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Global Authorship Representation in Otolaryngology Clinical Trials

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ABSTRACT

Objective: To investigate global authorship representation in clinical trials published in major general otolaryngology journals over the past two decades.

Methods: We conducted a bibliometric analysis of clinical trials published in four major general otolaryngology journals between 2000 and 2020. The affiliated nationalities of authors in leading positions (first, senior, corresponding) were reviewed for each trial. Countries were classified by World Bank income group. The temporal trajectory of representation was estimated in multivariable logistic regression models, adjusting for publication environment and study design. The academic impact of trials across income groups was also compared.

Results: Among 1432 trials, the leading authors for most were affiliated with non-USA nations (57%) and high-income countries (HIC) (87%). Trials led by authors from upper-middle income countries (UMIC), lower-middle income countries (LMIC), and low-income countries (LIC) were severely underrepresented (11%, 3%, 0%, respectively). Over time, non-USA representation increased (+0.5%, 95% CI [+0.13%, +0.92%] per year), HIC representation decreased (−0.45% [−0.77%, −0.12%]), UMIC representation remained stable (0.19% [−0.13%, 0.51%]), LMIC representation mildly increased (0.26% [0.16%, 0.35%]), and LIC representation remained absent (0%). UMIC author-led trials (aIRR 0.80 [0.68, 0.94]) received significantly fewer citations compared to HIC author-led trials regardless of study design and publication year.

Conclusions: The clinical trial literature in the four most widely circulated OHNS journals is dominated by HIC authorship, with only marginal growth in LMIC contributions and no representation from LICs over the past two decades. This underrepresentation may impact the applicability of clinical guidelines in lower-income regions.

This study has not been presented.

1 | Introduction

Clinical trials are widely recognized as the gold standard for evidence in clinical research, fundamentally shaping medical knowledge and the formulation of clinical practice guidelines [1]. According to previous research, the demographic diversity of authorship in randomized controlled trials tends to reflect the diversity of the patient population enrolled [2]. Consequently, a globally diverse authorship is essential for the inclusive representation of diverse patient groups and the development of clinical guidelines that are broadly applicable across worldwide populations. However, significant deficiencies in global authorship diversity are known to pervade the medical science literature. A 2004 bibliometric analysis of the top five medical journals found that authorship from outside the UK, USA, and affluent Euro-American countries comprised less than 7% of total contributions [3]. This trend of underrepresentation has been similarly observed in the global surgery literature, where only 30% of first or senior authors are from low-income countries (LICs) or middle-income countries (MICs) [4].

In the field of otolaryngology–head and neck surgery (OHNS), authorship from low- and middle-income nations (LMIN, including LICs and MICs) is underrepresented despite the disproportionate burden of otolaryngological diseases in these countries. A recent study revealed that scholars from LMIN constituted only 6% of first authors in major OHNS journals [5]. However, LMINs were estimated to account for 67% of head and neck cancer cases and 82% of related deaths [6–8]. Moreover, LMINs are projected to incur $394 billion USD in economic losses due to head and neck cancer mortality between 2018 and 2030 [6–8]. Given the pivotal role of clinical trials in shaping clinical practice, promoting leadership and participation from LMINs, as reflected by authorship representation, is essential to producing high-quality evidence that addresses the specific needs of these populations.

To date, no study has examined the global authorship representation within the OHNS clinical trial literature. In this study, we analyze the affiliated nationalities of lead authors in clinical trials published in major general OHNS journals over the past two decades. Our objective is to evaluate the current state and historical trends in global authorship diversity of OHNS clinical trials. We hypothesize that although HIC authorship remains dominant, the gap between HIC and LMINs may have narrowed over time.

