Comparing the Characteristics of Randomized Controlled Trials of Poststroke Upper Extremity Rehabilitation in Low-Middle-Income and High-Income Countries

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Abstract: This review aimed to systematically identify and compare randomized controlled trials of poststroke upper extremity rehabilitation interventions conducted in low-middle-income countries and high-income countries over time and their differences in study characteristics and quality. Searches were conducted in CINAHL, Embase, PubMed, Scopus, and Web of Science up to April 1, 2021. Randomized controlled trials were included if ≥50% of the study population had stroke, if participants were adults (≥18 yrs), and if the randomized controlled trial examined an intervention to the hemiparetic upper extremity. A total of 1276 randomized controlled trials met inclusion criteria, and of these, 978 randomized controlled trials were conducted in high-income countries and 298 in low-middle-income countries. The number of randomized controlled trials increased at a comparable rate to high-income countries since 2011 although from a lower baseline. A higher percentage of randomized controlled trials in high-income countries were conducted in the chronic poststroke phase, and a higher percentage of randomized controlled trials in low-middle-income countries were conducted in the subacute phase. While the randomized controlled trials in low-middle-income countries were found to have comparable quality to randomized controlled trials of high-income countries, they were published in aggregate in journals with lower impact factors. It is important to better understand the potential barriers to publication in higher impact journals for randomized controlled trials conducted in low-middle-income countries.

Key Words: Stroke Rehabilitation, Upper Extremity, Income, Country, Study Quality, Impact Factor

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Stroke is one of the leading causes of physical disability globally,[1] with higher morbidity and mortality in low-middle income countries (LMICs) compared to high income countries (HICs).[2] Challenges such as limited availability of healthcare resources, barriers to implementation of evidence-based interventions and significant gaps in the quality and quantity of rehabilitation services have contributed to a higher burden of stroke in LMICs.[3]

Randomized controlled trials (RCTs) of poststroke rehabilitation interventions are the primary source of research contributing to the evidence-based recommendations for rehabilitation therapies in stroke survivors. An exponential increase in the volume of stroke rehabilitation RCTs over the years has been previously reported.[4] In addition to the importance of research in informing clinical practice, knowledge transition needs to be appropriate to the target populations and health settings.

Despite the higher incidence and burden of stroke-related disabilities in LMICs, current clinical practice guidelines are derived more from RCTs conducted within HICs with more resource intensive rehabilitation models for poststroke care.[5] This raises concerns about the feasibility and applicability of these recommendations to LMICs, where rehabilitation resources are often limited.[2] It also underscores the need for RCTs within LMICs,[6] enabling the integration of evidence that aligns with their particular rehabilitation settings, resource constraints, and infrastructural considerations.

Studies have demonstrated a reciprocal relationship of research development and economic status.[7] LMICs are underrepresented in global clinical trials as they continue to face barriers to trial initiation and implementation.[8] The challenges in LMICs may continue after study completion as researchers experience difficulties publishing their work in higher quality journals, often due to financial limitations, perceived bias, and language barriers.[9] A recent review of 662 traumatic brain injury management RCTs showed differences in postinjury time, sample size, and even the impact factor (IF) of journals between HICs and LMICs.[10] Another review of poststroke rehabilitation studies showed that the quality of stroke rehabilitation research was not different in studies across world regions, regardless of their income.[4]

Journal impact factor (JIF) serves as a measurement of a journal's influence at the time of publication.[11] It is commonly used to evaluate research performance and make decisions about future funding.[12] Publishing studies in journals with higher IFs is often viewed as more prestigious and influential because of presumed greater "citedness."[12] However, a high IF does not necessarily correlate with high study quality,[13] and there should be awareness about its limitations. Given these disparities, little is known about the similarities and differences in stroke rehabilitation research being conducted in LMICs and HICs. A better understanding of stroke rehabilitation research in relation to country income level may help identify potential gaps in stroke rehabilitation research worldwide.

