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Global output of clinical application research on artificial intelligence in the past decade: a scientometric study and science mapping

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Abstract

Background Artificial intelligence (AI) has shown immense potential in the field of medicine, but its actual effectiveness and safety still need to be validated through clinical trials. Currently, the research themes, methodologies, and development trends of AI-related clinical trials remain unclear, and further exploration of these studies will be crucial for uncovering AI's practical application potential and promoting its broader adoption in clinical settings.

Objective To analyze the current status, hotspots, and trends of published clinical research on AI applications.

Methods Publications related to AI clinical applications were retrieved from the Web of Science database. Relevant data were extracted using VOSviewer 1.6.17 to generate visual cooperation network maps for countries, organizations, authors, and keywords. Burst citation detection for keywords and citations was performed using CiteSpace 5.8.R3 to identify sudden surges in citation frequency within a short period, and the theme evolution was analyzed using SciMAT to track the development and trends of research topics over time.

Results A total of 22,583 articles were obtained from the Web of Science database. Seven-hundred and thirty-five AI clinical application research were published by 1764 institutions from 53 countries. The majority of publications were contributed by the United States, China, and the UK. Active collaborations were noted among leading authors, particularly those from developed countries. The publications mainly focused on evaluating the application value of AI technology in the fields of disease diagnosis and classification, disease risk prediction and management, assisted surgery, and rehabilitation. Deep learning and chatbot technologies were identified as emerging research hotspots in recent studies on AI applications.

Conclusions A total of 735 articles on AI in clinical research were analyzed, with publication volume and citation counts steadily increasing each year. Institutions and researchers from the United States contributed the most to the research output in this field. Key areas of focus included AI applications in surgery, rehabilitation, disease diagnosis, risk prediction, and health management, with emerging trends in deep learning and chatbots. This study also provides detailed and intuitive information about important articles, journals, core authors, institutions, and topics in the field through visualization maps, which will help researchers quickly understand the current status, hotspots,

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and trends of artificial intelligence clinical application research. Future clinical trials of artificial intelligence should strengthen scientific design, ethical compliance, and interdisciplinary and international cooperation and pay more attention to its practical clinical value and reliable application in diverse scenarios.

Introduction

Artificial intelligence (AI), first proposed in 1956, has experienced substantial advancements and has become a key interdisciplinary and leading-edge scientific domain [1, 2]. Advancements in computing power, data storage, and algorithms have accelerated AI applications in medicine [3–5], resulting in a significant increase in AI publications over the past decade across areas such as disease prediction, medical imaging, health management, diagnosis, robotics, gene sequencing, nursing, and treatment decision-making [6–8], while emerging technologies like medical image diagnostics, clinical decision support systems, robotic assistants, and tools such as ChatGPT are revolutionizing healthcare and being applied in clinical practice to enhance efficiency; however, their effectiveness and clinical value still require further validation [2, 9–13].

Clinical trials are studies conducted on humans to evaluate the safety, efficacy, and side effects of new drugs, treatments, medical devices, or interventions, providing high-quality evidence of their effectiveness. With the growing potential of AI in medicine, an increasing number of researchers are conducting clinical trials to explore new applications of AI-related interventions [8, 14, 15], but the theme and development trend of these studies are not clear. Understanding the research progress and emerging hotspots in AI clinical trials is crucial for guiding both clinical practice and scientific research [15–17]. While qualitative and systematic reviews can provide in-depth analyses of specific aspects or subsets of AI clinical trials, their scope is often limited and may not fully capture the overall landscape or emerging trends in the entire field. In contrast, bibliometric analysis is a statistical and quantitative tool that extracts measurable data through the analysis of published research and the utilization of knowledge within these publications. Bibliometrics involves analyzing data such as the number of publications, distribution, citations, and keywords to reveal patterns, trends, and structures in scientific research activities. It has been widely applied across various research domains to evaluate research performance, assess academic impact, construct collaboration networks, and identify hot topics [18–20]. Previous bibliometric studies have explored AI research across diverse domains [7, 14, 21–27]. However, many of these studies include a significant number of review articles and nonclinical research, which may introduce bias and

potentially exaggerate the current state of AI applications in certain areas [15]. To date, no bibliometric analysis has specifically focused on AI clinical trials. This study aims to fill this gap by providing a comprehensive overview of the field's hotspots and trends, evaluating academic impact, identifying research gaps, and offering data support to advance AI innovation and application in healthcare.

Bibliometric analysis was conducted to answer the following research questions of AI clinical trials: (1) Which are the top contributing countries, institutions, and authors? (2) What is the current status of international, institutional, and author collaboration in this field? (3) Which are the most influential clinical trials and top contributing journals? (4) What are the history, hot spots, and future trends of the research topic? It is believed that this bibliometric analysis can not only assist researchers in quickly identifying key articles, journals, potential collaborators, and institutions in this field but also provide valuable insights for selecting future research directions.

Methodology

Search strategy and studies selection

Web of Science is one of the most authoritative academic databases globally, covering multiple disciplines and providing comprehensive citation data and research tools, making it a preferred choice for bibliometric studies [19]. A comprehensive search was conducted in the Web of Science Core Collection database for clinical trials related to AI published between January 2012 and December 2022. The detailed search strategy is provided in Additional file 1: Appendix 1. The search terms were developed through repeated revisions and discussions with experts who have over 10 years of professional background in information retrieval. The main search terms included the following: "Artificial Intelligence" OR AI OR "Computational Intelligence" OR "Machine Learning" OR "Deep Learning" OR "Machine Intelligence" OR "Neural Network*" OR "Natural Language Processing" OR "Computer Vision" OR "Predictive Modeling" OR "Reinforcement Learning" OR "Knowledge Representation*" OR "Knowledge Acquisition" OR "Sentiment Analysis" OR "Expert System*" OR "Fuzzy Logic" etc.) AND ("Clinical Trial*" OR "Randomized Controlled Trial*" OR "Randomised Controlled Trial*" OR RCT OR "Controlled Trial*" etc.).