2 | Methods

2.1 | Study Population and Design

We performed a bibliometric analysis of clinical trials published in the four most widely circulated general OHNS journals during the study period according to Yao et al. [9] and Banglawala et al. [10]: *The Laryngoscope, Otolaryngology–Head and Neck Surgery* (*OHNS*), *JAMA Otolaryngology–Head and Neck Surgery* (*JAMA-OHNS*), and *Annals of Otology, Rhinology, & Laryngology* (*A-OLR*). Articles were included if they were published between 2000 and 2020, categorized as clinical trials, and had an abstract available on PubMed. Articles were excluded if they were retracted or erroneously classified as clinical trials. We examined the representation of clinical trials led by authors from country income groups over time and compared the academic impact of trials based on the income classification of the lead authors' affiliated nationalities. As this study did not involve human subjects, IRB approval was not required. Study data are available upon request from the corresponding author.

2.2 | Variable Characterization

Two variables were computed for affiliated nationality: a dichotomous variable evaluating whether the affiliated institution was located in the United States (US), and a four-level ordinal variable based on the World Bank Country and Lending Group (WB) classification of the affiliated nation (high-income country [HIC], upper-middle-income country [UMIC], lower-middle-income country [LMIC], or low-income country [LIC]) [5, 11]. In this article, UMIC, LMIC, and LIC are collectively referred to as low- and middle-income nations (LMIN). For each clinical trial, the affiliated nationality was assessed for the first author (FA), senior author (SA), and corresponding author (CA). For authors with multiple affiliations across institutions in different income groups, an internet search was conducted to determine the institution with which the author has the closest association or most significant appointment.

Article impact was measured by the number of citations on Google Scholar as of June 2023. The subspecialty related to the trial topic was recorded. Though study quality can be characterized by many dimensions, in this study, study design quality was characterized using two metrics: trial randomization (binary variable: randomized vs. non-randomized) and sample size (linear variable) [12–17].

2.3 | Statistical Analyses

Two research hypotheses were tested. First, we hypothesized that disparities in authorship representation narrowed over time. Specifically, we expected an increase in the proportion of trials led by authors from non-USA nations and LMINs over time. To evaluate this hypothesis, we constructed multivariable regression models estimating the proportion of USA-led trials and the proportion of trials led by authors from nations of different WB classifications. Publication year was incorporated as the primary covariate of interest in both models. Binary logistic regression models were used to evaluate author affiliated nationality (USA/non-USA), and multinomial logistic regression models were used to evaluate WB classification.

Second, we hypothesized that trials led by authors from higher income nations would have accumulated a greater number of citations compared to trials led by authors from lower income nations. We constructed multivariable negative binomial regression models estimating citation count per trial with WB classification as the primary covariate. All models adjusted for journal, publication year, subspecialty, study randomization, and sample size.

We performed three iterations of each model: one for FA, one for SA, and one for CA. Statistical significance was defined as $\alpha = 0.05$. All statistical analyses were performed with Stata, Version 17.

3 | Results

A total of 1432 trials were included, 41% ($n=587$) by *The Laryngoscope*, 31% ($n=444$) by *OHNS*, 18% ($n=258$) by *JAMA-OHNS*, and 10% ($N=143$) by *A-ORL*. The distribution of trials by subspecialty was as follows: 23% rhinology, 20% otology, 14% head and neck, 13% laryngology, 9% pediatric otolaryngology, 9% comprehensive otolaryngology, 9% sleep medicine, and 4% facial plastics and reconstructive. Most trials were randomized (64%) and reported positive findings (83%).

Table 1 provides a summary of the affiliated nationalities of leading authors in clinical trials. The FA (57.4%), SA (56.5%), and CA (56.7%) for most trials were affiliated with non-USA nations. At the leading positions, 86%–87% of trials were led by authors from a HIC, 11% of trials were led by authors from an UMIC, 3% of trials were led by authors from a LMIC, and 0% of trials were led by authors from a LIC.

Table 2 and Figure 1 detail authors' affiliated nationality. Among non-USA nations, the highest representation of HIC authorship originate from South Korea (5%), Germany (5%), Canada (4%), and Italy (4%). The highest FA representation of UMIC authorship originate from Turkey (6%), China (2%), and Brazil (2%). The highest FA representation of LMIC authorship originate from Iran (1%), Egypt (1%), and India (1%).