It is reasonable to assume that there might be differences in study characteristics of stroke motor rehabilitation trials between RCTs from HICs and LMICs. This study aims to examine RCTs of poststroke upper extremity (UE) motor rehabilitation worldwide and to compare: 1) the number of RCTs published in HICs and LMICs over time; 2) time after stroke of RCTs from HICs and LMICs; 3) sample size, 4) study quality measured by Physiotherapy Evidence Database (PEDro) scores, and JIFs between RCTs from HICs and LMICs; and 5) the correlation between sample size and JIFs, and between PEDro score and JIFs in RCTs from HICs and LMICs.

METHODS

This review was conducted following guidelines from the Preferred Reporting Items for Systematic reviews and Meta Analyses statement (See Supplementary Checklist, http://links.lww.com/PHM/C719).[14] A protocol was not preregistered for this review. The present study uses the same database as a previously published review and, therefore, shares the same search strategy, inclusion criteria, and quality evaluation.[15–17]

Search Strategy

Five electronic databases, PubMed, Scopus, Web of Science, EMBASE and CINAHL, were searched from inception to April 1, 2021. A hand search was performed in the Evidence-Based Review of Stroke Rehabilitation (EBRSR.com), "chapter 10: upper extremity interventions" to identify studies that were not captured by the literature search. The detailed search strategy has been published elsewhere.[16]

Eligibility Criteria

Studies were eligible for inclusion in this review if they met the following criteria: 1) were RCTs, either parallel groups or crossover design, 2) included poststroke adults ≥18 years old, 3) at least 50% of participants were diagnosed and affected by ischemic and/or hemorrhagic stroke if studies included mixed etiologies, 4) applied an intervention to the hemiparetic UE as the primary objective of the study, and 5) were written in English. Protocols of RCTs were excluded.

Study Selection and Data Extraction

Studies were imported to Covidence software (www.covidence.org), and duplications were removed. Titles and abstracts were screened against inclusion criteria. Studies meeting the inclusion criteria were reviewed in full and assessed for eligibility, and data extraction was done using a Covidence custom template. All steps from initial screening to data extraction were done by two independent reviewers and any conflict was resolved by an independent third reviewer. Data extracted were as follows: study author(s), year of publication, country of origin, intervention and outcome measure(s), sample size, time after stroke, PEDro scores, and journal names and JIFs (Clarivate). For studies that had previously been extracted into the EBRSR database, existing data was used all aspects of the screening and data extraction were performed using the Covidence software. All extracted data was exported to online Excel for descriptive analysis.

Evaluation of Methodological Quality

Assessment of methodological quality of the RCTs was performed using the PEDro scale.[18] The scale consists of 11 'yes' or 'no' items that examine randomization procedures, baseline comparability, blinding, study attrition, between group comparisons, presentation of point estimates, and measures of variability. Articles were assessed based on each item, then given a total score between 1–10 (the first item is excluded). A higher score is indicative of greater methodological quality. Four of the PEDro items have been empirically validated (i.e., randomization, concealed allocation, blinding and adequacy of follow-up) while the remainder have face validity.[18] The official PEDro database (www.pedro.org.au) was primarily checked by one reviewer for each RCT, and the study was scored according to the database if it was available. For those RCTs, which were not in the official PEDro database, two independent reviewers scored the items, and a third reviewer was available for consensus in case of any conflict.

Definitions

Countries

The country of origin for each study was determined by the affiliation of the corresponding author and the site where the study was conducted. In case of any discrepancy between the two, the country of origin was considered as the country where the study was conducted, and the ethical committee issued approval. Countries were divided into LMICs and HICs according to the World Bank country classification with the threshold of $13,205 USD Growth National Income per capita.[19]

Time After Stroke

The time after stroke was determined according to the time between stroke onset and start of the trial and divided into three phases: acute (<1 mo), subacute (1–6 mos), and chronic (>6 mos).[20]

Journal Impact Factor

JIF is considered as an indicator of how often articles in a journal are cited related to the number of published papers over an initial 2-yr period.[12] For the purpose of this review, the JIF was determined for each RCT by searching the journal name and the year of publication in Clarivate Journal Citation Reports (Clarivate).

