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ORIGINAL ARTICLE

Worldwide scientific production in obstetrics: a bibliometric analysis

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Abstract

Background Randomised clinical trials are considered to be the most reliable study design for assessing the efficacy and safety of health interventions.

Aims To analyse worldwide obstetrics research carried out through randomised clinical trials, from 2002 to 2013.

Methods A bibliometric analysis was performed. Publications on obstetrics that were published journals indexed in the MEDLINE database from 2002 to 2013 were analysed. The major medical subject headings used in the search were obstetrics, pregnancy complications and obstetrics surgical procedures. The main study outcome was index of research productivity.

Results Our study search strategy yielded a total of 142,659 articles and 9967 clinical trials. The growth rate of scientific production in obstetrics during this period was 55.43% ($n = 5094$). The growth rate of production of randomised clinical trials in this specialty, meanwhile, was 97.84% ($n = 544$). Most of the identified authors ($n = 22{,}622$, 71.21%) published only one paper during the study period. Patterns of co-authorship among the 20 most productive authors were identified. After applying Bradford's law, six journals in the nucleus (the most prolific journals) were found. Of all the clinical trials in obstetrics published between 2002 and 2013, 10.3% were published in journals belonging to categories other than Obstetrics and Gynecology. The most common research topic in 2002 and 2013 was the use of analgesia and anesthesia in obstetrics.

Conclusions Total scientific production rate in obstetrics increased from 2002 to 2013, especially randomised clinical trials. However, randomised clinical trials continue to represent a small proportion of total production.

Keywords Bibliometrics · Gynaecology · Obstetrics · Randomised clinical trials

Introduction

Obstetrics is a medical and surgical specialty concerned with the management and care of women before, during and after childbirth [1]. A considerable number of obstetricians worldwide are involved in clinical practice and research efforts. Publications constitute a central part of the research process, and scientific research productivity can be measured by the number of publications produced by research groups. In recent years, the number of scientific publications in the field of obstetrics has increased rapidly worldwide, but not everything published contributes to scientific progress. Randomised clinical trials (RCTs) are considered to be the most reliable study design for assessing the efficacy and safety of health interventions, as they are subject to the least amount of bias [2].

Bibliometrics is a set of methods used to evaluate scientific publications within a discipline on a specific topic [2]. Bibliometric studies are useful for evaluating the social and scientific importance of a specific discipline during a given period of time. As objective instruments, they can be used together with expert judgements to produce an unbiased assessment of scientific activity and its possible evolution and trends [3]. However, this type of analysis is rarely used in the literature to benchmark performance in the field of obstetrics. Although there are bibliometric studies on obstetrics and gynecology as a specialty and on specific areas of gynecology [4, 5], any studies that examine the production of RCTs in the field of obstetrics were found. For this reason, a bibliometric study to analyse

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worldwide obstetrics research carried out through RCTs was conducted, covering the period from 2002 to 2013.

Material and methods

An observational, descriptive, retrospective study was conducted through a review of the articles on obstetrics that were published by journals indexed in the MEDLINE database from 2002 to 2013. The major medical subject headings (MeSH) used in the search were *obstetrics*, *pregnancy complications* and *obstetrics surgical procedures*. A search was performed with PubMed in July and August 2014 using the following search strategy: ("obstetrics"[MeSH Terms] OR "obstetrics"[All Fields]) OR ("pregnancy complications"[MeSH Terms] OR ("pregnancy"[All Fields] AND "complications"[All Fields]) OR "pregnancy complications"[All Fields]) OR (("obstetrics"[MeSH Terms] OR "obstetrics"[All Fields]) AND ("surgical procedures, operative"[MeSH Terms] OR ("surgical"[All Fields] AND "procedures"[All Fields] AND "operative"[All Fields]) OR "operative surgical procedures"[All Fields] OR ("surgical"[All Fields] AND "procedures"[All Fields]) OR "surgical procedures"[All Fields])) AND ((Clinical Trial[ptyp] OR Randomized Controlled Trial[ptyp]) AND ("2002/01/01"[PDAT]: "2013/12/31"[PDAT]) AND "humans"[MeSH Terms]).

