4. The keyword with the highest centrality was “Chinese medicine injection”, indicating that the active surveillance of drug safety of Chinese medicine injection was more carefully studied.

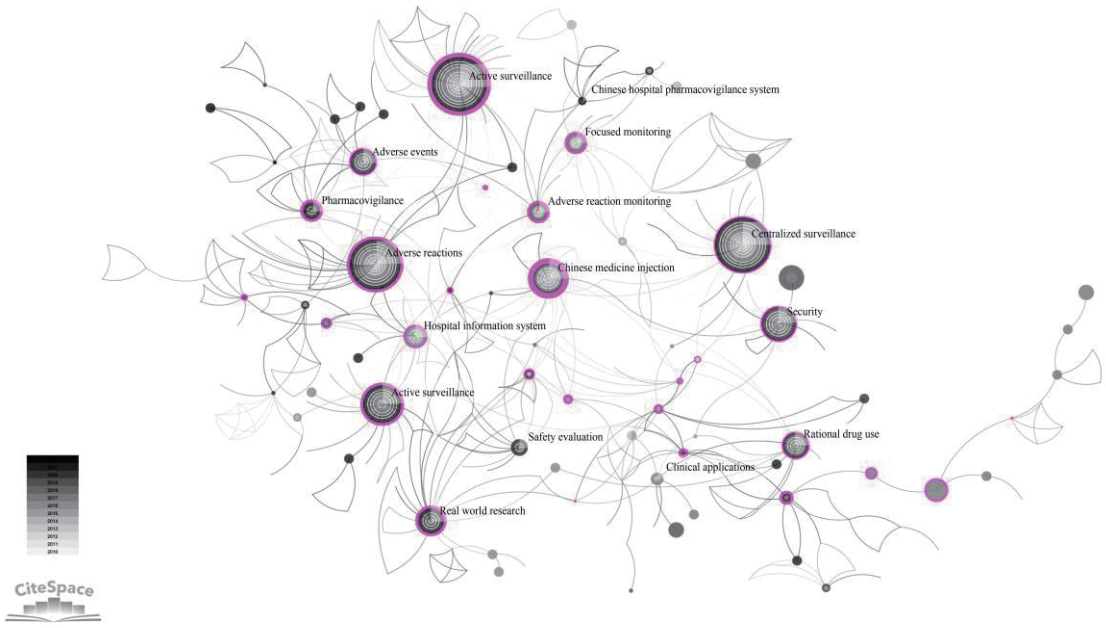

Fig. 5 Keyword co-occurrence map

Table 4 High frequency keywords

No.	Keywords	Frequency	Centrality	No.	Keywords	Frequency	Centrality
1	Adverse reactions	167	0.29	9	Hospital information system	17	0.13
2	Centralized surveillance	79	0.19	10	Real world research	17	0.28
3	Active surveillance	77	0.48	11	Pharmacovigilance	15	0.25
4	Automatic surveillance	53	0.28	12	Safety evaluation	13	0.06
5	Security	26	0.11	13	Adverse reaction monitoring	13	0.30
6	Adverse events	24	0.11	14	Focused monitoring	11	0.21
7	Chinese medicine injection	22	0.61	15	Clinical applications	10	0.05
8	Rational drug use	21	0.11	16	Chinese hospital pharmacovigilance system	10	0.08

2.4.2 Keyword clustering analysis

Based on keyword co-occurrence, the keyword labels were extracted using likelihood ratio (LLR) algorithm, and the visualization of keyword clustering analysis was presented in Fig. 6. Each closed graph in the keyword clustering mapping represented a cluster, and there were 14 clusters with node number > 10. From Fig. 6, it can be seen that modularity $Q = 0.804\ 0 > 0.3$, mean silhouette $S = 0.929\ 6\ (> 0.9)$, indicating that the clustering structure was significant and the results were credible. The shear value of each cluster was greater than 0.8, indicating good homogeneity results of individual clusters.