Figure 2 illustrates the temporal trajectory in global authorship representation between 2000 and 2020. Over time, there was a significant increase in the proportion of trials led by non-USA affiliated FAs (adjusted 0.5%, 95% CI [0.1%, 0.9%] increase per year), from an adjusted rate of 49% [45%, 54%] in 2000 to 60% [55%, 64%] in 2020. There was also a significant increase in the proportion of trials led by non-USA affiliated SAs (adjusted 0.4% [0.03%, 0.85%] increase per year), from an adjusted rate of 49% [44%, 54%] to 58% [53%, 62%]. Similar trends were also observed at the CA position.

With respect to WB classification, the proportion trials led by HIC-affiliated FAs decreased over time (adjusted −0.5% [−0.1%, −0.8%] per year), from an adjusted rate of 91% [87%, 94%] in 2000 to 82% [78%, 86%] in 2020. The proportion of trials led by UMIC-affiliated FAs remained stable over time (adjusted +0.2% [−0.1%, +0.5%] per year). The proportion trials led by LMIC-affiliated FAs increased over time (adjusted 0.3% [0.2%, 0.4%] increase per year), from an adjusted rate of 0.2% [0%, 0.6%] to 5.4% [3.6%, 7.1%]. Similar trends were observed at the SA and CA positions, Figure 2.

The crude and adjusted citation counts per trial stratified by authors affiliated nationality are illustrated in Figure 3. The citations of trials led by USA affiliated authors did not differ significantly from those of trials led by non-USA affiliated authors at the FA (aIRR 1.08 [0.96, 1.21]), SA (aIRR 1.11 [0.99, 1.25]), and CA (aIRR 1.05 [0.94, 1.18]) positions. Compared to trials led by FAs from HIC nations, trials led by FAs from UMIC nations received significantly fewer citations (aIRR 0.80 [0.68, 0.94], adjusted citations: UMIC 46 [54, 63] vs. HIC 68 [65, 72]). Similar findings were observed at the SA (aIRR 0.76 [0.64, 0.90]) and CA (0.79 [0.67, 0.92]) positions. Citations of trials led by FAs from LMIC nations did not differ significantly compared with those of trials led by FAs from HIC nations (aIRR 0.92 [0.62, 1.35]). Similar findings were observed at the SA (0.76 [0.51, 1.13]) and CA (0.95 [0.66, 1.38]) positions.

4 | Discussion

In this bibliometric analysis of clinical trials published in the four most widely circulated OHNS journals during the first two decades of the 2000s, authorship in leading positions was overwhelmingly dominated by HICs, with only a marginal increase in LMIC representation over time. Notably, our analysis revealed a complete absence of LIC authorship in leading positions throughout the entire 20-year period.

4.1 | Global Disparities in Authorship Representation

Bibliometric analyses of Cochrane reviews across various fields have consistently highlighted the underrepresentation of authorship from LMINs [2, 18, 19]. Our analysis of OHNS clinical trials adds to this literature noting that 86% of lead authorship originated from HICs, while only 3% and 0% originated from LMICs and LICs, respectively. Although the journals included

TABLE 1 | Summary of leading author affiliated nationality of clinical trials published in four major otolaryngology journals.

Clinical trials ($N=1432$)	First author (FA)	Senior author (SA)	Corresponding author (CA)
Affiliated nationality			
Non-USA	57.4%	56.5%	56.7%
USA	42.6%	43.5%	43.3%
World Bank Country and Lending Group classification (WB)			
High income (HIC)	85.9%	86.5%	86.1%
Upper-middle income (UMIC)	11.3%	10.9%	11.1%
Lower-middle income (LMIC)	3.0%	2.9%	3.0%
Low income (LIC)	0%	0%	0%

TABLE 2 | Detailed distribution of author affiliated nationality and world bank country.