The National Library of Medicine (MEDLINE) PubMed database was used to select RCTs in obstetrics published between 2002 and 2013. To identify the impact factor (IF) and quartile (Q) of each journal, the Web of Science database was consulted. Lastly, the Scopus database (an abstract and citation database of peer-reviewed literature) was used to identify the institutions employing the most productive authors, the articles written by two or more of these authors in co-authorship and the number of citations received by these articles during the study period.

For each record, the following information was collected and analysed: names, addresses and affiliations of authors; country, language and date of publication; MeSH terms; journal name and journal title abbreviation.

As a methodological basis for analysing the results, a series of standard bibliometric indicators were applied. The number of published articles was used as an index of research productivity. The growth rate, defined as the total number of articles divided by the number of articles obtained in the first year of study multiplied by 100, was analysed. As a bibliometric indicator of production, the Price's law was applied. According to this law, the growth of scientific production follows an exponential function until reaching a saturation point, after which it slows down to become linear. To determine whether the increase in data reflected exponential growth or linear growth, a linear curve fitting ($y = 44{,}871x\text{-}89{,}247$) and an exponential curve fitting ($Y = 3E\text{-}45e^{0.545x}$) were used.

Then, the productivity index (PI) of each author was calculated. Using the PI (logarithm of n values for each author), four levels of productivity were established: PI = 0 for authors with a single publication (this level determines the transience index, or percentage of authors with one published document); $0 < PI < 1$ for authors who published between two and nine articles; $1 < PI < 1.3$ for highly productive authors, with ≥ 10 articles; and $PI \geq 1.3$ for top producers, with more than 20 published articles.

To measure the degree of collaboration among authors, the collaboration index, or mean number of authors per paper was used. Then, the extent of collaboration was mapped through social network analysis. The 20 most productive authors and the co-authorship patterns among them were identified. To visualise this network the VOSviewer v.1.6.3 software tool was used. In the figures produced by this tool, the size of the spheres reflects the total number of citations received by the co-authored papers, and the thickness of the lines connecting two spheres reflects the number of articles published by two authors working in collaboration.

The Bradford's law was used to measure the scattering of scientific information. The model proposed by Bradford consists of concentric zones (Bradford's zones) arranged in decreasing order of productivity. Each zone contains a similar number of articles, but the number of journals increases on moving away from the nucleus.

The address/affiliation data or first authors' addresses were used to identify the institutional affiliation. To determine changes in topics of publication, the MeSH terms obtained at the beginning of the study period (2002) and at the end (2013) were analysed.

The IBM SPSS Statistics software (v.22.0) was used to analyse the data. A logistic regression analysis was performed to calculate growth rate, author productivity and journal dispersion. To determine correlation between two variables the chi-square test was used, with $p < 0.05$ considered an indicator of statistical significance.

Results

Our study search strategy yielded a total of 142,659 articles and 9967 RCTs (6.95% of the total) in obstetrics published from 2002 to 2013. Online Resource 1 shows the annual distribution of obstetrics RCTs. In all medical disciplines, 389,207 RCTs were published in the study period. The mean proportion of RCTs within the total scientific production in all medical fields was 4.28%.

The growth rate of total scientific production in obstetrics from 2002 to 2013 was 55.43%. Obstetrics RCTs, meanwhile, experienced a growth rate of 97.84%. To analyse productivity and determine the location of obstetrics production from 2002 to 2013 on the growth curve, the Price's law was applied. In

the mathematical curve fitting, the curve was best fitted to a linear model ($y = 458.61x\text{-}908968$, $R^2 = 0.97149$). The data on RCTs in obstetrics published between 2002 and 2013 were fitted linearly ($y = 44.871x\text{-}89{,}247$, $R^2 = 0.91263$) and exponentially ($y = 3E\text{-}45e^{0.0545x}$). These results confirm that the growth of RCTs in obstetrics during the study period was in the linear growth phase described by Price in his theory on the expansion of scientific literature.