Studies selection

Studies were included if they met the following criteria: the publication language was restricted to English, and the publication date was limited to the past 10 years; the research involved the application of AI technologies (e.g., natural language processing, machine learning, computer vision); the research focused on the field of medicine; and only clinical trials related to AI were considered. Studies that had not undergone peer review (e.g., protocols, correspondence, theses, and conference papers) were excluded. Titles and abstracts were screened independently by two reviewers to exclude records not meeting the inclusion criteria, with full texts reviewed as needed to determine eligibility. Any disagreements during the selection process were resolved through discussion with a third reviewer.

Data analysis

VOSviewer 1.6.17 software was used to analyze the network relationship of authors, countries, keywords, and organizations of the AI clinical trials. The size of the nodes reflects the number of publications or frequency, two nodes were connected by a line if they published the clinical trial together, while the color of the nodes represented different clusters [26–28]. Different expressions for the same author or keyword were standardized into a uniform expression to reduce bias in data analysis. CiteSpace 5.8 R3 software was used to perform burst detection for co-cited references and keywords [19]. The parameters for CiteSpace were set as follows: time slicing (2012–2022), years per slice (1), term source (all selections), node type (analyzed individually), selection criteria (top 50), pruning (none), and visualization (static cluster view with merged networks). Bursts detect, defined as items cited frequently within a specific period, were identified with the top 20 results per slice. Additionally, a dual-map overlay of journals was generated using CiteSpace [18, 29]. Descriptive statistics for the year of publication, number of citations, authors, countries, organizations, and journals were performed using Microsoft Excel 2016. The thematic evolution of AI clinical trials was analyzed using SciMAT (Science Mapping Analysis Software Tool). Keyword expressions were standardized for consistency through a combination of SciMAT's automatic and manual cleaning functions. The thematic evolution map was created by dividing the dataset into three time slices (2012–2016, 2016–2019, and 2019–2022), enabling an analysis of topic progression across these periods. Keywords were selected as the primary unit of analysis, with a co-occurrence matrix and the simple centrality algorithm for clustering. The evolution map was standardized using the Jaccard index, the minimum number of

clustering keywords was set to 5, and the maximum was set to 20.

Results

Publication time

A total of 22,583 articles were obtained from the Web of Science database, and 735 articles proved eligible for this study. The average number of related publications per year before 2017 increased slowly and did not exceed 20 times. After 2016, the annual average number of related publications has increased rapidly, with the number of publications exceeding 100 times in 2020 and 200 times in 2021, respectively (Fig. 1). There was a significant correlation between polynomial curve fits and annual literature growth trend, with a high coefficient of determination ($R^2=0.9776$). According to the fitting curve, the number of publications may continue to grow rapidly in the coming years. In the past decade, the total number of citations for 735 AI clinical research has reached a staggering 12,698 times, with an average of more than 17 citations per study. The total number of citations per year exceeded 100 times in 2015, over 1000 times in 2019, and reached 4336 times in 2022. The explosive growth in the number of citations also means that related research has received increasing attention (Fig. 1).

Countries

In total, 53 countries were involved in the publication of AI clinical research, and the United States (243 times) published the most articles, followed by China (233 times), the UK (64 times), South Korea (63 times), and Germany (61 times). There were 22 countries that published more than 5 articles in the network map of the country generated by VOSviewer (Fig. 2). The cooperation between countries is divided into four teams, of which the first team is composed of Germany, Japan, Switzerland, Netherlands, Sweden, Denmark, and Norway; the second team is composed of the United States, China, South Korea, Singapore, and Israel; the third team is composed of Australia and Canada; and the fourth team is composed of the UK, France, Spain, and Italy. The cooperation network map is mainly composed of developed countries, with relatively few developing countries.

Institutions

A total of 1764 institutions participated in the relevant research of AI clinical research. The top five institutions involved in AI clinical research were Harvard University of the United States (31 times), California University of the United States (26 times), Seoul National University of South Korea (24 times), Stanford University of the United States (17 times), and University of Pennsylvania of the United States (16 times); the remaining institutions have

