

RESEARCH ARTICLE

Bibliometric analysis of reference intervals in clinical laboratories research area

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ABSTRACT

Objective: This study conducts a bibliometric analysis of reference interval in clinical laboratory research to evaluate scholarly output.

Methods: Articles published since 2000 on the term “reference value” and “reference interval” in the field of the clinical laboratory were found in the Web of Science Core Collection SCIE index. VOS viewer and Microsoft Excel were employed to perform bibliometric and visual analyses.

Results: The study analysed 664 articles on reference intervals in 85 countries, with the United States leading with 120 publications. The top organizations contributing to the research were the Hospital for Sick Children and the University of Toronto, followed by Yamaguchi University, the University of Copenhagen, and the University of Southern Denmark. The data also showed a significant increase in research funding distribution, with the United States Department of Health and Human Services, National Institutes of Health, Japan Society for the Promotion of Science, Ministry of Education, Culture, Sports, Science and Technology (MEXT), Japan, and Canadian Institutes of Health Research holding notable records. The statistics indicated a notable rise in citations, with 2021 recording the highest number of citations. The study also highlighted the importance of keywords in the dataset, with “reference intervals” appearing 166 times and “reference interval” appearing 97 times.

Conclusion: This study provides a systematic and objective perspective for evaluating the characteristics of publications on reference intervals in clinical laboratory research and for generating evidence-based scientific insights.

Keywords: Publications, bibliometric analysis, reference intervals, reference values

ÖZET

Klinik laboratuvar araştırma alanında referans aralıkların bibliyometrik analizi

Amaç: Bu çalışma, akademik çıktıyı değerlendirmek amacıyla klinik laboratuvar araştırmalarında referans aralıklara ilişkin bibliyometrik bir analiz gerçekleştirmektedir.

Yöntem: Klinik laboratuvar alanında “referans değer” ve “referans aralık” terimi üzerine 2000 yılından itibaren yayımlanan makaleler Web of Science Core Collection SCIE indeksinde bulunmuştur. Bibliyometrik ve görsel analizler VOSviewer ve Microsoft Excel kullanılarak yapılmıştır.

Bulgular: Çalışmada 85 ülkeden referans aralıklar üzerine 664 makale incelenmiş olup, en fazla yayına sahip ülke 120 yayın ile Amerika Birleşik Devletleri olmuştur. Araştırmaya en çok katkı sağlayan kurumlar arasında Sick Children Hastanesi ve Toronto Üniversitesi ilk sırada yer almış, bunları Yamaguchi Üniversitesi, Kopenhag Üniversitesi ve Güney Danimarka Üniversitesi izlemiştir. Veriler ayrıca, Amerika Birleşik Devletleri Sağlık ve İnsan Hizmetleri Bakanlığı, Ulusal Sağlık Enstitüleri, Japonya Bilimi Teşvik Derneği, Japonya Eğitim Kültür Spor Bilim ve Teknoloji Bakanlığı (MEXT) ve Kanada Sağlık Araştırmaları Enstitüleri’nin dikkat çekici kayıtlara sahip olduğu, araştırma fonlarının dağılımında önemli bir artış olduğunu göstermiştir. Veriler ayrıca, 2021 yılının en yüksek atıf sayısına sahip yıl olmasıyla, atıf eğiliminde belirgin bir artış olduğunu da ortaya koymuştur. Çalışma ayrıca veri setindeki anahtar kelimelerin önemini vurgulamış, “referans aralıkları” ifadesi 166 kez ve “referans aralığı” ifadesi 97 kez yer almıştır.

Sonuç: Klinik laboratuvarlarda referans aralıkları alanındaki yayınların niteliklerini değerlendirmek ve bilimsel cevaplar elde etmek için bu çalışma, sistematik ve objektif bir bakış açısı sunmaktadır.