	Author	First	Senior	Corresponding
WBC	**Country**		**% Trials**	
HIC	USA	42.6	43.5	43.3
	South Korea	5.4	5.5	5.4
	Germany	4.6	4.7	4.7
	Canada	4.4	4.8	4.4
	Italy	3.8	3.4	3.6
	Netherlands	2.9	3.0	3.0
	Japan	2.2	2.1	2.2
	Australia	2.1	1.7	1.9
	Finland	1.8	1.7	1.7
	Sweden	1.8	2.0	1.9
	Taiwan	1.8	1.8	1.8
	UK	1.7	1.9	1.7
	Israel	1.5	1.6	1.5
	Spain	1.5	1.4	1.5
	Greece	1.0	1.1	1.0
	France	0.8	0.9	0.8
	New Zealand	0.7	0.6	0.6
	Singapore	0.7	0.4	0.6
	Belgium	0.6	0.6	0.6
	Norway	0.5	0.4	0.4
	Austria	0.4	0.4	0.4
	Hong Kong	0.4	0.5	0.5
	Ireland	0.4	0.4	0.4
	Switzerland	0.4	0.4	0.4
	Denmark	0.3	0.3	0.3
	Hungary	0.3	0.2	0.2
	Portugal	0.2	0.1	0.2
	Romania	0.2	0.1	0.2
	Scotland	0.2	0.2	0.2
	Chile	0.1	0.1	0.1
	Czech Republic	0.1	0.1	0.1
	Poland	0.1	0.1	0.1
	Qatar	0.1	0.1	0.1
	Saudi Arabia	0.1	0	0.1
	Slovenia	0.1	0.1	0.1
	Trinidad	0.1	0.1	0.1
	Kuwait	0	0.1	0
	Lithuania	0	0.1	0

(Continues)

TABLE 2 | (Continued)

	Author	First	Senior	Corresponding
WBC	**Country**		**% Trials**	
UMIC	Turkey	5.9	5.9	5.9
	China	2.2	2.2	2.2
	Brazil	1.5	1.4	1.5
	Thailand	0.8	0.8	0.8
	Mexico	0.5	0.4	0.4
	Argentina	0.1	0	0.1
	Malaysia	0.1	0.1	0.1
	Russia	0.1	0	0
	Serbia	0.1	0.1	0.1
LMIC	Iran	1.1	1.1	1.1
	Egypt	0.8	0.8	0.8
	India	0.7	0.7	0.7
	Jordan	0.1	0.1	0.1
	Lebanon	0.1	0.1	0.1
	Pakistan	0.1	0.1	0.1
	Vietnam	0.1	0	0.1

Note: Sorted by proportion of trials with first authors affiliated with the respective countries (high to low).

FIGURE 1 | Global distribution of first (left blue), senior (middle green) and corresponding (right orange) author affiliated nationality.

in this study are US-based, the majority of clinical trials they published (57%) were not led by US authors. This highlights their global reach and readership, despite being based in the US. As leading journals with the highest platform and exposure in the field, they bear the responsibility of ensuring proper global representation of scientific evidence, particularly from lower-income nations where the burden of disease is disproportionately higher.

The disproportionate distribution of global burden of otolaryngology disease underscores the need to prioritize the specific clinical challenges faced by LMINs, particularly through clinical trials tailored to their unique circumstances [20–23]. It is estimated that LMINs account for 67% of head and neck cancer cases and 82% of related deaths [6–8], and that nearly 80% of individuals with hearing loss reside in LMINs [6, 24, 25]. Yet, in the present study, we found that only 3% of trials published in major OHNS journals were led by authors from LMICs, and none by authors from LICs. Clinicians from LMINs are most familiar with the clinically-relevant questions in LMIN health systems, yet the representation of LMIN authorship has shown minimal improvement over time. Lead authorship from LICs has been completely absent from clinical trial publications for 20 years. The increase in LMIC lead authorship has also been marginal, rising by just 0.3% per year. As such, not only is the representation of LMIN authorship low, but current trends portend that significant improvements are unlikely without deliberate intervention. This trend is also seen more broadly in medicine, as research has shown that fewer than 20% of clinical trials are conducted in developing countries [26]. In 1990, the Commission on Health Research for Development published a landmark report identifying the "gross mismatch" between the burden of illness in developing countries and investment in health research, which was termed the "10/90 health research gap", reflecting that only 10% of the world's health resources at that time were being allocated for research into 90% of world health issues [27, 28].