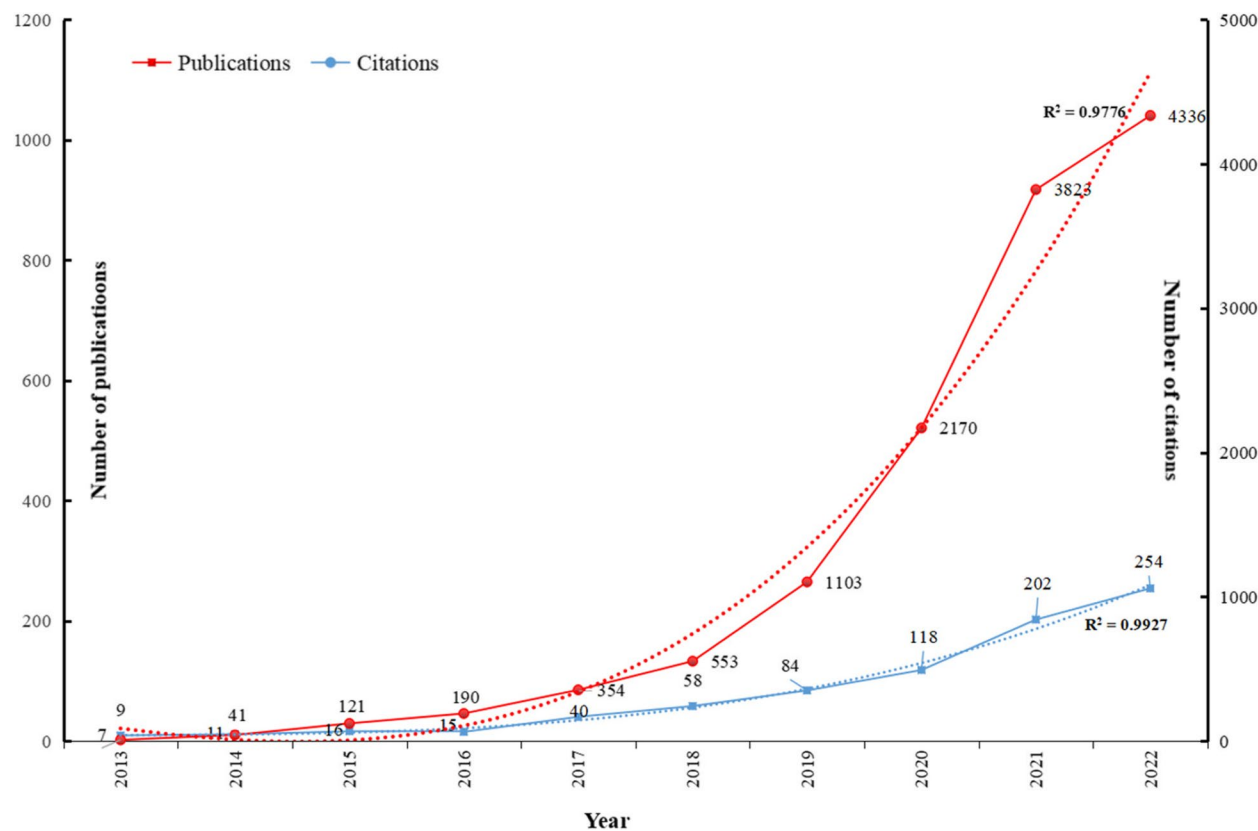


Fig. 1 Number of publications and citations in AI clinical trials

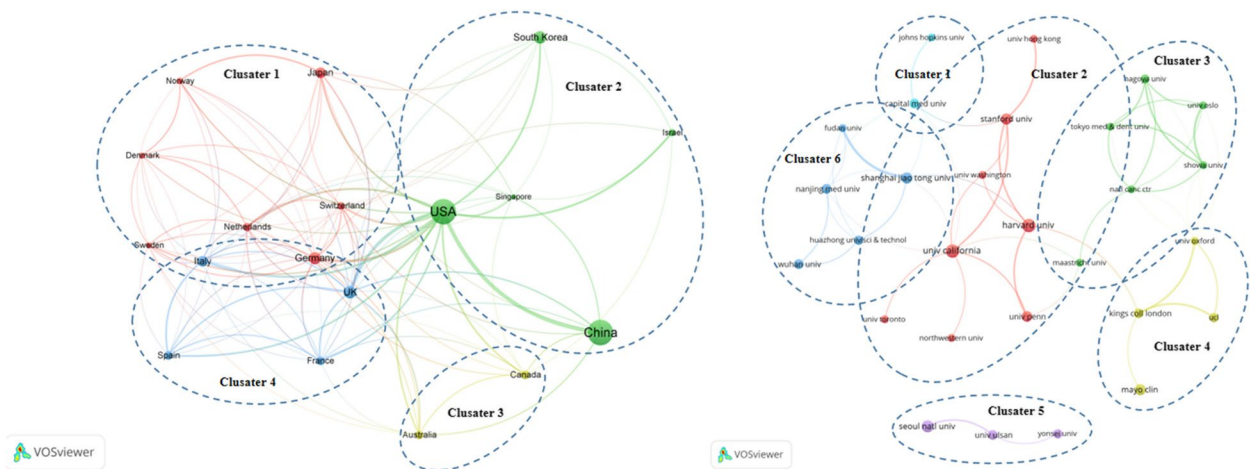


Fig. 2 Network map of cooperation between high-output countries (left) and institutions (right) of AI clinical trials

published less than 15 articles. Based on the analysis of the cooperation of 25 research institutions participating in more than 7 AI clinical research (Fig. 2), these 25 institutions formed 5 clusters, and there were active collaborations among the institutions, especially among the institutions in the same cluster. The Capital Medical

University and Johns Hopkins University in Cluster 1 are from China and the United States, respectively. In Cluster 2, except for two universities (the University of Toronto and the University of Hong Kong), the other universities are well-known universities and hospitals from the United States. All universities in Cluster 4, with the

exception of the Mayo Clinic, are from the UK. Cluster 3 consists solely of universities from Japan, Cluster 5 comprises only universities from South Korea, and Cluster 6 is made up entirely of universities from China. As can be seen from the institutional cooperation network map, most institutions prefer to cooperate with domestic institutions, and cross-border cooperation needs to be further strengthened.

Authors and co-cited authors

A total of 1706 authors participated in the study of AI clinical trials, and only 6 authors with more than 7 papers, in order: Liu J. ($n=9$ times, Wuhan University), Mori Y. ($n=8$ times, University of Oslo), Mori K. ($n=8$ times, Nagoya University), Wu L. ($n=8$ times, Wuhan University), Zhang J. ($n=8$ times, Wuhan University), and Misawa M. ($n=8$ times, Showa University). Based on the analysis of the cooperation of 98 authors who participated in 3 or more articles (Fig. 3), only 40 authors had formed a cooperation network, which indicated that there was a lack of cooperation among other high-yield authors involved in AI clinical research. Although there are few transnational collaborations among high-yielding authors, it is not difficult to see that Sharma P. (University of Kansas) and Mori Yzai (University of Oslo) have played an important role in transnational cooperation (Fig. 3). The collaboration network map of co-cited authors is presented in Fig. 3. Co-cited authors usually indicate that two (or more) authors are cited simultaneously in one or more studies, and collaboration network map of co-cited authors can quickly and intuitively provide information about highly influential research groups and potential collaborators in this field.