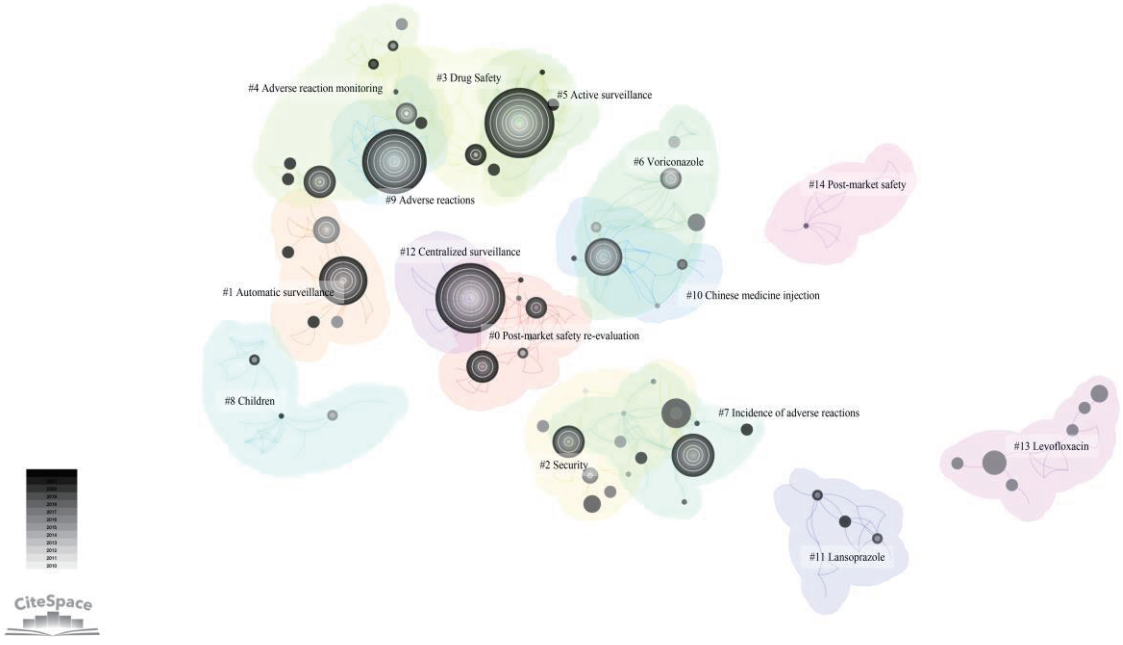

Fig. 6 Keyword clustering map

The clustering labels and main keywords indicated the main research content, which were manually classified (Table 5), and the 14 clusters were divided into 3 major categories: Surveillance objects, surveillance methods and surveillance results. In terms of surveillance objects, Chinese active drug safety surveillance studies involved both traditional Chinese medicine and chemical drugs,

with more studies focused on pediatric patients. In terms of surveillance methods, automatic surveillance and centralized surveillance were used as the main research methods. In terms of surveillance results, the study results on drug reactions, incidence of adverse reactions, and safety evaluation could be obtained through active surveillance of drug safety.

Table 5 Comparison of keyword clustering and summarization

Classification	Cluster number	Clustering label	Number of nodes	Shear value	Main keywords
Surveillance objects	#6	Voriconazole	19	0.942	Adverse reactions; pharmacogenic liver injury; triazole antifungal drugs; fluconazole; hospitalization for adverse reactions
	#8	Children	18	0.933	Comparison; lamotrigine; clinical use; adults; cephalosporins
	#10	Chinese medicine injection	17	0.889	Quality management; mini-sentinel study; study design; risk management; US FDA
	#11	Lansoprazole	14	0.935	Propensity scores matching method; linezolid; cefoperazone/ sulbactam; basal platelet values; omeprazole
	#13	Levofloxacin	13	0.918	Adverse reactions; levofloxacin; incidence; flurbiprofen ester; national essential drugs
Surveillance methods	#1	Automatic surveillance	25	0.963	Adverse reaction case feedback; active monitoring of adverse events and intelligent assessment alert system; analysis; text information extraction; evidence-based approach
	#4	Adverse reaction monitoring	22	0.917	Spontaneous reporting system for nephrotoxicity; vancomycin; serious adverse drug reactions; drug regulation
	#5	Active surveillance	22	0.966	Distributed databases; risk management programs; anemia; implementation challenges; collaborative research on data sources
	#12	Centralized surveillance	13	0.938	Feverfew injection; ambroxol hydrochloride injection; compliance; respiratory medicine; Wuling capsule
Surveillance results	#0	Post-market safety re-evaluation	29	0.900	Management plan; postmarket drugs; implementation and management; tenofovir disoproxil fumarate tablets; real world evidence
	#2	Security	24	0.965	Acute decompensated heart failure; sodium hepaticoside for injection; ultrafiltration therapy; medium-term; herbal broken wall tablets
	#3	Drug safety	23	0.890	Public-private partnerships; medication management; observing medical outcomes partnership; pharmaceutical companies; medication safety
	#7	Incidence of adverse reactions	19	0.866	Safe and reliable; ADR characteristics; allergic-like reactions; allergic reactions; mechanisms of allergic reactions
	#9	Adverse reactions	17	0.967	Observational medical outcomes partnership; pharmacovigilance systems; health observation data science and informatics; antineoplastic drugs; natural language processing technologies
	#14	Post-market safety	11	0.928	Adverse reactions; active surveillance; centralized surveillance; post-market safety; standards