Medical knowledge developed with data from HICs may not be applicable to patients in LMIN health systems, and the underrepresentation of data from LMINs could compromise the effectiveness and quality of patient care. In a study aimed at establishing global consensus on priority otolaryngology conditions, experts from LMINs identified benign thyroid disease and

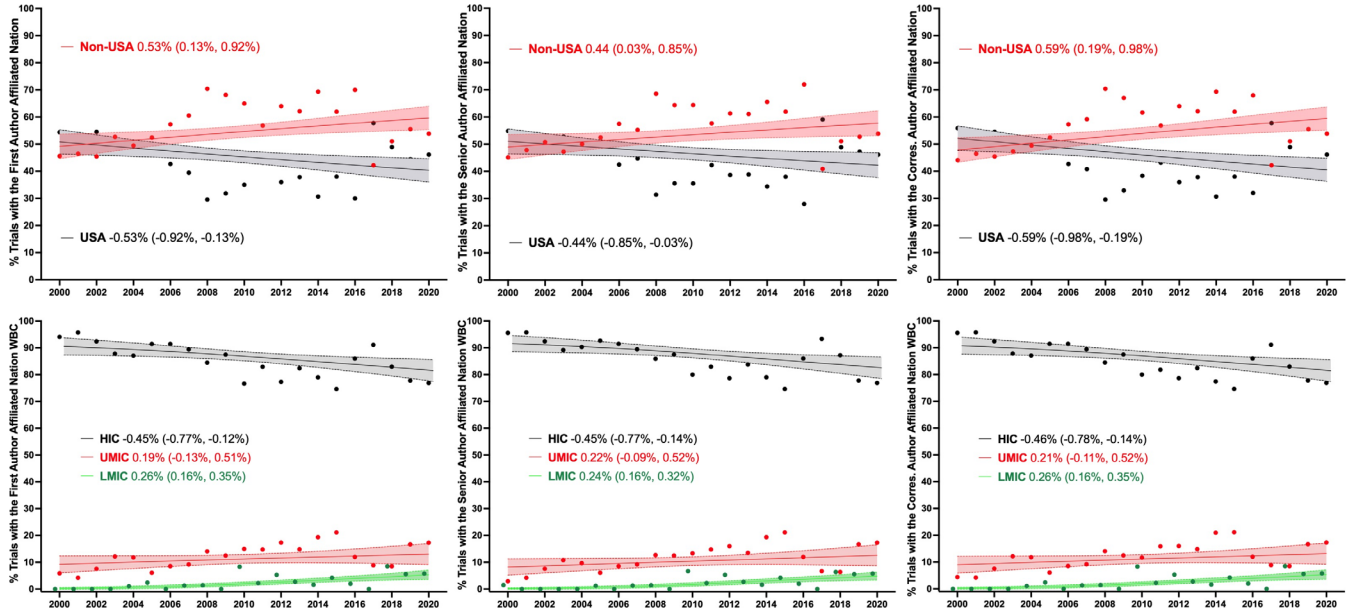

FIGURE 2 | Rates of clinical trials with first (left), senior (middle), and corresponding (right) authors of the respective affiliated nationality over time. Raw annual rates (dots) and adjusted regression estimates ±95% confidence interval (line ± error margins) are illustrated. Adjusted change in percentage per year and 95% confidence intervals are provided in the legends.