Keywords

The main high-frequency keywords include AI (111 times), machine learning (82 times), stroke (47 times), deep learning (46 times), risk (46 times), management (45 times), classification (42 times), rehabilitation (42 times), outcomes (41 times), surgery (37 times), chatbot (36 times), diagnosis (36 times), robotics (36 times), and cancer (35 times). Cluster analysis was carried out on 36 keywords with a frequency greater than 20 and finally clustered into four categories (Fig. 4). The first cluster includes 10 keywords: machine learning, management, chatbot, depression, anxiety, obesity, etc. It mainly focused on evaluating the application effects of AI technologies such as machine learning and chatbots in patient disease management. The second cluster includes nine keywords, such as AI, deep learning, classification, diagnosis, prevention, and disease, which mainly focus on the application effects of AI technology represented by deep learning in disease diagnosis and classification. The third cluster includes nine keywords, such as robotics surgery, system, outcomes, survival, mortality, and RCT. It mainly evaluated the effectiveness and safety of robotic-assisted surgery. The last cluster included eight keywords, such as robotics, rehabilitation, performance, therapy, and reliability, which mainly focused on evaluating the application effect and performance of intelligent robots in patient rehabilitation. In Fig. 5, the keywords with the strongest citation burst were robotics (started in 2014 and ended in 2017), followed by health (started in 2019 and ended in 2020), and randomized control trials (started in 2017 and ended in 2018). The keywords with the strongest burst in recent years were chatbot, gait, mHealth, validation, and intervention.

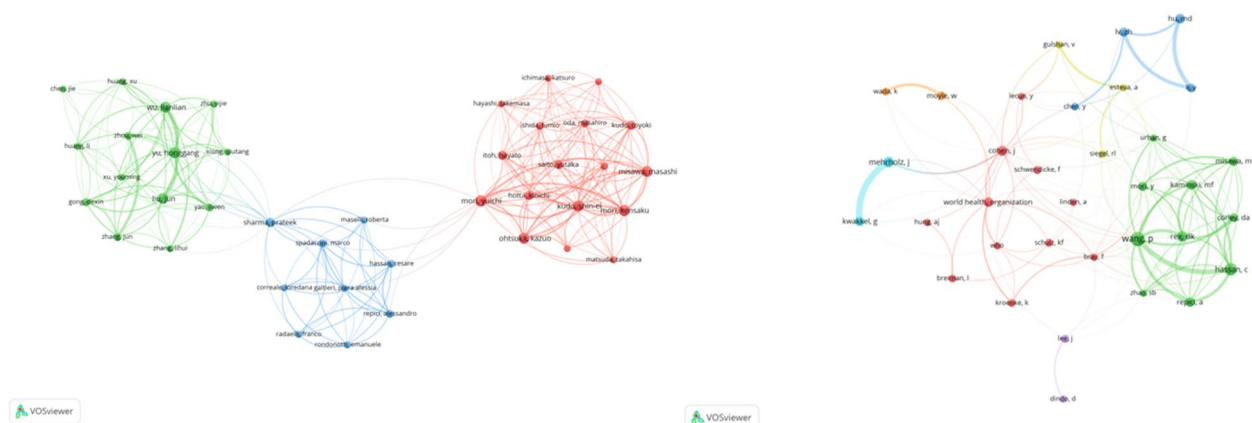


Fig. 3 Network map of cooperation between high-output authors (left) and high co-cited authors (right) of AI clinical trials

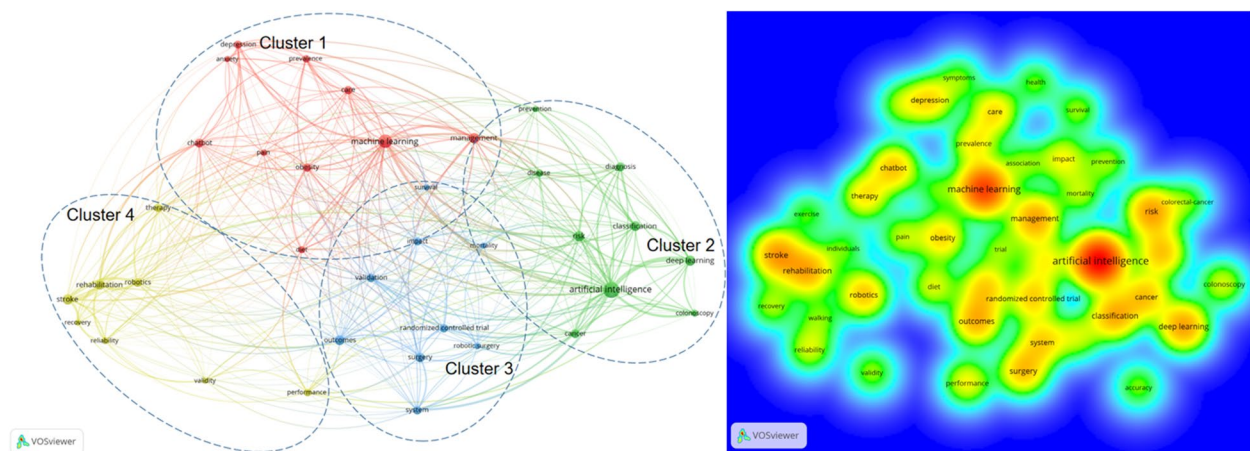


Fig. 4 Network map (left) and density map (right) of keywords in AI clinical trials