Anahtar kelimeler: Yayınlar, bibliyometrik analiz, referans aralıkları, referans değerleri

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INTRODUCTION

Clinical laboratory test results are crucial for diagnosing, making treatment decisions, follow-up, and monitoring clinical status. The typical way of interpreting patient results is practically population-based reference intervals (RIs). There are two methods to determine reference intervals: the direct method from the selected population and the indirect method from the archive records [1]. However, defining and verifying reference intervals can be complicated due to variations between populations and clinical laboratories, in addition to financial challenges, especially in direct methods. Scientific organisations in clinical chemistry recommend using direct methods to determine the reference intervals with published guidelines and funds initiatives to promote best practices in reference interval determination [2]. Clinical decision limits (CDLs) are used in data interpretation as well as reference intervals. While reference intervals and CDLs are sometimes incorrectly used interchangeably, in a reductive manner, reference intervals represent the average state of a healthy population. In contrast, CDLs indicate the point at which results are clinically actionable [3].

Reference intervals facilitate the interpretation of clinical laboratory data by aiding medical decision-making in health assessment and illness diagnosis and therapy [4,5]. Reference intervals are the 95% parts in the centre range of analyte values from a healthy reference population after the elimination of 2.5% of upper and lower limits [6].

Data interpretation has been a matter of curiosity from the beginning time of the analysis of human samples. The Coleman paper clarified a fundamental idea that still presents difficulties for the modern laboratory community [3]. Reference intervals have evolved due to changes in measurement techniques. A reference interval conference began, introducing statistical methods like Hoffmann and Bhattacharya in 1969. Systemic evaluations in the late 1980s and early 1990s focused on defining RIs and determining them. Dr. Helge Erik Solberg contributed to this evaluation [7, 8]. The theory of reference interval has progressed, with the initial phase from 1960 to 1980 emphasizing biological variability, preanalytical conditions, standardization of measurement techniques, quality control procedures, and statistical methodologies for establishing reference intervals. The second movement developed and implemented initial works from 1980 to 2000. Reference intervals have become a subject of numerous textbooks and conferences globally. Nonetheless, obstacles persist, especially for certain laboratories generating their own reference intervals and the applicability of the notion to emerging technology [7]. During the past several years, the International Federation of Clinical Chemistry and Laboratory Medicine, Association for Diagnostics & Laboratory Medicine, and Clinical and Laboratory Standards Institute

(CLSI) have established a scientific division for reference intervals [9].

Bibliometric analysis is one technique to measure the scientific output of a field both quantitatively and qualitatively [10-12]. The research landscape of reference interval was visualised from a macroscopic perspective using big data facilitating tools such as VOSviewer.

MATERIALS and METHODS

This study did not require ethical approval because there were no animals or experiments in this study. The data were acquired from the Science Citation Index Expanded (SCI-EXPANDED) database under the Web of Science Core collection.

The search period was selected as January 1, 2000-October 30, 2023. The search was carried out on November 1, 2023. All data were collected in a single day to prevent bias from database updates.

Search terms were as below: Medical Subject Headings (MESH) terms Reference Value (Title) OR Value, Reference (Title) OR Values, Reference (Title) OR Normal Range (Title) OR Normal Ranges (Title) OR Range, Normal (Title) OR Ranges, Normal (Title) OR Normal Values (Title) OR Normal Value (Title) OR Value, Normal (Title) OR Values, Normal (Title) OR Reference Ranges (Title) OR Range, Reference (Title) OR Ranges, Reference (Title) OR Reference Range (Title) and the Word term Reference interval (Title) and Article (Document Types).

The language category was English.

Documents other than research articles were excluded.

Bibliometrics and visualisation analysis

Included publications' complete records were obtained from the Web of Science database, saved in txt format, and subsequently imported into VOSviewer (version 1.6.19) for additional analysis.

Author, country, and rising foci of reference interval terms over the last 23 years were analysed using the bibliometric analysis software VOSviewer. VOSviewer is a complimentary software application that enables the creation and visualization of bibliometric maps. It focuses on graphical representation and is especially useful for displaying large maps in an understandable format [13, 14].

The SCI-EXPANDED database yielded 17,196 results since January 1, 1970, for various search phrases about reference values, normal ranges, and reference intervals. 11,607 of these publications were research articles. Among the citation topics micro, 954 articles mainly address laboratory medicine. When the language filter was limited to English, 904 English-language research articles remained. After subsequently restricting the publication period to January 1, 2000 - October 30, 2023, 664 articles met the eligibility criteria. These 664 articles constituted the sample of this study. VOSviewer and Microsoft Excel were used to conduct the bibliometric and visual analyses.

