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Cross-Registry Coverage of Registered Septal-Reduction Studies for Hypertrophic Cardiomyopathy: A WHO ICTRP Audit

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Original Research

Cross-Registry Coverage of Registered Septal-Reduction Studies for Hypertrophic Cardiomyopathy: A WHO ICTRP Audit

Running title: Cross-Registry Audit of Septal-Reduction Trials

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Abstract

Background: Septal-reduction therapy is the definitive treatment for drug-refractory outflow tract obstruction in hypertrophic cardiomyopathy, but the composition of its registered evidence is unknown.

Methods: We searched the WHO International Clinical Trials Registry Platform (ICTRP) on 9 October 2026 using nine prespecified searches covering the condition and all septal-reduction modalities. Eligibility required a septal-reduction modality in the WHO Trial Registration Data Set intervention field or, failing that, the title; pharmacological-only and peri-procedural-care studies were excluded. Registry source, prospective registration, recorded recruitment country, portal-visible results and record freshness were extracted; proportions carry Wilson 95% confidence intervals and contrasts are reported as odds ratios.

Results: The nine searches returned 210 rows representing 92 unique registrations, of which 73 were eligible (ClinicalTrials.gov 40, ChiCTR 27, four further registries 6). A recruitment country was recorded for 63 registrations, 48 in China. Percutaneous or endocardial septal ablation accounted for 29 of the 45 China-recruited registrations using that technique or surgery, versus 3 of 20 elsewhere (odds ratio 10.3, 95% CI 2.6-40.4; $p = 0.0003$); significance was not preserved under the most conservative assignment of the ten registrations lacking a recorded country ($p = 0.075$). Prospective registration was recorded for 40 registrations (54.8%) and portal-visible results information for 1 (1.4%, 95% CI 0.2-7.4).

Conclusions: The retrieved portfolio is concentrated in two registries, dominated by registrations recruiting in China, and almost devoid of portal-visible results information, although registered studies have published findings. Completion date and summary results already form part of the WHO Trial Registration Data Set; the priority is timely, complete entry and verified transmission of those elements to the aggregator.

Data: WHO ICTRP, 9 October 2026; data and screening log in Supplementary Material.

Keywords: hypertrophic cardiomyopathy; septal reduction; trial registration; WHO ICTRP; research transparency

1. Introduction

Hypertrophic cardiomyopathy is the most common inherited cardiac muscle disorder, with an estimated prevalence of approximately 1 in 500 adults in the general population [1]. It is characterised by unexplained left ventricular hypertrophy and is a recognised cause of sudden cardiac death in young people, heart failure and atrial fibrillation [2]. Contemporary practice guidelines from the American Heart Association and the American College of Cardiology, and from the European Society of Cardiology, define the diagnostic pathway and specify septal reduction therapy as the treatment of choice for patients with drug-refractory symptoms attributable to left ventricular outflow tract obstruction [3, 4].

Obstruction is not a fixed property of the disease. Exercise-induced left ventricular outflow tract obstruction can be demonstrated in a substantial proportion of symptomatic patients who have no obstruction at rest [5], and the magnitude of obstruction, together with other variables, determines the risk of sudden cardiac death and the intensity of surveillance [6]. Because obstruction is dynamic, the decision to intervene is made on a combination of symptoms, gradients and anatomy rather than on a single measurement.

Two procedures have constituted septal reduction therapy for three decades. Surgical septal myectomy relieves outflow obstruction and is associated with improved long-term survival and low operative mortality when performed in experienced centres [7, 8]. Alcohol septal ablation, introduced as a catheter-based alternative [9], produces haemodynamic improvement and has been compared directly with myectomy in imaging and clinical studies [10, 11], summarised in a meta-analysis [12], examined in a propensity-matched cohort [13] and pooled again in a systematic review of long-term outcomes [14]. Outcomes for both procedures are strongly related to the volume of cases managed by the treating centre [15].

Newer procedures have expanded the field. Percutaneous intramyocardial septal radiofrequency ablation was developed in China as a catheter-based technique that does not require an iatrogenic myocardial infarction [16], and its efficacy and midterm outcomes have since been reported in prospective and observational series [17, 18]. Transapical beating-heart septal myectomy, also developed in China, performs a myectomy without cardiopulmonary bypass or cardiac arrest [19], with outcomes reported after the learning curve [20]. Transcatheter myotomy using septal scoring along the midline endocardium has been described as a further catheter-based alternative [21]. These procedures differ fundamentally in route, in the myocardial substrate they address, and in the equipment they require, and they are therefore likely to be distributed unevenly between health systems.