2.4.3 Keyword emergent analysis

Keyword emergence refers to the obvious increase in the frequency of a keyword within a short period of time, which can show the research with high attention, so as to judge the hot spots and frontiers of the research field. The results of the keyword emergence analysis were shown in Fig. 7,

which indicated that there were more studies on Danhong injection in the early active surveillance of drug safety, and a number of related articles were found to be supported by the National Science and Technology Major Project Fund for "Major New Drug Creation", showing that the support of special funds could promote the research in various aspects [18, 19]. The high focus on intensive monitoring from 2013 to 2015 may be due to the requirement for intensive monitoring of drugs in the revised 2011 "Administrative Measures for the Reporting and Monitoring of Adverse Drug Reactions" [20]. The keyword "Yunnan Baiyao Capsules" increased a lot in from 2018 to 2019, which was the research result of the "Yunnan Baiyao Capsules Clinical Safety Surveillance Project" led by Yunnan Baiyao Group in conjunction with multi-provincial centers, indicating that the support of enterprises could promote multi-centers to jointly carry out drug safety Active surveillance research [21-23]. The emergent term was Chinese hospital pharmacovigilance system from 2020 to 2022, and the emergent intensity was greater than 3, indicating its research impact was great.

Keywords	Year	Strength	Begin	End	2010-2022
Danhong injection	2011	2.9	2011	2014	
Intensive monitoring	2010	3.28	2013	2015	
Yunnan Baiyao Capsules	2018	4.63	2018	2019	
Chinese hospital pharmacovigilance system	2019	3.35	2020	2022	
Active surveillance	2010	3.52	2021	2022	

Fig. 7 Keyword emergence mapping

3 Discussion

Although China's drug safety active surveillance research started late, in the past decade, it has reached a relatively stable state after experiencing ups and downs. This indicates that drug safety active surveillance will continue to receive more attention in the future.

In terms of author collaboration, there were three major research groups with close collaboration, indicating that research on drug safety active surveillance has received much attention in China. Guo Daihong and Xie Yanming were the main authors, leading their team to conduct research on active surveillance of drug safety through automatic surveillance mode and registry-based hospital centralized surveillance mode respectively with the help of computer software technology, and achieving remarkable results with high research reference value.

In terms of research institutions, the collaboration network among domestic institutions seemed immature, with weak cooperation and a lack of cross-regional in-depth research. Multiple institutions tended to engage in only one-time partnerships, and most research institutions carried out the study alone. Active drug safety surveillance research typically requires large samples, long-period monitoring, and large amounts of data, which can result in high research thresholds. Therefore, research institutions are dominated by hospitals and large research centers. The analysis chart of institutional cooperation network showed that the Center for Drug Reevaluation of NMPA had the greatest influence in this area, indicating that China's regulatory agencies were oriented in this area of research. For example, the Chinese People's Liberation Army General Hospital and the Institute of Basic Research In Clinical Medicine, China Academy of Chinese Medical Sciences had made some achievements in this field, and the research results were worthy of reference. At the same time, promoting stronger cooperation among research institutions and overcoming the technical barriers that make it difficult to exchange information across regions of research should be a direction for future research.

In terms of research content, Chinese medicine

injections, centralized surveillance, and automatic surveillance were popular topics in this field. Analysis of keywords revealed that the literature on China's active surveillance of drug safety mainly focused on children, traditional Chinese medicine injections, chemical drugs and other objects. Besides, active surveillance studies were mainly carried out by automatic surveillance or centralized surveillance to obtain the results of adverse reactions, incidence of adverse reactions and safety evaluation.

Combined with the keyword emergence analysis, "Chinese hospital pharmacovigilance system" appeared as one of the latest emergent words from 2020 to 2022. The Chinese hospital pharmacovigilance system is an information system developed by the National Center for Adverse Drug Reaction surveillance to assist in surveillance adverse drug reactions in hospitals. It can be interfaced with the HIS and laboratory information management system (LIS) of hospitals to directly extract information and realize active surveillance, which can reduce the problems of missing reports and missing information while reporting adverse drug reactions [24]. By designing and using a unified data model, the Chinese hospital pharmacovigilance system solves the differences of different data formats in different medical institutions. It is currently an important platform for active drug safety surveillance research in China [25, 26]. Therefore, using the Chinese hospital pharmacovigilance system for active drug safety surveillance research is a future research trend.

4 Conclusion

This study uses CiteSpace 6.1.R6 software to manually mine and analyze the information behind the visualization mapping nodes. The results intuitively reveal the current situation, hot spots and future trends of domestic research on active surveillance of drug safety in China, providing reference for other research on the same topic. However, one limitation of this study is that the literature was obtained only from the CNKI, so the findings may not fully represent the entire field. Further research should involve searching databases such as Web of Science and PubMed to obtain foreign research literature data, which can be combined with domestic research to conduct a more comprehensive comparison of the research situation at home and abroad. This can help researchers identify global research hotspots and trends in the field.

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