Statistical Analysis

Study characteristics and extracted variables were summarized using standard descriptive statistics. Data analyses were performed using SPSS and RStudio v.4.3.1, and figure generation was performed using the ggplot2 v3.4.4 package in RStudio.[21] Data was assessed for normality using the Kolmogorov-Smirnov, histograms, Q-Q plots, and residual plots. Accordingly, the Mann-Whitney *U* test was used to compare sample size and PEDro score between the two groups of RCTs. The general linear regression model was used to evaluate the increase rate in number of RCTs over time in both groups. The χ^2 test was used to compare the percentage of RCTs with different characteristics in the groups, including time after stroke and JIFs. The spearman correlation test was used to examine the correlation of sample size and JIFs. The spline regression model was used to understand the relationship of PEDro score and JIFs in both groups of RCTs. The *P* value of ≤0.05 was considered as significant for all analyses.

Ethics

There were no human participants in this review study. This study did not require informed consent or ethics approval.

RESULTS

A total of 5408 records were identified. After removing duplicates, 2288 records were assessed for eligibility. Finally, 1276 RCTs met inclusion criteria and underwent data extraction (Fig. 1). The included RCTs examined 76 unique interventions, including controls, for poststroke UE rehabilitation with many RCTs having more than one intervention. The RCTs were conducted across 50 different countries, consisting of 32 HICs (978 RCTs), and 18 LMICs (298 RCTs) (See Supplemental Digital File, http://links.lww.com/PHM/C720).

The United States was the leading country with 246 RCTs, followed by South Korea (154), Mainland China (114), Taiwan-China (78), United Kingdom (77), Italy (67), Germany (51), Turkey (50), Canada (44), and Australia (43). Mainland China and Turkey were the only countries from the LMICs group among the top 10 countries in terms of numbers of RCTs.

Number of RCTs Over Time

Figure 2 shows the number of RCTs for UE stroke rehabilitation interventions. More RCTs were published in HICs than LMICs each year, with a limited number of RCTs in LMICs in earlier years. Before 2000, there was only one RCT of a UE stroke rehabilitation intervention conducted in LMICs, compared to 49 RCTs in HICs during the same period. From 2000 to 2010, RCTs conducted in LMICs were rare with only 25 RCTs, compared to 274 RCTs conducted in HICs. From 2011 to April 1, 2021, the number of RCTs in LMICs (n = 272) started to rise at a comparable rate as HICs (n = 655) (P = 0.58). In total, 28 (9.4%) RCTs in LMICs and 198 (20.2%) RCTs in HICs were conducted in multiple sites.

Time After Stroke

Table 1 shows the percentage of RCTs conducted in different phases after stroke in each group. RCTs conducted in the acute poststroke phase were comparable between the two groups (HICs 18.3%; LMICs 22.5%; P = 0.1). A higher percentage of RCTs in LMICs (37.2%) were conducted in the subacute phase than HICs (21.1%); however, the opposite was true for the chronic phase, with more RCTs being conducted in the chronic phase in HICs (58.4%) compared to LMICs (35.6%) (P < 0.001).

Sample Size

Overall, the mean sample size for RCTs published by HICs and LMICs had fluctuations over time, with no specific trend. In total, the mean sample sizes in RCTs conducted in LMICs were higher, with a mean (SD) sample size of 58.7 (67.2), compared to a mean (SD) sample size of 42.5 (51.2) in HICs (P < 0.001).