Numerous bibliographic components were gathered, such as the number of publications per year, the frequency of citations, the countries and regions, the institutions, the journals, and the keywords—the collaboration, co-citation and co-occurrence analysis done with VOSviewer.

RESULTS

Number of publications

The retrieval criteria were met by 664 articles in total. With 67 articles published (10.09%), 2021 was the year with the highest publication count. 2022 and 2019 came in second and third, respectively, with 62 (9.34%) and 48 (7.23%) articles. There were peaks in

the number of publications in 2015 (44 articles, 6.63%) and 2014 (42 articles, 6.33%), with earlier years like 2003 (6 articles, 0.90%) and 2002 (5 articles, 0.75%) having noticeably fewer publications. The first ten years, from 2000 to 2009, show a total of 162 articles, with a varying number each year. The next ten years (2010–2019) show a more significant increase in publications, with 414 published articles indicating greater emphasis and output in this area. The count of 176 articles for the most recent period (2020–2023) shows that research and publication on reference values and reference ranges in this particular domain are still on the rise (Figure 1).

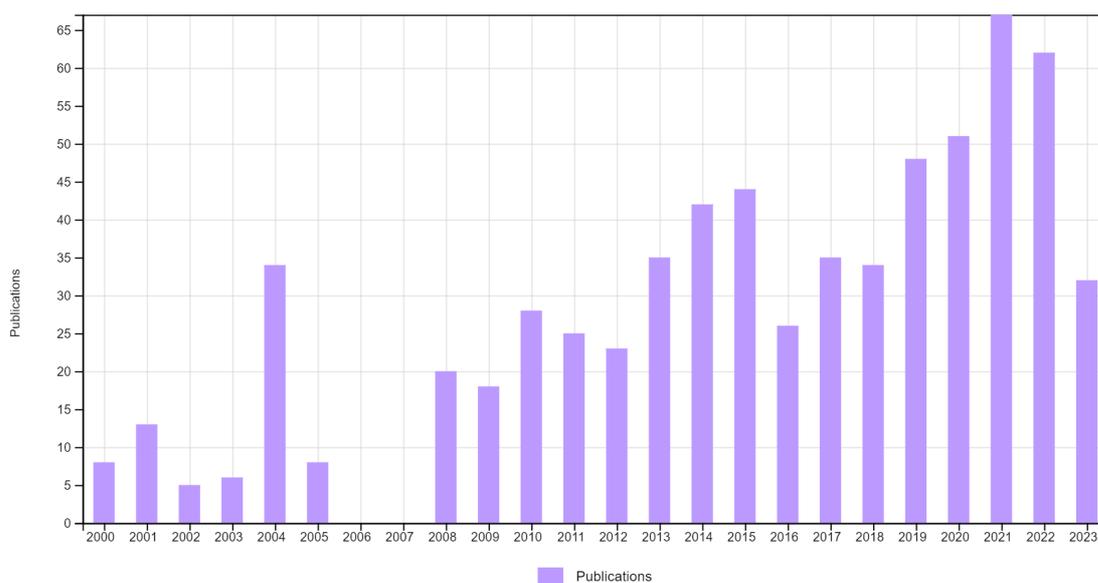


Figure 1. Number of publications by years

Countries

Studies on reference interval have been published in 85 regions/countries. The data demonstrated the distribution of articles on reference intervals among various countries and regions.

The United States of America (USA) led the ranking of countries with the most publications with 120 publications, with articles originating from the USA accounting for approximately 18.07% of the total publications. In the second place, China contributed 88 publications (13.25%), while Canada and Germany ranked 3rd and 4th, producing 68 (10.24%) and 55 (8.28%) publications, respectively (Table 1).

Organisations/universities and funders

The data presented the distribution of publications across 120 different organisations/universities that addressed reference interval. Among the top affiliations were the University of Toronto and the Hospital for Sick Children (SickKids), which contributed 56 (8.43%) and 55 (8.28%) articles, respectively. Furthermore, a considerable amount of articles were given by associations like Yamaguchi University, the

University of Copenhagen, and the University of Southern Denmark (Table 2).