Pharmacological alternatives have begun to shift the treatment landscape. The cardiac myosin inhibitors mavacamten and aficamten improve symptoms and outflow gradients in obstructive hypertrophic cardiomyopathy and reduce eligibility for septal reduction therapy [22–24]. Chinese patients have been studied within this programme [25], and the clinical profile of hypertrophic cardiomyopathy in Chinese cohorts has been described separately [26]. The arrival of effective drug therapy makes it more, not less, important to know what interventional evidence is being generated and where.

Clinical trial registries are the primary public record of that activity. The WHO International Clinical Trials Registry Platform aggregates records contributed by primary registries and republishes them under a common minimum dataset, the 24-item WHO Trial Registration Data Set [27]. That data set already includes a completion date and a summary-results element carrying the date of first posting, the date of first journal publication and links to the results (https://www.who.int/clinical-trials-registry-platform/network/who-data-set). The platform is recommended as a source for identifying ongoing and unpublished studies [28]. The Chinese Clinical Trial Registry has operated as a WHO primary registry since 2007 [29] and its accumulated holdings have been analysed across disease categories [30]. Registration, however, is only the first step: the quality of registered information has repeatedly been shown to be incomplete [31, 32], the policy environment has evolved since registration became a

precondition for publication and for marketing approval [33, 34], protocols frequently diverge from publications [35, 36], and registered studies are often never published [37]. Interventional research carries additional reporting problems of its own [38].

The gap this study addresses is specific. It is not known how the registered septal-reduction portfolio is distributed across registries, whether the registrations precede enrolment, whether results information is visible in the aggregated record, or whether the geographic distribution of registrations tracks the geographic origin of the competing procedures. A record-level audit would answer these questions directly and would provide the denominator against which later evidence syntheses and research-priority decisions can be calibrated. The objective of this study was therefore to characterise the registrations of septal-reduction interventions for hypertrophic cardiomyopathy retrieved by a prespecified search of the WHO International Clinical Trials Registry Platform, to quantify cross-registry coverage, prospective registration, portal-visible results information and record currency, and to compare procedure route between registrations that record China as a recruitment country and registrations that do not.

2. Materials and Methods

2.1 Study design and setting

This was a cross-sectional audit of a public trial-registration aggregator. The unit of observation was one registration. The data source was the WHO International Clinical Trials Registry Platform (ICTRP) search portal at https://trialsearch.who.int/, queried on 9 October 2026. The portal republishes records contributed by the registries in the WHO Registry Network and presents each record as a 24-item WHO Trial Registration Data Set (TRDS; version 1.3.1, https://www.who.int/clinical-trials-registry-platform/network/who-data-set). Two of those items are central to this audit: a completion date, and a summary-results element that carries the date of first posting, the date of first journal publication and links to the reported results. The portal states that each displayed record shows only the TRDS elements and links to the source record in the primary registry. Throughout, the audit records what the portal displayed for those elements and does not infer whether the underlying study had reported its findings. Registry names are reported as they appear in the aggregated record set, with the abbreviation used by the portal in parentheses. Portal data use is governed by the WHO ICTRP Terms and Conditions for Use of WHO ICTRP Data. No human or animal participants were involved, and no personally identifying data were extracted; contact fields were discarded at the point of extraction.

2.2 Search strategy

Nine searches were executed in the portal's simple search box. The search vocabulary combined the condition with every septal-reduction modality and its common synonyms, so that a registration would be retrieved by route description as well as by procedure name. Each string was entered in the portal's free-text search box without field restriction and without a manual synonym list:

1. hypertrophic cardiomyopathy AND septal
2. hypertrophic cardiomyopathy AND myectomy
3. hypertrophic cardiomyopathy AND ablation
4. hypertrophic cardiomyopathy AND Morrow
5. hypertrophic cardiomyopathy AND transapical
6. hypertrophic cardiomyopathy AND radiofrequency
7. hypertrophic cardiomyopathy AND Liwen

8. hypertrophic cardiomyopathy AND PIMSRA

9. hypertrophic cardiomyopathy AND "septal reduction"

The portal reported record and trial counts for each query. Results were displayed at 100 rows per page and every result row was captured. Registrations retrieved by more than one query were recorded once, with the list of retrieving queries retained. The record count reported by the portal for each query was compared with the number of rows parsed; the two agreed for all nine queries (62, 32, 55, 3, 11, 31, 5, 5 and 6 records respectively, 210 in total).