According to our results, a total of 31,623 authors published scientific articles during the study period. After calculating author PI, 88 (0.28%) were top producers (> 20 articles published), 329 (1.05%) were highly productive authors, 8582 (27.45%) published between two and nine articles and 22.622 published only one article. To calculate the transience index, this figure was divided by the total number of authors and multiplied by 100, giving 71.5%.

In addition, the names of the 20 authors who had published the most articles in the study period were identified and, also, the number of articles they had published as first authors, then the proportion of their total scientific production represented by these articles was calculated (Table 1).

Most articles identified in our study were published in Europe (41.06%) and North America (25.96%). Asia represented 19.55% of scientific production; South America, 4.74%; Oceania, 4.56%; and Africa, 3.51%. Table 2 shows the absolute growth and percentage growth of scientific production in each continent during the study period. The difference in scientific production rate of all continents from the beginning to the end of the study period was statistically significant ($p = 0.004$).

Universities were the most productive institutions, representing 44.6% of total production, while 14.4% of the literature was generated in the clinical context. Collaboration between hospitals and the universities represented 20% of total production, while the remaining 21.9% came from public and private institutions.

The mean number of authors per article (± standard error of the mean) during the study period was 5.87 (± 0.035). The collaboration index increased during the study period by 21.7% (5.26 in 2002 and 6.40 in 2013). All the authors except for Creinin MD and Fawzi WW formed co-authorship ties. Figure 1 shows a graphical depiction of this network, created using VOSviewer.

The 9967 RCTs in obstetrics were published in 1034 different journals. Online Resource 2 shows how the literature was divided into Bradford's zones. Table 3 shows the journals in Bradford's nucleus and zone 1, their impact factor (IF) in the first year (2002 or the first year the journal was included in *Journal Citation Reports* (JCR)) and in 2013, and the category they belong to. The mean IF for the journals in the nucleus in the first year was 2.579 and in the last year, 4.0 (increase of 55.1%). The mean IF for the journals in Bradford's zone 1 in the first year was 2.667 and in the last year 5.134 (increase of 92.5%). A value of $p = 0.01$ was considered to indicate statistical significance.

Table 1 Names of the 20 authors who published the most articles between 2002 and 2013, number of articles published by each author (and percentage of total published articles), number of articles published as first author (and percentage of that author's total published articles) and institutional affiliation

Rank	Author	No. (%) of articles	No. (%) of articles as first author	Institution from
1	Mol, B. W.	126 (1.26)	0 (0)	Amsterdam
2	Crowther, C. A.	69 (0.69)	18 (26.1)	Sydney
3	Zullo, F.	47 (0.47)	8 (17.0)	Naples
4	Hofmeyr, G. J.	46 (0.46)	19 (41.3)	Johannesburg
5	Palomba, S.	46 (0.46)	35 (76.1)	Naples
6	Ho, P. C.	44 (0.44)	0 (0)	Hong Kong
7	Khan, K. S.	39 (0.39)	0 (0)	London
8	Nappi, C.	38 (0.38)	4 (10.5)	Naples
9	Van der Veen, F.	38 (0.38)	0 (0)	Amsterdam
10	Creinin, M. D.	37 (0.37)	8 (21.6)	Sacramento
11	Fawzi, W. W.	36 (0.36)	5 (13.8)	Boston
12	Caritis, S. N.	35 (0.35)	2 (5.7)	Pittsburgh
13	Spong, C. Y.	35 (0.35)	0 (0)	USA
14	Wapner, R. J.	34 (0.34)	1 (2.9)	New York
15	Alfirevic, Z.	33 (0.33)	10 (30.3)	Liverpool
16	Ng, E. H.	33 (0.33)	8 (24.2)	Hong Kong
17	Rouse, D. J.	33 (0.33)	3 (9.1)	Providence
18	Russo, T.	33 (0.33)	1 (3)	Messina
19	Falbo, A.	32 (0.32)	0 (0)	Galveston
20	Winikoff, B.	32 (0.32)	0 (0)	Baltimore