In terms of research funding distribution, the United States Department of Health and Human Services (10 articles), the National Institutes of Health (9 articles), the Japan Society for the Promotion of Science (8 articles) and the Ministry of Education, Culture, Sports, Science and Technology (MEXT), Japan (8 articles), and Canadian Institutes of Health Research (6 articles) held notable records.

Citations

The data analysed citations and the H-Index, indicating a scientist's impact. The total number of citations was 13,308, the cumulative H-index for the dataset was 56, and the average citations per item were 24.87. Since 2005, there has been a rising trend in citation frequency. Specifically, 2021 saw the greatest citation count, totalling 888 (Figure 2).

Mappings

According to VOSviewer, labels and circles represent items in network visualisation, with weight determining their size and colour. The cluster of an item determines its colour. Lines represent links by default.

| Country* | Documents | Citations | Total link strength** |
|--------------------------|-----------|-----------|-----------------------|
| United States of America | 120 | 4520 | 1749 |
| China | 88 | 896 | 1083 |
| Canada | 68 | 1894 | 901 |
| Germany | 55 | 1109 | 645 |
| Denmark | 45 | 1328 | 737 |
| Japan | 43 | 926 | 1358 |
| England | 41 | 1530 | 567 |
| Norway | 40 | 1577 | 754 |
| Türkiye | 36 | 685 | 759 |
| Italy | 32 | 871 | 450 |

*Showing 10 out of 85 entries. ** Total link strength: Represents the sum of all co-authorship link strengths between each country and other countries in the network, as calculated by VOSviewer. Higher values indicate more extensive international collaboration.

Table 1. Most publishing countries on the reference interval

| Organisations/universities* | Number | % |
|---------------------------------------|--------|------|
| University of Toronto | 56 | 8.43 |
| Hospital for Sick Children (SickKids) | 55 | 8.28 |
| Yamaguchi University | 33 | 4.97 |
| University of Copenhagen | 20 | 3.01 |
| University of Southern Denmark | 20 | 3.01 |
| Odense University Hospital | 18 | 2.71 |
| University of Bergen | 18 | 2.71 |
| University of Erlangen Nuremberg | 15 | 2.26 |
| University of Milan | 15 | 2.26 |
| Capital Medical University | 14 | 2.11 |

*Showing 10 out of 1.210 entries

Table 2. Most publishing organisations/universities on the reference interval

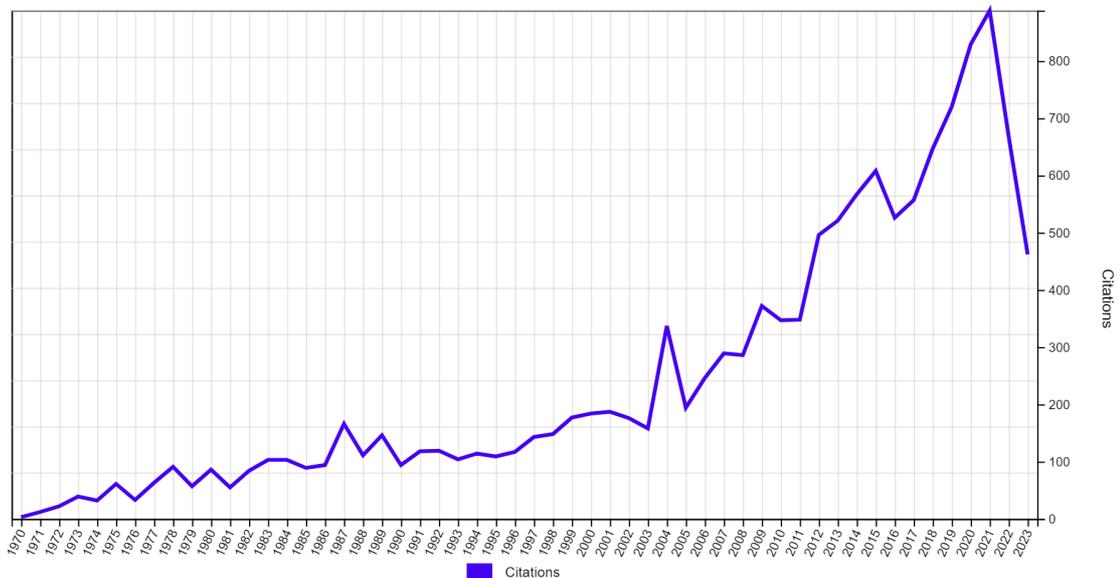


Figure 2. Number of citations by years

The distance between the two countries/authors indicates their similarity in co-citation links. Wider lines represent stronger connections.