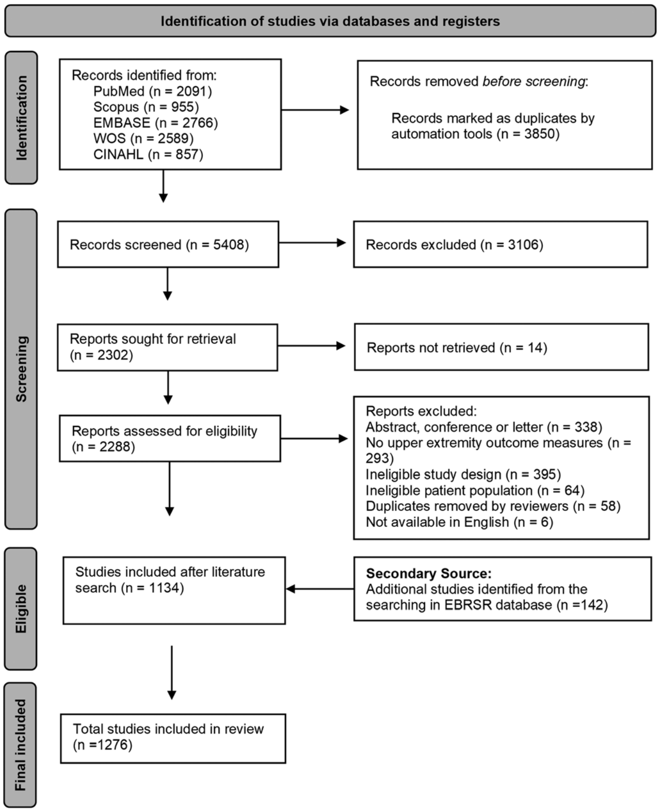

FIGURE 1. PRISMA flow diagram.

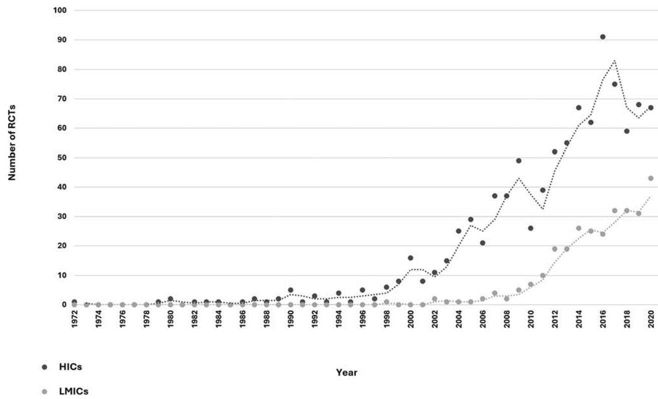

FIGURE 2. Number of RCTs conducted in HICs and LMICs from 1970 to 2020.

Study Methodological Quality

Both HICs and LMICs published RCTs had comparable PEDro scores ($P = 0.98$). Table 1 shows the number of RCTs based on the methodological quality. In both groups, the majority of RCTs had good study quality, followed by fair quality studies, with small numbers of RCTs with poor quality and excellent quality. Figure 3 shows the percentage of RCTs in which each PEDro criterion has been met, and it was comparable between the RCTs in HICs and LMICs for all 10 components. In both HIC and LMIC groups of RCTs, the most frequent unmet criteria were blinding of therapists, blinding of subjects, concealed allocation for randomization, and intention to treat analysis.

TABLE 1. Study characteristics of RCTs in HICs and LMICs

Characteristics	LMICs	HICs	P
No. RCTs (%)	298 (23.4%)	927 (76.6%)	-
Multisite studies	28 (9.4%)	198 (20.2%)	
Sample size			
Mean (SD)	58.7 (67.2)	42.5 (51.2)	<0.001
Median (IQR)	40 (33)	29 (25)	
Time after stroke			
Acute (<1 mo)	67 (22.5%)	179 (18.3%)	0.1
Subacute (1–6 mos)	111 (37.2%)	206 (21.1%)	<0.001
Chronic (>6 mos)	106 (35.6%)	571 (58.4%)	<0.001
Not reported	14 (4.7%)	22 (2.2%)	-
PEDro score			
Mean (SD)	6.1 (1.5)	6.1 (1.6)	0.98
Median (IQR)	6 (2)	6 (2)	
No. RCTs (%)			-
Scores 1–3 (poor)	11 (3.7%)	54 (5.5%)	
Scores 4–5 (fair)	97 (32.6%)	276 (28.2%)	
Scores 6–8 (good)	177 (59.4%)	606 (61.7%)	
Scores 9–10 (excellent)	13 (4.4%)	45 (4.6%)	
Journal impact factor			
Mean (SD)	2.2 (1.4)	3.2 (3.5)	
Median (IQR)	2 (1.6)	2.4 (2.3)	<0.001
Range	0.14–10.7	0.1–60.4	

Journal Impact Factors

The JIFs were unknown for 199 RCTs, including 33 RCTs published before 1997, when Clarivate Impact Factors were not recorded for journals. For the remaining 166 RCTs, either the JIF was not recorded for the year of publication (53 RCTs in LMICs and 60 RCTs in HICs), or the journal could not be found on the Journal Citation Reports database (20 RCTs in LMICs and 33 RCTs in HICs).