Top 20 Keywords with the Strongest Citation Bursts

Keywords	Year	Strength	Begin	End	2013 - 2022
rehabilitation	2013	2.8808	2014	2015	<div></div>
robotics	2013	6.4904	2014	2017	<div></div>
upper limb	2013	3.8359	2014	2016	<div></div>
resection	2013	3.581	2014	2017	<div></div>
robotic surgery	2013	3.7737	2014	2019	<div></div>
motor recovery	2013	3.8619	2014	2018	<div></div>
exercise	2013	3.0762	2014	2016	<div></div>
walking	2013	2.6728	2015	2019	<div></div>
analgesia	2013	2.7181	2016	2017	<div></div>
complication	2013	3.3758	2017	2020	<div></div>
total mesorectal excision	2013	2.7605	2017	2018	<div></div>
randomized clinical trial	2013	4.848	2017	2018	<div></div>
pattern	2013	4.654	2018	2020	<div></div>
adolescent	2013	3.6504	2018	2020	<div></div>
validation	2013	4.2986	2019	2020	<div></div>
chatbot	2013	2.7521	2019	2020	<div></div>
gait	2013	3.1148	2019	2022	<div></div>
mhealth	2013	3.8085	2019	2020	<div></div>
health	2013	5.5308	2019	2022	<div></div>
intervention	2013	3.4763	2019	2020	<div></div>

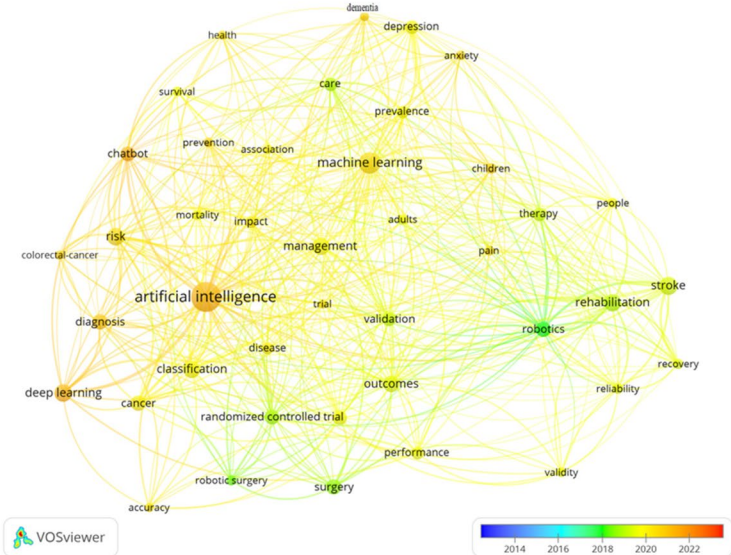


Fig. 5 Keywords burst map (left) and time overlay network map (right) of keywords in AI clinical trials

Keywords burst and theme evolution

The dynamic evolution map can intuitively analyze the evolution process of keywords in the field of AI clinical research in different periods (divided into three periods: 2012–2016, 2016–2019, 2019–2022). Each node represents a cluster of similar keywords, and the size of the node is consistent with the frequency of keyword occurrences; The thickness and color depth of the connecting lines between nodes are proportional to the strength of the correlation between themes. Dark and thick lines indicate that these two adjacent themes have a high degree of similarity and strong evolutionary ability. The solid line represents the mainstream evolution

direction of the keyword, while the dotted line represents the evolution direction of the tributary. Isolated points indicate that the topics that appear separately in this research stage are new themes that have not been followed up in the future. Most of the topic words, such as robot-assisted surgery, disease risk prediction, and management, have certain continuity, while keywords such as chatbot and deep learning have been emerging research topics in recent years (Fig. 6).

Journal

Seven-hundred thirty-five AI clinical trials have been published in 342 journals. The top 5 journals with the