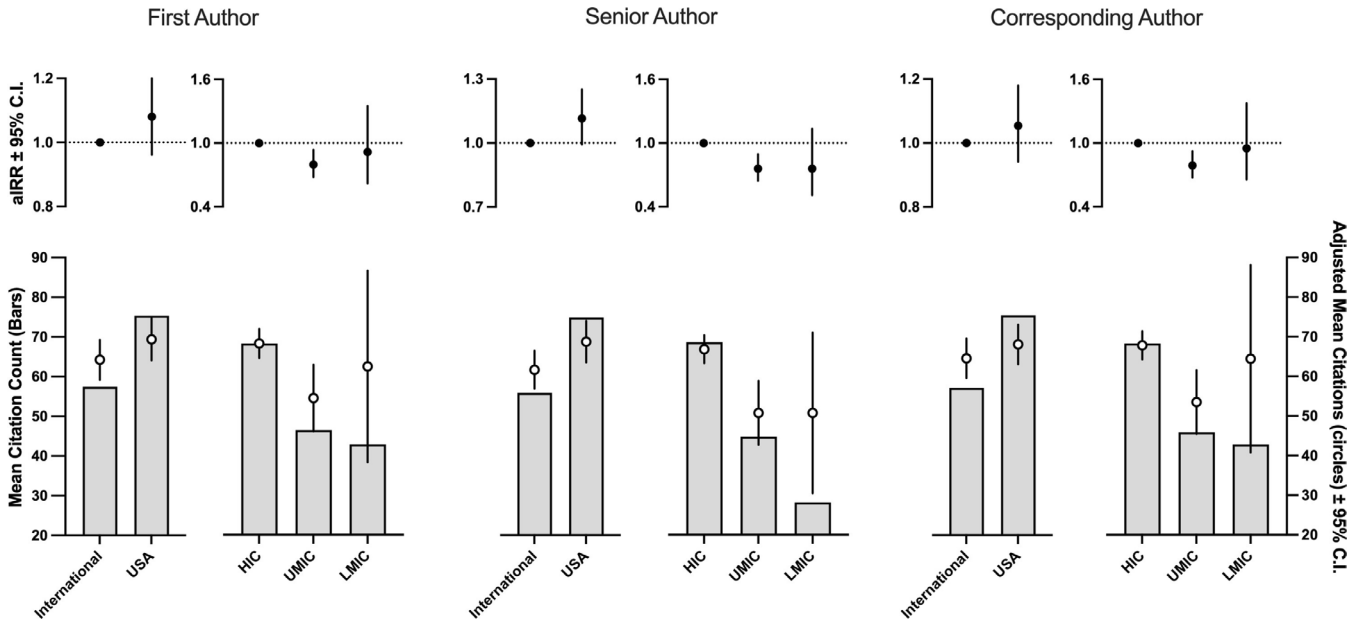

FIGURE 3 | Citation counts by first (A), senior (B), and corresponding (C) author gender, race, academic seniority, and affiliated nationality (left to right). Crude (bars) and adjusted (circles ±95% confidence interval) average citations per clinical trial are illustrated. Confidence intervals for groups of small cell numbers are not presented. aIRR = adjusted incidence rate ratio.

acquired middle ear disease as key priorities, while experts from HICs did not [29]. Furthermore, factors like antibiotic availability and population vaccination may influence disease incidence and prevalence. For instance, high-income nations typically have high vaccination rates for the pneumococcal conjugate vaccine (PCV13), which has been shown to reduce the incidence and prevalence of otitis media [30, 31]. PCV13 vaccination rates are around 90% in the US and Australia, but only around 20% in Nigeria, the most populous country in Africa [32]. As such, the disease burden and epidemiology of otitis media likely vary significantly across regions, and similar clinical guidelines may not be appropriate. Resource-stratified guidelines have therefore been developed for a wide variety of otolaryngologic diseases [33, 34].

4.2 | Barriers to LMIN Authorship Representation

The factors contributing to the underrepresentation of LMIN authorship are likely complex and multifaceted. Immediate barriers to submission may range from open access publishing fees to a preference for the English language [5, 35]. At the review stage,

trials from lower-income nations often face unfavorable assessments due to perceived poorer quality [27]. Previous research has found that trials from lower-income nations tend to have smaller sample sizes compared to those from higher-income nations, which may be perceived by some reviewers as lower level of evidence [20]. We also found that trials led by authors from lower-income nations accumulate fewer citations compared those led by authors from higher-income nations, even after adjusting for publication year, which may stem from the perception of poorer quality. Implicit bias may also reduce the likelihood of trials from lower-income nations being accepted for publication in high-impact journals. A study using a computer-based Implicit Association Test found that many healthcare professionals and researchers subconsciously associate the quality of research with wealthier countries [36].