Table 2 Absolute growth and percentage growth of scientific production in each continent from 2002 to 2013

Continent	% total production		Absolute growth (%)	Percentage growth (%)
	2002 (%)	2013 (%)		
Europe	46.1	32.7	− 13.4	− 29.11
North America	23.9	22.7	− 1.2	− 5.20
Asia	12.1	20.1	8.1	67.04
Oceania	4.5	6.4	1.9	43.43
South America	1.6	3.7	2.2	139.74
Africa	1.2	3.7	2.6	219.65

Twenty-one different languages were identified. The vast majority of the articles (96%) were written in English. Chinese was the second most common language but was used in only 1.7% of the total number of articles. French and Spanish were the third and fourth most common languages, at 0.5% in both cases.

A total of 156,806 MeSH terms were obtained: 7932 in 2002 (14 per article) and 25,197 in 2013 (22 per article). By the end of the study period, the number of MeSH terms per article had increased by 8, or 57%. Online Resource 3 shows the 50 most frequent MeSH terms (representing 37.7% of the total). After analysing these descriptors, they were grouped into seven categories: (1) descriptors that can be classified as diseases or procedures according to the International Classification of Diseases, Ninth Revision (ICD-9); (2) descriptors related to sociodemographic data; (3) descriptors related to nonspecific medical terminology; (4) descriptors related to epidemiology and statistical methodology; (5) descriptors related to general obstetrics; (6) descriptors related to general gynecology; and (7) miscellaneous, including descriptors related to organisational and educational aspects. Online Resource 4 shows the distribution of the MeSH terms among these seven categories in 2002 and 2013 ($p < 0.001$). Only 38% of the MeSH terms found in 2002 and 31% of those found in 2013 could be classified as diseases or procedures according to the ICD-9. Online Resource 5 shows the distribution of the descriptors by disease chapters in 2002 and 2013. The difference between these proportions was statistically significant ($p < 0.001$).

Discussion

For this study, a worldwide bibliometric analysis of obstetrics over 12 years was conducted. This long period, together with the exhaustive nature of the bibliographic search, enabled us to correctly apply bibliometric methods and indices in order to reduce data relativity as far as possible.