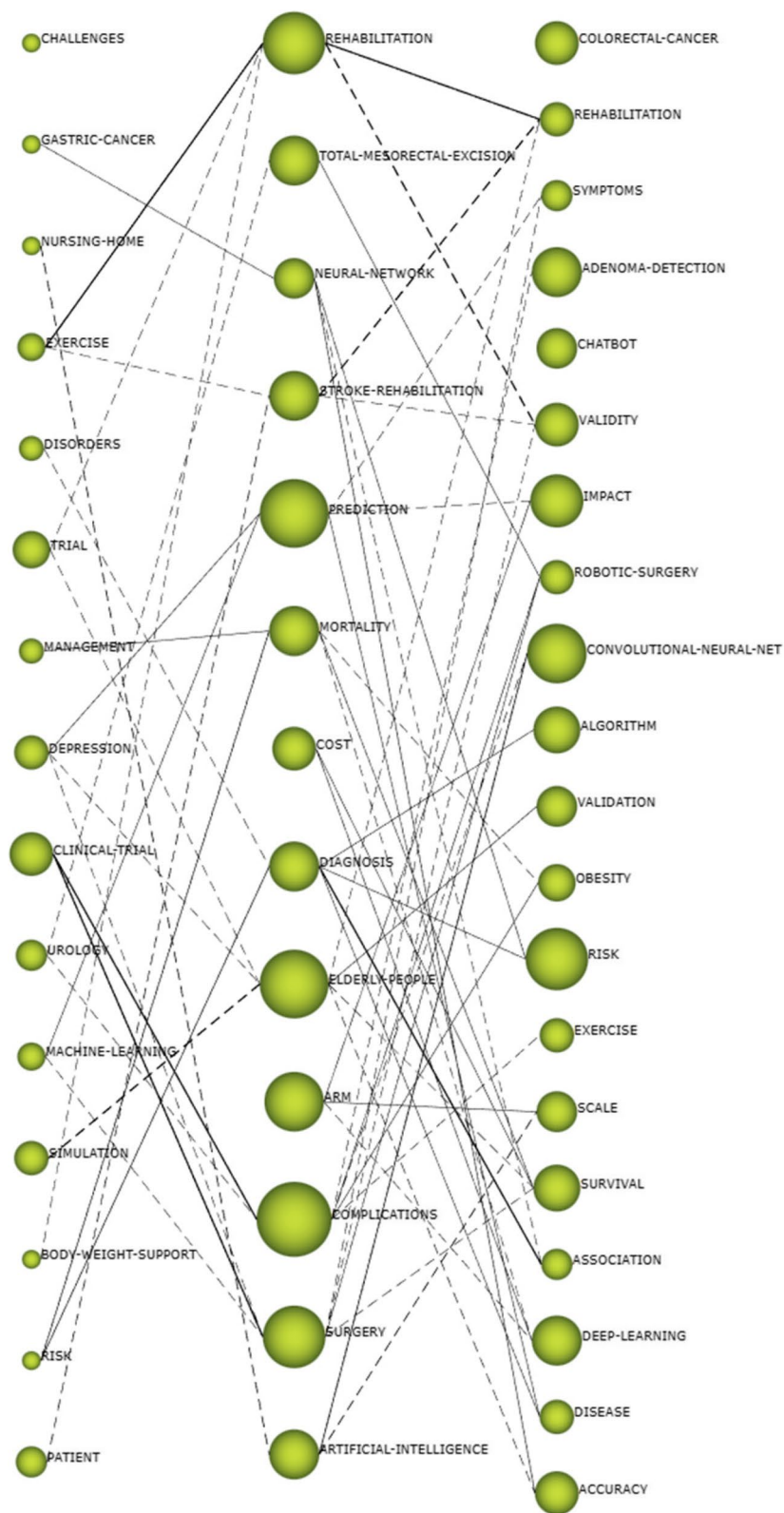


Fig. 6 The thematic evolution map for AI clinical trials — key theme evolution across three periods

largest number of AI clinical trials were *Computational and Mathematical Methods in Medicine* (26 times), *Contrast Media Molecular Imaging* (23 times), *Journal of Healthcare Engineering* (21 times), *Journal of Medical Internet Research* (17 times), and *JAMA Network Open* (13 times). *The New England Journal of Medicine* was the most co-cited journal, with 294 co-citations, followed by *Gastrointestinal Endoscopy* (251 co-citations), *Gastroenterology* (246 co-citations), *JAMA* (221 co-citations), and *Lancet* (219 co-citations). Figure 7 shows the dual-map overlay of journals. The left side represented the map of citing journals, and the right side represented the map of cited journals. The label represented the subject covered by the journal. Curves represent paths of references, originating from the citing map on the left and pointing to the cited map on the right. There were three main citation paths shown on the map. The green paths mean papers published in medicine/medical/clinical mostly cited journals in molecular/biology/genetics, health/nursing/medicine, and psychology/education/social.

References citations

The number of citations for clinical research of AI that we have included has increased rapidly. Among the TOP 10 most cited articles, the most cited research (645 citations), performed by Jayne (2017) and published in *JAMA*, evaluated the safety and effectiveness of robotic-assisted laparoscopic surgery in patients undergoing rectal cancer resection [29]. The second most-cited research, conducted by Haenssle (2018) and published in the *Annals of Oncology*, compared deep learning convolutional neural networks' diagnostic performance with a diagnostic team of 58 dermatologists [30]. The third most-cited research, performed by Wang (2019) and published in *Gut*, compared the difference in detection rates

between a deep learning-based automatic polyp detection system and a standard colonoscopy [31]. Four of the remaining high-cited articles assessed the effectiveness of AI in the diagnosis of colorectal cancer [32–35]. The other three high-cited papers evaluated the effect of the application of companion robots on the mental health of the elderly, the safety and effectiveness of robotic-assisted minimally invasive thoracoscopic esophagectomy, and the application effect of the machine learning-derived early warning system for intraoperative hypotension [36–38]. Citation bursts can help researchers quickly identify hot topics and important references in different periods. In Fig. 8, the time period in which a reference was found to have a burst is displayed by a red line, indicating the first year and the last year of the duration of the burst [19]. The strongest burst started in 2019 due to a 2021 paper published in *Gut* [31].

Discussion

AI technology has flourished, transforming traditional medical practices and shifting from technical development to clinical applications, showing great potential for future healthcare use. Before 2018, the annual publication count was under 50, but in the following years, there was a rapid surge in the number of articles (Fig. 1). It is anticipated that the volume of literature in this field will continue to grow. Clinical trials on AI have primarily been published in recent years, yet the total number of citations has risen sharply, reaching 4336 in 2022. The average citation count per study was 17, reflecting the widespread attention and significant academic impact of the research. Despite challenges such as data privacy, security concerns, low acceptability, and ethical issues, the immense potential and benefits of AI applications in medicine continue to drive researchers' enthusiasm,

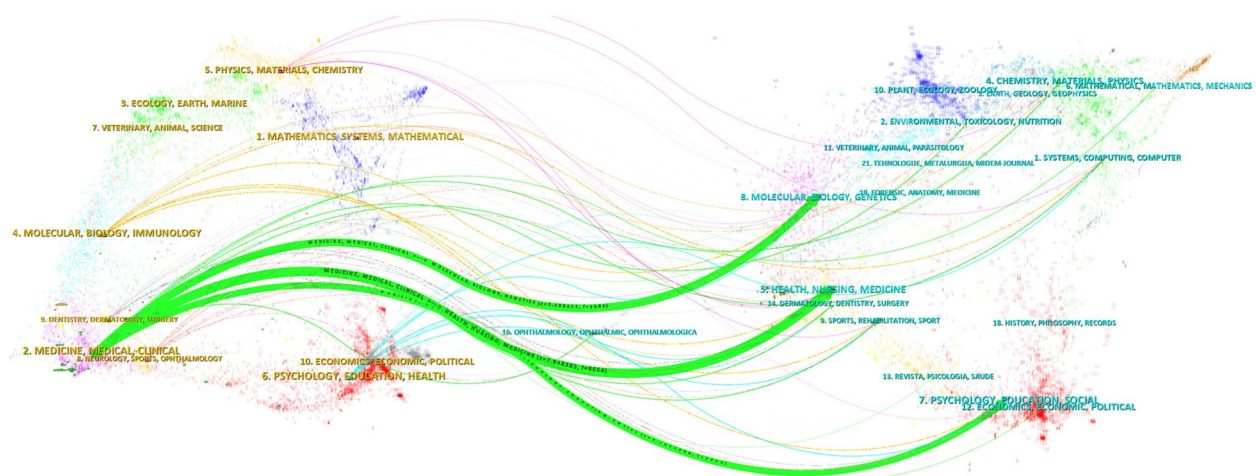


Fig. 7 The dual-map overlay of journals related to AI clinical trials — the citation relationship between journals