According to a co-authorship analysis of the most published countries, 36 countries produced more than five documents. VOSviewer was used for this analysis (Figure 3).

Table 3 displays research metrics for various countries, including the number of documents, citations, and total link strength. The United States leads with 120 documents and 4520 citations, demonstrating active research and influence. Other countries with significant research output include China, Canada, Germany, Denmark, and Japan, with varying citation counts and link strengths.

According to a co-authorship analysis of the most published organisations, 51 produced more than five documents. VOSviewer was used for this analysis. The University of Toronto and the Hospital for Sick Children emerge as the top contributors, with 54 and 43 documents displaying significant citation counts and link strength, respectively. Other well-known institutions, such as Yamaguchi University, Odense University Hospital, and the University of Bergen, demonstrate significant collaboration through co-authorship, with varying citation counts and link strengths (Table 4).

Figure 4 shows the citation analysis between countries. Thirty-six countries produced more than five citations. Lines represent the most robust co-citation links between countries. A citation link establishes a connection between two entities, wherein one references the other. VOSviewer treats citation connections as randomized. Consequently, there is no difference between a reference going from item A to item B and

one going the other way. A bibliographic coupling link associates two items that reference the identical document. A co-citation link associates two items that have been cited by a common document. The United States leads in documents with 120 and citations with 4520, for a total link strength of 1749. Following that, the People's Republic of China has a high level of research activity, with 88 documents and 896 citations, for a total link strength of 1083. Countries like Canada, Germany, and Denmark generate substantial research with differing citation frequencies and overall connection strengths (Table 1).

Figure 5 depicts the co-occurrence keywords network visualisation map with an extraction frequency of 10 or more times. There were 1328 keywords, and 71 of them appeared more than five times, and 24 of them occurred more than ten times. The keyword analysis, occurrences, and total link strengths presumably represent their significance or prevalence within a specific context, such as a research field or dataset. The keyword "reference intervals" appears 166 times and has a relatively high total link strength of 138, indicating its significant relevance and influence within the dataset. The term "reference interval" is mentioned 97 times, exhibiting a connection strength of 62, demonstrating its significance. Other keywords such as "reference values," "pediatric," "hematology," and "reference change value" have significant occurrences and link strengths, highlighting their importance in the dataset. Keywords like "reference ranges" and "clinical chemistry" appear with fewer occurrences and link strengths, indicating a lower prominence in this context or dataset.