Overall, for the remaining 1077 RCTs, the JIF for RCTs of HICs (mean = 3.2; median = 2.4) was significantly higher than RCTs conducted in LMICs (mean = 2.2; median = 2) ($P < 0.001$). Table 2 shows the JIF of RCTs in both groups. The proportion of RCTs published in journals with IFs 1–4 were comparable between the two groups. A higher percentage of RCTs in HICs (21.1%) were published in journals with an IF greater than 4, compared to only 6.6% in LMICs ($P < 0.001$). Among RCTs published in journals with an IF of ≤1, a higher percentage of RCTs were conducted in LMICs compared to HICs ($P = 0.013$).

Sample Size and JIF Correlation

The correlation of sample size and JIF showed a small positive and significant correlation in RCTs published in HICs ($r = 0.18$, $P < 0.001$), but no similar correlation was found in RCTs published in LMICs ($r = 0.036$, $P = 0.57$).

PEDro Score and JIF Correlation

Higher PEDro scores were correlated with higher JIFs in both groups of RCTs (LMICs: $r = 0.3$, $P < 0.001$; HICs: $r = 0.2$, $P < 0.001$). However, the regression of PEDro score and JIF for RCTs in each group showed that for the same level of PEDro score, RCTs of HICs were published in journals with significantly higher IF than RCTs of LMICs ($P < 0.001$). Figure 4 shows that this difference is more highlighted for lower quality RCTs and became smaller for higher quality RCTs.

DISCUSSION

Comparing poststroke UE motor rehabilitation RCTs between HICs and LMICs, there has been a rapid increase in the total number of RCTs worldwide, and particularly in LMICs during the last decade. In general, a higher percentage of RCTs in LMCs were conducted in the acute and subacute phases after stroke, whereas a greater percentage of RCTs in

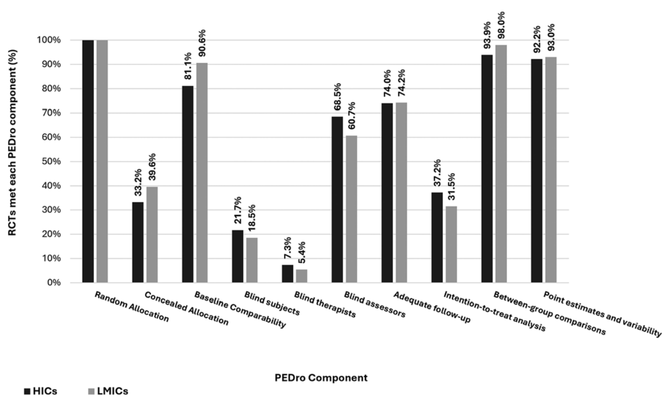

FIGURE 3. The percentage of RCTs met each PEDro component in HICs and LMICs.

HICs were conducted in the chronic phase. RCTs in LMICs had greater sample sizes compared to RCTs in HICs, and the study qualities were comparable in both groups. RCTs in HICs were published in journals with higher IFs despite showing similar methodological quality. While PEDro score and JIFs were positively correlated to each other in both groups, studies from HICs with the same level of PEDro scores as studies from LMICs were published in journals with higher IFs.

As the number and percentage of RCTs originating from LMICs increases, it is important to understand this literature, its strengths, and weaknesses, and to determine how it compares to RCTs from HICs. RCTs conducted in LMICs meeting the inclusion criteria were essentially nonexistent before 2000 and much less common before 2010, compared to HICs, and then started to increase at a comparable rate to HICs from 2011, recognizing LMIC RCTs were starting from a lower baseline. Reasons for this observation are likely multifactorial. For instance, LMICs may have experienced challenges related to availability of resources and ability to provide rehabilitation services to stroke survivors,[22] particularly in earlier years. Based on the upward trajectory in number of RCTs from LMICs, their impact is growing and there is a need to better understand RCTs originating from both HICs and LMICs.