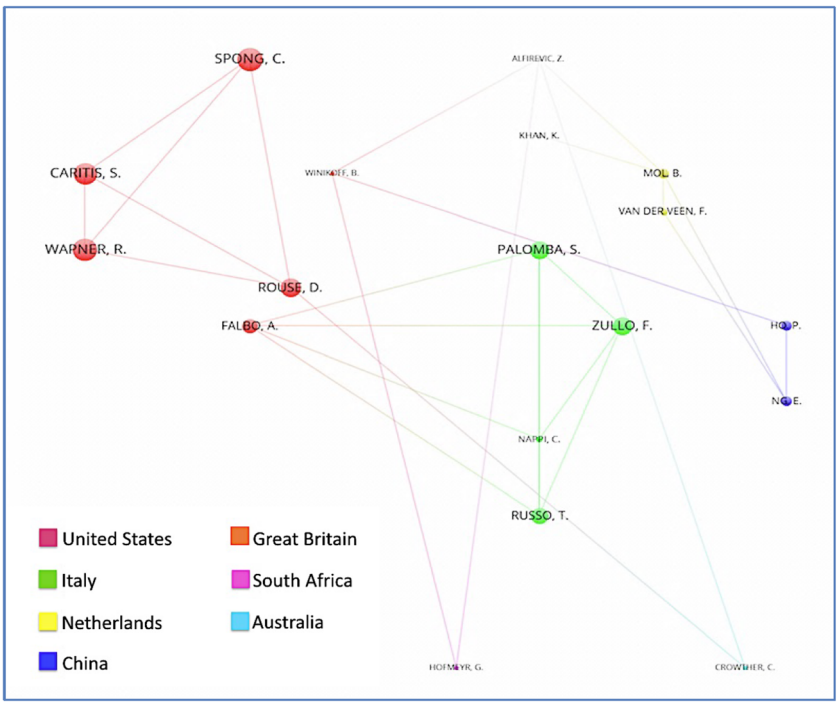

Fig. 1 Network of co-authorship among the most productive authors

Table 3 Number of articles within Bradford's nucleus and zone 1, and their percentage as a proportion of total articles published during the study period, IF of journals within Bradford's nucleus in the first year (2002) or the first year the journal was included in the JCR and last year (2013)

		Journal	No. articles (%)	IF-2002	IF-2013
Nucleus	1	The Cochrane Database of Systematic Reviews	505 (5.2)	4.654[a]	5.939
	2	American Journal of Obstetrics and Gynecology	461 (4.7)	2.556	3.973
	3	Fertility and Sterility	453 (4.6)	3.202	4.295
	4	Obstetrics and Gynecology	432 (4.5)	2.482	4.368
	5	BJOG: An International Journal of Obstetrics and Gynaecology	381 (4.0)	1.864	3.862
	6	International Journal of Gynaecology and Obstetrics: the Official Organ of the International Federation of Gynaecology and Obstetrics	288 (3.0)	0.719	1.563
		Total	2520 (26)		
Zone 1	1	Human reproduction	251 (2.5)	3.253	4.585
	2	Contraception	213 (2.2)	1.443	2.932
	3	European journal of obstetrics, gynecology, and reproductive biology	175 (1.8)	0.854	1.627
	4	Acta obstetricia et gynecologica Scandinavica	173 (1.7)	1.241	2.005
	5	Archives of gynaecology and obstetrics	164 (1.6)	0.666 ([a]2007)	1.279
	6	Gynecologic oncology	126 (1.3)	2.115	3.687
	7	The journal of maternal-fetal and neonatal medicine: the official journal of the European Association of Perinatal Medicine, the Federation of Asia	109 (1.2)	1.000 ([a]2007)	1.208
	8	BMC pregnancy and childbirth	97 (1.1)	2.834 ([a]2011)	2.152
	9	Gynecological endocrinology: the official journal of the International Society of Gynecological Endocrinology	96 (1)	0.899	1.136
	10	The journal of obstetrics and gynaecology research	95 (1)	0.474 ([a]2004)	0.931
	11	Maturitas	94 (1)	2.068	2.861
	12	Anesthesia and analgesia	91 (1)	2.332	3.422
	13	BMJ: British Medical Journal	86 (0.9)	7.585	16.378
	14	Journal of the Medical Association of Thailand	86 (0.9)	No included in JCR	No included in JCR
	15	Menopause	85 (0.9)	3.217	2.807
	16	Journal of minimally invasive gynecology	82 (0.9)	1.633 ([a]2006)	1.575
	17	The Journal of clinical endocrinology and metabolism	76 (0.8)	2.097 ([a]2010)	6.31
	18	International journal of obstetric anesthesia	74 (0.8)	0.963	1.832
	19	Lancet	71 (0.7)	15.397	39.207
	20	The Australian and New Zealand journal of obstetrics and gynaecology	68 (0.7)	0.608	1.62
		Total	2.261 (24)		

[a] The Cochrane Database of Systematic Reviews was included in the JCR in 2007

The growth rate of total scientific production in obstetrics from 2002 to 2013 was 55.43%. Obstetrics RCTs, meanwhile, experienced a growth rate of 97.84%. This upward trend coincides with the findings of previous studies. Other authors [6] observed a growth rate of 58% in obstetrics and gynecology literature between 2003 and 2012. RCTs represent a surprisingly small proportion of total scientific production, both in obstetrics and in medicine in general, despite being considered the gold standard of study designs. This is probably due to the complexity of conducting these studies: they require advanced knowledge of methodology and considerable funding, and they are very time consuming [2]. In obstetrics, the task is further complicated by certain ethical issues, particularly in perinatal medicine, and the difficulty of recruiting enough pregnant women who consent to participate in a study. According to Stockmann et al. [7], there is a great deal of unpublished research in obstetrics. This author found that in 2014, there were more than 5000 obstetric studies registered on the website *ClinicalTrials.gov*, but only 7% of these studies had been published. Previous authors [8] identified the 100 most cited articles between 1957 and 2004; only 7 were RCTs.