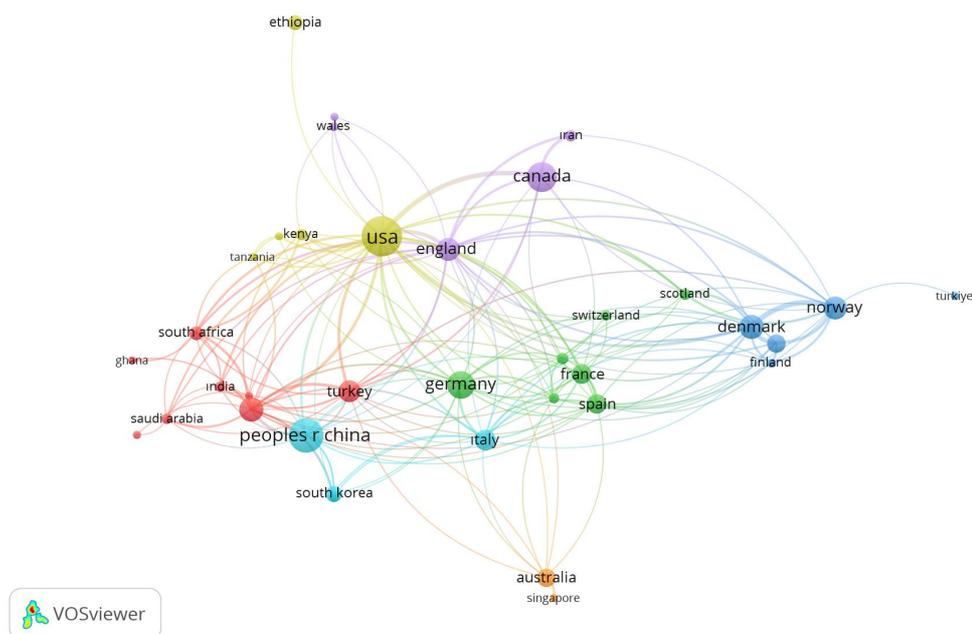


Figure 3. Co-authorship analysis of the most published countries

| Country | Documents | Citations | Total link strength* |
|--------------------------|-----------|-----------|----------------------|
| United States of America | 120 | 4520 | 116 |
| China | 88 | 896 | 32 |
| Canada | 68 | 1894 | 41 |
| Germany | 55 | 1109 | 37 |
| Denmark | 45 | 1328 | 64 |
| Japan | 43 | 926 | 65 |
| England | 41 | 1530 | 67 |
| Norway | 40 | 1577 | 55 |
| Türkiye | 36 | 685 | 37 |
| Italy | 32 | 871 | 36 |
| France | 30 | 1192 | 24 |
| Spain | 28 | 780 | 28 |
| Australia | 26 | 469 | 12 |
| Sweden | 26 | 894 | 30 |

*Total link strength: Represents the sum of all co-authorship link strengths between each country and other countries in the network, as calculated by VOSviewer. Higher values indicate more extensive international collaboration.

Table 3. Co-authorship analysis between top publishing countries

| Organisation | Documents | Citations | Total link strength |
|---------------------------------------|-----------|-----------|---------------------|
| University of Toronto | 54 | 1399 | 70 |
| Hospital for Sick Children (SickKids) | 43 | 1081 | 68 |
| Yamaguchi University | 32 | 805 | 30 |
| Odense University Hospital | 18 | 779 | 23 |
| University of Bergen | 17 | 707 | 30 |
| University of Milan | 15 | 526 | 11 |
| Capital Medical University | 13 | 89 | 13 |
| Klinikum Bremen Mitte | 13 | 289 | 18 |
| China Medical University | 12 | 177 | 43 |
| University of Bremen | 12 | 290 | 17 |
| Fürst Medical Laboratory | 11 | 629 | 9 |
| University Hospital Erlangen | 11 | 228 | 11 |
| Uppsala University | 11 | 246 | 1 |
| Abbott Diagnostics | 10 | 635 | 14 |
| Fudan University | 10 | 127 | 43 |
| University of Copenhagen | 10 | 86 | 12 |