Top 20 References with the Strongest Citation Bursts

References	Year	Strength	Begin	End	2013 - 2023
MOYLE W, 2013, J GERONTOL NURS, V39, P46, DOI	2013	3.5531	2015	2018	
JARRASSE N, 2014, FRONT HUM NEUROSCI, V8, P0, DOI	2014	2.0624	2015	2017	
CHANG WH, 2013, J STROKE, V15, P174	2013	2.2189	2015	2018	
RYU JH, 2015, SURG ENDOSC, V29, P163, DOI	2015	2.2153	2016	2017	
ROBINSON H, 2013, J AM MED DIR ASSOC, V14, P661, DOI	2013	2.4102	2016	2018	
HESSE S, 2014, CLIN REHABIL, V28, P637, DOI	2014	2.2153	2016	2017	
JORANSON N, 2015, J AM MED DIR ASSOC, V16, P867, DOI	2015	2.893	2016	2018	
FLESHMAN J, 2015, JAMA-J AM MED ASSOC, V314, P1346, DOI	2015	2.1525	2017	2018	
STEVENSON ARL, 2015, JAMA-J AM MED ASSOC, V314, P1356, DOI	2015	2.6913	2017	2018	
SALE P, 2014, J NEUROENG REHABIL, V11, P0, DOI	2014	2.6913	2017	2018	
WANG P, 2019, GUT, V68, P1813, DOI	2019	11.4262	2021	2023	
ZHAO SB, 2019, GASTROENTEROLOGY, V156, P1661, DOI	2019	10.64	2021	2023	
FITZPATRICK KK, 2017, JMIR MENT HEALTH, V4, P0, DOI	2017	7.0294	2021	2023	
VAIDYAM AN, 2019, CAN J PSYCHIAT, V64, P456, DOI	2019	5.1557	2021	2023	
BRAY F, 2018, CA-CANCER J CLIN, V68, P394, DOI	2018	10.8799	2021	2023	
LV ZH, 2020, FUTURE GENER COMP SY, V109, P103, DOI	2020	8.5801	2021	2023	
WANG P, 2020, LANCET GASTROENTEROL, V5, P343, DOI	2020	8.0059	2021	2023	
MISAWA M, 2018, GASTROENTEROLOGY, V154, P2027, DOI	2018	6.7979	2021	2023	
LIU WN, 2020, SAUDI J GASTROENTERO, V26, P13, DOI	2020	6.2852	2021	2023	
DE FJ, 2018, NAT MED, V24, P1342, DOI	2018	4.5673	2021	2023	

Fig. 8 Citation burst of references in AI clinical trials — references suddenly cited frequently in different periods

with many striving to integrate AI into clinical practice. While previous studies have analyzed AI research across various fields, such as ethics, prostate cancer, COVID-19, and cerebrovascular and heart disease, they often include reviews, commentaries, and technical studies, making it difficult for researchers and clinicians to pinpoint trends in AI clinical trials [27]. This can lead to an exaggerated view of the current state of AI's clinical applications. The number of articles included in this study is significantly lower than in previous bibliometric analyses, primarily due to our strict exclusion of technologies unrelated to AI and nonclinical trial studies.

Among the top 10 countries contributing the most to AI clinical research, 4 are from Europe, 2 from the Americas, and 3 from Asia. Only 23 countries have published more than 5 articles, while 43.4% of countries have published fewer than 6. The United States leads with 33.1% of the total AI clinical research publications, reflecting its dominant position in the field. China stands as the only developing country among the top 10 contributors. The US influence on AI clinical research is significant, likely due to its open policies, strong technological capabilities, and substantial financial support for researchers. International cooperation has formed four main collaborative groups, primarily among developed countries, highlighting the need for stronger partnerships, particularly between developed and developing nations, to prevent

further widening the gap in medical science and technology (Fig. 2). The study involved 1706 authors, with only 6 publishing more than 7 papers; Liu J. ($n=9$ times, Wuhan University), Mori Y. ($n=8$ times, University of Oslo), and Mori K. ($n=8$ times, Nagoya University) contributed most articles, and an analysis of collaboration patterns showed limited cooperation among high-yield authors (Fig. 3), with only 40 out of 98 forming networks. Since many AI technologies require vast amounts of data for model training, their clinical applications necessitate extensive collaboration among international, interdisciplinary teams. However, current institutional cooperation remains insufficient. Future international organizations and government bodies should focus on promoting talent exchange and facilitating project collaboration to enhance global efforts in AI healthcare development. Machine learning, deep learning, chatbot, and robotics were the most frequently used AI technology keywords, while stroke and cancer were the most frequently used disease keywords. Other high-frequency keywords used were risk, management, classification, rehabilitation, outcome, surgery, and diagnosis.