In this review, the quality of RCTs conducted in HICs and LMICs was comparable, based on PEDro scores. Previous studies showed that RCTs conducted in LMICs had limitations in methodological quality.[23] The present study did not find any significant differences between LMICs and HICs RCTs in any of the 10 individual components that make up the PEDro score, with weaknesses and strengths in individual quality markers in HICs mirroring those in LMICs.

Overall, sample size was larger in LMICs versus HICs. Larger sample sizes decrease the overestimation of true effect size and provide sufficient power to determine the statistical significance.[24] Despite RCTs from LMICs exhibiting comparable mean PEDro scores and larger mean sample sizes, those same RCTs, in aggregate, were published in journals, which were on average a full point lower in JIF when compared to RCTs from HICs. This finding suggests that the observed difference in JIFs may not be solely attributed to study methodological quality in LMICs, thereby prompting a reconsideration of potential factors influencing this difference. Other related

TABLE 2. Journal impact factors for RCTs in HICs and LMICs

		HICs			LMICs				
Journal Impact Factor		***No. RCTs***	***% From 945 RCTs[a]***	***% From Each Impact Factor Category***	***No. RCTs***	***% From 298 RCTs***	***% From Each Impact Factor Category***	***Total***	***P***
>10		13	1.4%	92.9%	1	0.3%	7.1%	14	<0.001
>5–10		106	11.2%	93.8%	7	2.3%	6.2%	113	
>4–5		80	8.5%	87.0%	12	4.0%	13.0%	92	0.021
>3–4		126	13.3%	81.3%	29	9.7%	18.7%	155	0.17
>2.5–3		77	8.1%	77.0%	23	7.7%	23.0%	100	1
>2–2.5		122	12.9%	74.8%	41	13.8%	25.2%	163	0.63
>1.5–2		166	17.6%	80.6%	40	13.4%	19.4%	206	0.17
>1.0–1.5		93	9.8%	72.1%	36	12.1%	27.9%	129	0.23
>0–1.0		69	7.3%	65.7%	36	12.1%	34.3%	105	0.008
Unrecorded JIF	Unrecorded year[b]	60	6.3%	53.1%	53	17.8%	46.9%	113	<0.001
	Unrecorded journal[c]	33	3.4%	62.3%	20	6.7%	37.7%	53	0.018

[a]Thirty-three RCTs in HICs were published before 1977, when no Clarivate JIF was recorded.
[b]Journal was found in the Journal Citation Reports database, but the JIF was not recorded in the publication year.
[c]Journal was not found in the Journal Citation Reports database.

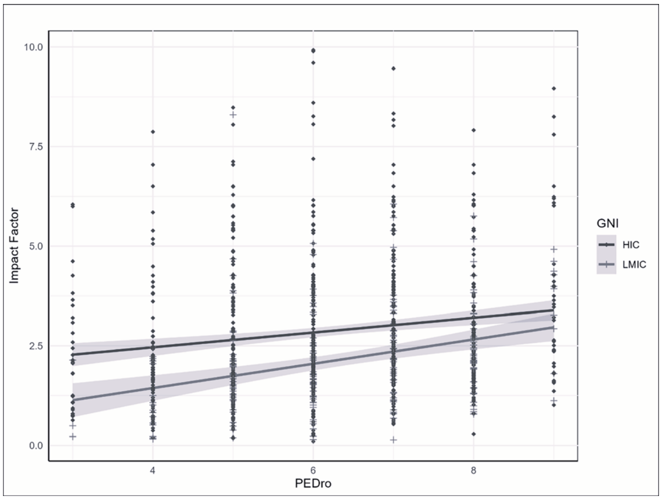

FIGURE 4. Regression of PEDro scores and journal impact factors for RCTs in HICs and LMICs.

factors to publishing in journals with higher JIFs may include the type of intervention and control treatments, including having multiple study arm comparisons. A review of gastrointestinal surgery RCTs in 12 international journals showed that JIF was correlated to methodological and ethical elements of the trials, such as industrial funding, and number of centers.[25] In the current review, a higher percentage of RCTs in HICs were conducted in multiple sites compared to LMICs; however, assessments of ethical quality and funding were not taken into consideration in the current study.