Table 4. Co-authorship analysis between top publishing organisations

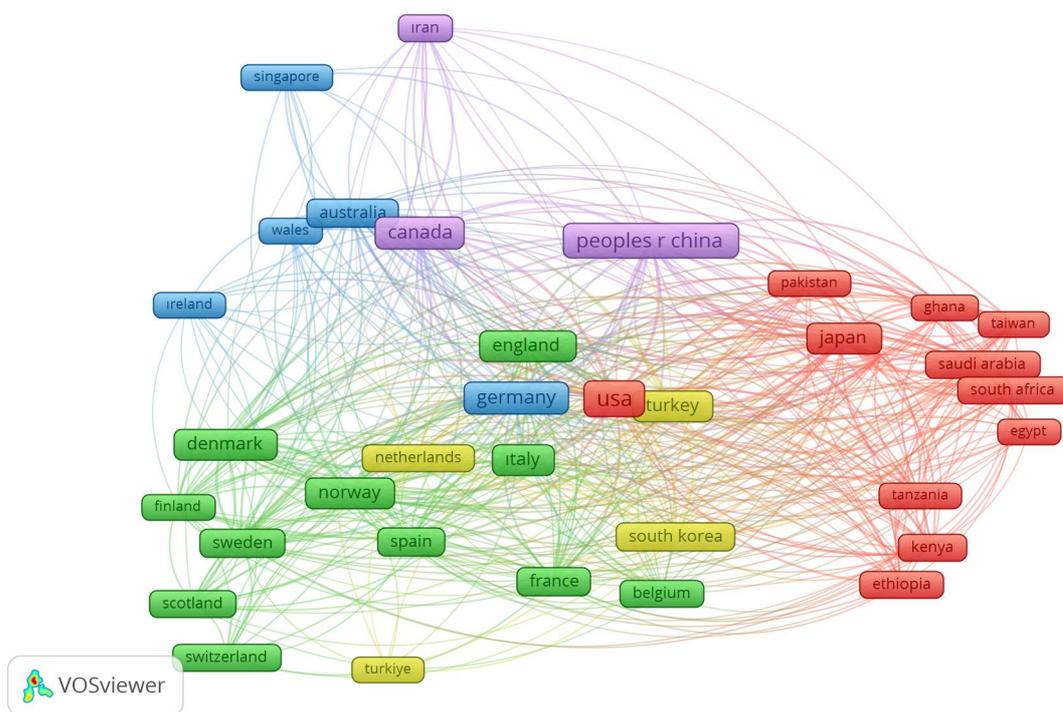


Figure 4. Citation analysis between countries

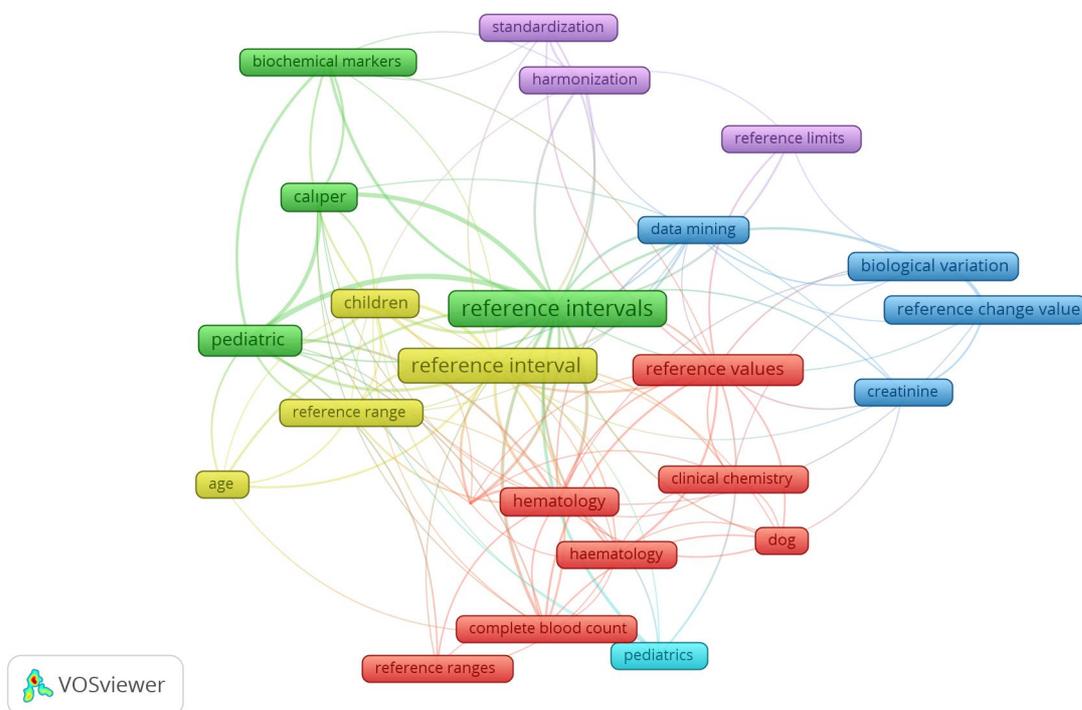


Figure 5. Keyword analysis

DISCUSSION

Bioinformatics/bibliometric analysis has recently become an increasingly important area of medicine [15-18]. Extensive data obtained through bibliometric analysis is structured and allows objective interpretation of scientific knowledge and topics [19].