The most critical obstacles arise long before the journal submission phase. A systematic review identified several key factors that posed barriers to conducting clinical trials in developing countries, including limited financial and workforce capacity, difficulty with ethical and regulatory system, operational barriers, research environment, and competing demands [22]. Among these, access to funding and the shortage of personnel were identified as the most significant barriers. A 2023 survey found that the Article Processing Charge Article Processing Charges are often unfordable for otolaryngology researchers in LMINs, limiting career advancement and the distribution of vital research that could improve patient care [37]. A recent study on the global otolaryngology workforce demonstrated that lower-income countries tend to have a lower density of clinicians compared to higher-income countries [38]. In many cases, personnel involved in clinical trials also have primary responsibilities as clinicians or academic staff, leading to competing demands [26]. With a reduced workforce, lower-income nations may have limited capacity to dedicate to labor-intensive research efforts like clinical trials, especially given the disproportionate burden of otolaryngologic diseases in these regions.

4.3 | Strategies to Improve LMIN Representation

Several existing global consortia have shown promise and could be further developed or adapted to improve LMIN authorship representation in OHNS. The Good Clinical Trials Collaborative is an initiative that partners with research networks in low-income regions to develop guidelines and resources on regulatory processes, ethical standards, and trial management [39]. The Clinical Research and Development Fellowship, supported by the WHO's Special Program for Research and Training in Tropical Diseases, trains clinical research fellows from LMINs and supports them with grants to continue their research upon return to home nations [40]. The integration of these frameworks, facilitated by leaders within OHNS, along with consortia like the Global OHNS Initiative—an organization fostering networks between HICs and LMINs with a focus on research equity and collaboration—could significantly improve LMIN leadership in clinical trials [6, 41]. In addition to these initiatives, expanding National Institutes of Health funding for LMIN researchers through programs that prioritize support for local research infrastructure (i.e., Fogarty Fellowship) may help alleviate barriers related to financial capacity and research environment [22].

For journals, deliberate efforts to actively solicit and publish high-quality clinical trials led by LMIN authors could boost their representation in the clinical trial literature. A recent study found that 33% of OHNS journals offer fee waivers for LMIN researchers, which is a promising step [42]. Participation from additional journals can further reduce the cost barriers to publication. Journals may also consider dedicating special issues to research from LMINs, showcasing strategies for addressing diseases unique to their populations.

4.4 | Limitations

This study has several limitations. The selection of journals for analysis was based on prior research which identified them as the most "widely circulated" during the study period [9, 10]. Several subspecialty journals, which have since gained prominence, were excluded because they began publishing later in the study period, preventing valid temporal comparisons. Furthermore, non-American journals, such as those from Europe and Latin America, were not included. Thus, our findings may not represent broader trends in regional, specialty, or non-American OHNS journals, where LMIN authorship could be more prevalent. Second, our method focuses on evaluating the affiliated nationality of the authors rather than the location where the clinical trial was conducted. Future studies could investigate whether the limited representation of LMIN authorship is influenced by the geographic location of the trials. Third, our reliance on institutional affiliation as a proxy for authorship nationality may introduce misclassification bias. Researchers from LMINs affiliated with HIC institutions could be misclassified, potentially leading to an overrepresentation of HIC authorship and underrepresentation of LMIN contributions. Future studies could address this by incorporating data on authors' self-reported nationality or funding sources to better capture global authorship diversity. Lastly, our study focused on lead authorship positions (FA, SA, CA), potentially overlooking contributions from LMIN authors in middle authorship roles. It is possible that LMIN authorship in these positions has increased over time, but this trend was not captured by our analysis.

4.5 | Conclusion

Authorship in the four most highly circulated OHNS journals is dominated by trials led by authors from HICs, with marginal growth in lead authorship representation from LICs and LMICs over the past two decades. The persistent underrepresentation may limit the applicability of established medical knowledge and clinical guidelines in these areas, potentially compromising the quality and effectiveness of patient care. Concerted efforts are needed to promote clinical trials led by scholars from lower-income regions, ensuring a more inclusive and globally representative body of research.

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The authors have nothing to report.

Conflicts of Interest

The authors declare no conflicts of interest.

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