Research hotspots are defined as scientific problems or topics extensively discussed in a series of publications within a specific timeframe, with these works demonstrating inherent interconnections [39]. Based on the density map and cluster map of co-occurring keywords

(Figs. 4, 5, and 6), previous AI clinical trials primarily focused on several key hotspots:

- (1) Cluster 1 focuses on the application of AI in disease risk prediction and management. For example, Popp et al. compared a machine learning-based personalized diet targeting postprandial glycemic response with standard low-fat diets in adults with abnormal glucose metabolism and obesity, finding no significant differences [40]. Similarly, another study found that a machine learning-based monitoring system improved compliance and cost-effectiveness in obstructive sleep apnea management [41]. Additionally, AI-powered chatbots, utilizing technologies such as deep learning and natural language processing, have emerged as a prominent area of research, with preliminary studies exploring their potential in managing conditions like depression, anxiety, obesity, and pain [42–46].
- (2) Cluster 2 focuses on evaluating the application of AI in disease diagnosis and classification. AI algorithms trained for medical image analysis have demonstrated value in diagnosing conditions such as colorectal cancer, pulmonary nodules, chronic atrophic gastritis, and early gastric cancer, as confirmed by clinical trials [33, 47–50]. Additionally, other studies have assessed the accuracy and effectiveness of AI tools in disease diagnosis and therapeutic support, further underscoring their broader potential in this field [51].
- (3) Cluster 3 mainly focused on evaluating the application value of robot-assisted surgery. Multiple randomized controlled trial RCTs have also verified the effectiveness and cost-effectiveness of robot-assisted minimally invasive surgery for patients [52, 53]. Although surgical robots have integrated certain AI technologies, they primarily function as facilitators in the surgical field and cannot fully replace surgeons. However, with the rapid advancement of AI, it is anticipated that this technology will fundamentally transform traditional surgical practices.
- (4) Cluster 4 focuses on the application of AI technology in rehabilitation. Several studies have explored the effectiveness of integrating AI algorithms, such as machine learning, with other rehabilitation interventions [54].

For instance, Liu et al. demonstrated that machine learning-powered rehabilitation robotic beds significantly improved motor function and lower limb activity in patients with stroke and hemiplegia [55]. Similarly, Bai et al. found that integrating AI-driven limb rehabilitation

systems with virtual reality effectively enhanced physical movement ability and activities of daily living in stroke patients [56]. While several studies have explored the use of AI-integrated robots in rehabilitation, most have been limited by small sample sizes, underscoring the need for large-scale randomized controlled trials (RCTs) to further validate their safety and efficacy [57].

In summary, the intervention effects of artificial intelligence in disease risk prediction and management, disease diagnosis and classification, robot-assisted surgery, and rehabilitation training have been preliminarily validated through clinical trials, and these directions may become key areas of clinical application. Moreover, generative AI has also demonstrated significant potential for future applications. The validation of the effectiveness and cost-effectiveness of artificial intelligence in clinical settings through high-quality clinical trials could drive increased investment and support for AI healthcare technologies from governments and healthcare institutions. Therefore, to facilitate the translation of more AI technologies into clinical practice and enhance efficiency, future researchers should broaden the scope of AI clinical trial topics to further explore its potential. Additionally, governments must strengthen regulation to address ethical issues such as data privacy, algorithmic bias, informed consent, and transparency while ensuring fairness and inclusivity to prevent discrimination in patient care.

Limitations

This study has several limitations. First, due to the limitations of the research methodology and objectives, the search was restricted to the Web of Science database, which may introduce bias by excluding relevant studies from other databases or sources. Second, while efforts were made to manually standardize varying expressions and ambiguous definitions of the same concept prior to data analysis, this process likely reduced but did not entirely eliminate errors. Third, the exclusion of conference papers, commentaries, and protocols may have led to the omission of some important publications. Fourth, the determination of whether a technology was AI related relied on the authors' descriptions and expert judgment, which may have introduced subjective bias. Additionally, the quality of the included studies was not assessed, meaning the reliability of some studies cannot be guaranteed. With the development of the SPIRIT-AI (Standard Protocol Items: Recommendations for Interventional Trials-Artificial Intelligence) extension and the CONSORT-AI (Consolidated Standards of Reporting Trials-Artificial Intelligence) [58, 59], future research should aim to enhance transparency, quality, and completeness in reporting AI-related studies.

Conclusions

This study offers a comprehensive overview of key articles, journals, leading authors, institutions, and themes within the field. While the number of publications and citations related to AI in clinical trials has grown rapidly, significant opportunities for further advancement remain. Continuous research, comprehensive regulation, and interdisciplinary collaboration are crucial for fully utilizing the potential of AI in advancing healthcare. Close collaborative relationships between institutions and authors are primarily concentrated in developed countries, and international and interdisciplinary cooperation needs to be further strengthened. Additionally, there is a pressing need to cultivate interdisciplinary, composite talents to drive collaboration and innovation across various fields. Previous AI clinical trials have been predominantly focused on the application of AI in surgery, and rehabilitation, disease diagnosis, disease risk prediction, and health management, chatbots, and deep learning are emerging hot research topics in recent years. In the future, more high-quality RCTs are still required to verify the clinical application value of AI technology across different fields.

Abbreviations

AI	Artificial intelligence
RCT	Randomized controlled trial
WOS	Web of Science

Supplementary Information

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Additional file 1. Appendix 1: The detailed search strategy for Web of Science Core Collection database.

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Patient and public involvement

Patients and/or the public were not involved in the design, conduct, reporting, or dissemination plans of this research.

Authors' contributions

Contributors, all authors made a substantial contribution to the research; concept and design, JYS, ZL, and YZ; acquisition, analysis, or interpretation of data, JYS and FYF; drafting of the manuscript, HSC, SJY, XLW, and JYS; and revised manuscript, JYS, SJY, HSC, ZL, CS, and JJX.

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Declarations

Ethics approval and consent to participate

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Consent for publication

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Competing interests

The authors declare that they have no competing interests.

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