Eckmann and Bandrowski[26] reported that developing countries experience challenges with publishing research, including language difficulties, high costs of publication, bias against LMICs in research, as well as a lack of institutional support and/or external funding.[26] Given that only articles published in English were reviewed, there will naturally be a bias against non-English speaking authors. English is the closest thing to a universal language in science and the overwhelming majority of journals, in particular high impact journals, are published in English. Publishing in journals, in particular high impact journals, can be very competitive with limited space, or when published in an online format, publishing cost may be a greater deterrent for authors from LMICs. There may be some biases toward LMIC RCTs but much of this can be mitigated by anonymous review processes and much of this is likely related to English writing skills, which can be a problem for some HIC writers as well but seems to be more prominent in LMIC RCT submissions. PEDro does not take into account the actual wording of the research question or of the data analysis. Anecdotally, some researchers from LMICs may not have the experience to publish in higher impact journals that researchers in HICs have or may prefer to publish in a more local journal that does not have a high IF.

HICs had a higher proportion of RCTs in the chronic phase while LMICs had a higher proportion of studies in the subacute and acute phases. This may be related to the availability of more rehabilitation resources and follow-up in wealthier countries in the chronic phase allowing for greater accessibility to participants after 6 mos after stroke. RCTs are often conducted in the chronic phase to avoid interacting active treatment effects and the impact of spontaneous recovery in the first months after stroke.[27] Tighter organizational and regulation policies may also limit ease of access to patients in acute and subacute phases in HICs. On the other hand, resources to manage stroke patients outside of the hospital setting, including follow-up would be more limited in LMICs, resulting in lesser access to participants and resources in the chronic phase.[2,28]

Implications

This systematic review shows an increasing number of RCTs are being conducted in LMICs during the last two decades and are contributing to the growing research evidence-base; however, publications of RCTs from LMICs in journals with lower IFs will inevitably reduce their influence when compared to similar RCTs from HICs. Recommendations based on the findings of the present review include: (1) facilitating communication and publication processes for researchers from LMICs with journals, which are well recognized as important to the field, particularly those with higher IFs, and (2) better recognizing potential barriers for LMICs and how the research differs relative to resource availability.

This systematic review shows an increasing percentage of RCTs are being conducted in LMICs so much so that LMICs are on the verge of annually surpassing HIC RCTs. LMIC RCTs conduct research in lower resource environments and a higher proportion are conducted in the acute/subacute phase, resulting in greater generalizability. RCTs from LMICs tend to be published in journals with lower IFs, which will likely reduce their influence when compared to similar RCTs from HICs. The future will see a greater impact of RCTs from LMICs, exceeding HICs, in a growing research evidence-base. It is important that we develop a better understanding of RCTs from LMICs.

Study Limitations

While this study included a large number of RCTs, only English publications were considered for this review, which could potentially exclude RCTs from non-English speaking countries in both HICs and LMICs. This review also did not take account other study differences, including intervention(s), outcome measure (s), and study arm designs including comparison types. Differences regarding participant biological sex has been reported elsewhere.[15]

This study compared RCTs based on the country of origin and did not take into account income variability within individual countries. In this review, the JIF was used as the only study impact marker. Future studies may use other journal metrics, such as total citations. According to the field of research and the scope of this review, PEDro scale was used as the methodological assessment tool in this study, however, future study may use other available tools such as Cochrane risk of bias for RCTs. An in-depth examination of RCTs, including the outcome measures used alongside the specific interventions may help better understand the differences in treatment needs and available resources in LMICs and HICs.

CONCLUSIONS

This review examined the landscape of UE motor rehabilitation stroke rehabilitation RCTs from HICs and LMICs. The number of RCTs from LMICs has increased during the last 2 decades, however, the majority of RCTs are conducted in HICs. More RCTs in HICs were conducted in the chronic poststroke phase, while more RCTs in LMICs were conducted in the subacute phase. Despite comparable samples sizes and methodological study quality in both settings, RCTs from HICs are consistently published in journals with higher IFs. Factors, other than study methodological quality markers used in this study, that prevent RCTs from LMICs being published in high impact journals need to be identified in future research.

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