The production of RCTs in obstetrics from 2002 to 2013 shows a linear growth rate, which means growth is constant but independent of sample size, and has not yet reached the saturation point. In a study on productivity of Spanish authors in obstetrics and gynecology from 1986 to 2002 [3], the authors found that the number of Spanish publications grew exponentially, and that the saturation process described by Price had been reached by the end of the study period.

The transience and productivity indexes of authors provide interesting data; the number of occasional or transient authors is lower in disciplines where scientific activity is well-

established, meaning that a high transience index reflects a lack of relevant working groups, although it could also indicate the presence of researchers from other related scientific areas or the passing collaboration of resident physicians during their training period. A transience index of 71.5% was obtained, and the top and highly productive authors accounted for 1.33% of the total. The authors of the Spanish study [3] reported a transience index of 70.9%, but 2.79% of the authors they identified were highly productive. In primary care, meanwhile, other authors [9] found a transience index of 83.17% between 2000 and 2004, and only 0.23% top and highly productive authors.

The most productive author identified in the present study was Prof. Dr. Mol. [10]. Aleixandre-Benavent et al. [6] also identified Prof. Mol as the highest ranking author, in terms of both articles published and number of citations received in obstetrics and gynecology.

The continent with the largest production of articles during the study period was Europe, followed by North America. Over the course of the study period, however, a downward trend in European and North American production (Table 2) was observed. This change may be due to the economic changes occurring over the study period. The financial crisis that emerged in 2007 in the USA and Europe could explain a drop in research funding. Furthermore, the World Bank [11] identified a number of countries (China, India, Brazil, South Africa and Turkey) as having emerging economies, which would justify the increase in scientific production in Asia, Africa and South America.

Universities were the most productive institutions of RCTs in obstetrics, as they are in other specialties, such as spinal surgery [12] and primary care [9]. In their article on papers published in Denmark from 2000 to 2009, previous authors [13] showed that the proportion of clinical trials in university-affiliated publications was twice that of other publications.

The authors/paper index was used as an indicator of collaboration among authors. The number of authors in the papers is associated with the level of financial support and the productivity indices of the authors [6, 14, 15]. Our collaboration index was relatively high at 5.87, having increased by 21.67% over the study period. In *Spinal Surgery* [12] from 2004 to 2013, this index was 5.0, and in *Cardiac Surgery* [16] in 2006, 73.9% of articles included six authors or more.

The social relationships established among the authors who produced the greatest number of obstetrics RCTs between 2002 and 2013 (Fig. 1) were identified and graphically represented. Two clear co-authorship networks, one in the USA and another in Italy, reveal a trend towards geographic collaboration within the same country. The co-authorship network linking Ng E. and Ho P. with Winikoff B. (Department of Biostatistics) and Mol B., (expert in epidemiology and statistics) gives us an idea of the complexity of these studies, which require the collaboration of experts in statistics and epidemiology.

Bradford's law can be used to find the most important journals in a given scientific community. The findings of this study showed that 89.7% of the articles were published in 19 journals included in the JCR category *Obstetrics & Gynecology*. Meanwhile, 10.3% of the articles were published in journals from other medical categories: 8% in *Medicine, General & Internal*; 1.8% in *Anesthesiology* and 0.8% in *Endocrinology & Metabolism*. A limitation of a previous study [8] was the fact that the search for the 100 most cited articles was only conducted on journals included in the category *Obstetrics and Gynecology*. Previously, an author [17] identified the 100 most cited articles published in the journal *JAMA*, and four of them were related to obstetrics and gynecology.