The current study used bibliometric analysis to evaluate scientific output in the domain of reference intervals quantitatively and qualitatively. The research landscape was investigated using the big data application tool VOSviewer, which provided a macroscopic view of the field. The study extracted data from the SCI-EXPANDED database in the Web of Science Core Collection from January 1, 2000, to October 30, 2023, for comprehensive analysis. The findings revealed a substantial rise in the quantity of research publications centred on "reference values." This increase has been especially noticeable in recent years, indicating a growing interest or emphasis on this topic among academic and scientific communities.

The analysis highlighted the countries that contributed the most to the work on reference intervals. The distribution of these publications in various countries revealed that the USA was the primary contributor. This dominance could be attributed to the United States's extensive scientific infrastructure, diverse research institutions, and a long tradition of academic excellence in various scientific domains. Also, China, Canada, and Germany are among the top contributors to reference interval research, indicating a global interest in this field. Specific institutions and universities within these countries were significant contributors to this field. Leading contributors included the Hospital for Sick Children, the University of Toronto, Yamaguchi University, the University of Copenhagen, and the University of Southern Denmark. Considering the Canadian Laboratory Initiative on Pediatric Reference Intervals (CALIPER) studies, these findings are unsurprising. CALIPER started in 2008. After the pilot studies to evaluate the feasibility, the first study covered the reference interval for 40 common biochemical markers with the direct method in accordance with the Clinical and Laboratory Standards Institute (CLSI) guidelines and was published in 2012 [20, 21]. CALIPER has generated age and gender-specific reference intervals for over 200 biomarkers using a biobank of healthy children and adolescents [22-29]. CALIPER also assessed the relevance of reference intervals across several analytical platforms, as well as the influence of pre-analytical conditions, biological variation, ethnicity, and pubertal development on these intervals [20]. For this reason, the data obtained from CALIPER studies are precious, and the reference intervals in healthy children and adolescents obtained thanks to the developed application can be used worldwide [30].

Prominent funding bodies such as the USA's Department of Health and Human Services, the National Institutes of Health, the Japan Society for the Promotion of Science, and the Canadian Institutes of Health

Research have been identified for their significant support.

The VOSviewer software analysis offers valuable insights into scholarly research and collaborations in reference intervals. The tool effectively represents connections and interactions among various entities, revealing relationships between countries, organisations, citations, and keywords. The data revealed that 36 nations had significant involvement in research on reference intervals, with the United States being the frontrunner with 120 documents and 4520 citations. China also showed high engagement with 88 documents and 896 citations. Countries like Canada, Germany, and Denmark also displayed considerable research output, albeit with varying citation counts and link strengths.

The VOSviewer analysis also revealed prominent institutions involved in research on reference intervals, including the University of Toronto and the Hospital for Sick Children. Other institutions like Yamaguchi University, Odense University Hospital, and the University of Bergen also demonstrated collaboration. Keywords like "reference intervals," "reference interval," "reference values," "pediatric," and "hematology" were pivotal, while "reference ranges" and "clinical chemistry" were less prevalent. The findings offer insights into global dynamics, collaborations, and the prominence of specific research topics in reference intervals.

This is, to our knowledge, the first bibliometric study that highlights differences in article publication counts, publishing patterns, and research funding among various organ systems that have utilized reference intervals as a subject matter. The study's weakness is its exclusive reliance on the SCIE index of the Web of Science from the year 2000. Various public and commercially accessible bibliometric databases, including Scopus and Google Scholar, exist, and no single bibliometric database is inherently superior; discrepancies in data organization among these databases may lead to significant variations in search outcomes. In addition, because the search strategy was limited to article titles, some relevant studies may not have been captured. Journal analysis and content analysis were not conducted, and only a single data visualization tool was employed. Subsequent research may be organized.

Overall, the comprehensive examination of publication trends, country contributions, organisational affiliations, funding sources, citation patterns, and keyword relevance provides invaluable insights into the dynamic landscape and critical facets of reference value research. The findings highlight the collaborative nature of this field and its evolving trends, laying the groundwork for future research directions and collaborative opportunities.

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