The IF is the standard criterion for comparing scientific journals belonging to the same category. In order to compare journals belonging to different categories, the quartiles can be used. In this study, all but one of the journals in the nucleus were in Q_1. Of the journals in Bradford's zone 1, nine were in Q_1, three in Q_2, four in Q_3 and three in Q_4. This means that more than half of the journals identified (54%) were among the most relevant of their category. This result is consistent with the type of study analysed (RCTs). When the articles on obstetrics and gynecology published between January and June 2006 in six different journals were analysed in a previous study [18], these authors found that RCTs represented a quarter of the total, and the proportion of RCTs was three times higher in journals with a high IF that in those with a moderate IF. The results of this study showed an increase in mean journal IF at the end of the study period. Other authors [19] also found an increase in the mean IF of 43 journals included in the category *Obstetrics & Gynecology* from 1.68 in 2007 to 2.12 in 2013.

Most of the obstetrics RCTs were published in English. Publishing in English facilitates international communication and enables the information to be shared by a wide audience [20].

Identifying publishing subject areas and the evolution of research streams is an interesting area of analysis. The MeSH terms that could be classified as diseases or procedures according to the ICD-9 were found in practically all the diseases included in "complications of pregnancy, childbirth and the puerperium" and "certain conditions originating in the perinatal period".

In 2013, a larger number of MeSH terms were included in *early or threatened labor* and *diabetes mellitus and abnormal glucose tolerance*, and there was a slight reduction in mesh terms related to *hypertension complicating pregnancy, childbirth and the puerperium*. Research in the field of perinatal medicine also increased in 2013, in accordance with the current trend in obstetrics treating "*the foetus as a patient*". There was an increase in MeSH terms related to *noxious influences affecting fetus or newborn* via *placenta or breast milk* and *poor fetal growth*.

There was also an increase in the descriptors on *diagnostic ultrasound of gravid uterus*. Ultrasonography is an essential diagnostic tool in modern obstetrics, and the Doppler scan is essential in the management of foetuses with delayed growth.

A significant increase in the number of MeSH terms related to *external cephalic version* were found, indicating a probable resurgence of the technique in an attempt to reduce the rate of Caesarean sections due to breech presentation. In 2013, new descriptors related to *repair of obstetric laceration* appeared, perhaps in keeping with the current trend to prevent routine use of episiotomy.

The limitations of our study include the fact that the study data were obtained from the MEDLINE database, which is both bibliographic and non-bibliographic. As it only collects data from a single author affiliation, there is a risk of underestimating the scientific contribution of certain institutions or countries in the case of multicentre studies or international collaboration. Although the terms "obstetrics", "pregnancy complications" and "obstetrical surgical procedures" were used in the study search, it cannot be assured that there were no RCTs on assisted reproduction or gynecology including MeSH terms related to obstetrics among the retrieved articles. Nor can it be assured that there were no meta-analyses included in the sample, although the "clinical trial" was used as a methodological search filter.

Conclusion

Randomised clinical trials represent a small proportion of total scientific production, both in obstetrics and in medicine in general. Total scientific production rate in obstetrics increased from 2002 to 2013, specially randomised clinical trials. The findings of this study may provide an insight into worldwide obstetric research for obstetricians and researchers and may also help policy makers to evaluate the research performance of scientists within and across borders.

Author contribution AM Palacios-Marqués: project development, data collection, manuscript writing
C Carratala-Munuera: project development, data collection
J C Martínez-Escoriza: project development, data collection
V F Gil-Guillen: data analysis, manuscript writing
A Lopez-Pineda: data review, manuscript writing/editing
J A Quesada: data review, data analysis
D Orozco-Beltrán: data review, data analysis

Compliance with ethical standards

Conflict of interest The authors declare that they have no conflict of interest.

Ethical approval This is a bibliometric analysis not involving human subjects and is therefore exempt from institutional review board approval. For this type of study, formal consent is not required.

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