2.3 Eligibility criteria

Eligibility was decided by a mechanical rule and applied identically to every retrieved registration. A registration was eligible when the TRDS intervention field named a septal-reduction modality, or, when the intervention field named no modality, when the registered title named one. The modality vocabulary comprised surgical septal myectomy and myotomy (including Morrow procedures, septal resection and septal scoring along the midline endocardium), alcohol or ethanol septal ablation (including transcoronary ablation and trans-right ventricular approaches), percutaneous or endocardial septal ablation (including percutaneous intramyocardial septal radiofrequency ablation, transcatheter myocardial radiofrequency ablation, transthoracic radiofrequency or laser ablation, cryoablation of the septum and pulsed field ablation of the septum), and septal radiation ablation. Registrations were retained when a septal-reduction procedure was the registered intervention irrespective of whether the registered condition specified outflow tract obstruction, so the unit of analysis is a registered septal-reduction study rather than a trial of obstructive disease alone.

Two exclusions were applied. Registrations whose listed interventions were pharmacological only were excluded even when the title referred to eligibility for septal reduction, because such studies evaluate a drug rather than a procedure. Registrations were also excluded when the evaluated intervention was peri-procedural care rather than septal reduction itself, which covered anaesthetic management, postoperative analgesia (for example, regional analgesia after transapical beating-heart septal myectomy), intensive-care blood-pressure management and similar in-hospital management studies; such a registration is identified for exclusion by its evaluated intervention even when its registered title names a septal-reduction procedure. Two registrations that evaluated two modalities (the AMARONE pair) were each assigned to a single modality group, and the effect of the alternative assignment is reported in Section 3.7. Every decision, with its registry identifier and its reason, is itemised in a screening log released with the analysis code and summarised as Supplementary Table S1.

2.4 Variables extracted

For each registration the following TRDS fields were extracted from the portal's full record view: source registry, main identifier, date of registration, prospective registration status, primary sponsor, public and scientific titles, date of first enrolment, target sample size, recruitment status, study type, study design, phase, countries of recruitment, health condition, interventions, primary and key secondary outcomes, secondary identifiers, source of monetary support, ethics review status, portal-visible results information and the date the portal last refreshed the record. Free-text contact blocks were not retained.

2.5 Derived variables

Procedure modality was classified into four mutually exclusive groups: surgical septal myectomy, alcohol septal ablation, percutaneous or endocardial septal ablation, and septal radiation ablation. The percutaneous group was assigned first from the intervention field and refined to the radiation group when the record described stereotactic or radiation-based ablation. Recruitment country was taken from the TRDS countries-of-recruitment field and classified

in three levels: China when the field listed China, outside China when it listed any other country, and country not recorded when the field was empty or unassignable in the aggregated record. The principal contrast compares registrations recorded as China with all registrations not recorded as China, and the sensitivity of that contrast to the ten registrations whose country was not recorded is reported in Section 3.7. Record currency was expressed as the number of days between the portal's last-refresh date for that record and the retrieval date. Dual registration was identified by exact match of normalised public titles across different registry families. Target sample size was taken from the TRDS numeric field, or summed across arms when the portal carried per-arm counts.

2.6 Statistical analysis

The study is descriptive; the full eligible set was enumerated, so no sampling-based power calculation applies. Proportions are reported with Wilson score 95% confidence intervals. Comparisons of prospective registration between registries and between country groups used the two-sided Fisher exact test, and odds ratios are reported with Katz logit 95% confidence intervals. Comparison of procedure route between country groups used the two-sided Fisher exact test on the percutaneous-versus-surgical 2x2 table; the four-category contingency table was not tested because the minimum expected cell count was 0.68, which invalidates the chi-square approximation. Record currency was compared between the two largest registries with the two-sided Mann-Whitney U test, reported with the U statistic. Because the primary purpose was enumeration rather than hypothesis testing, no adjustment for multiple comparisons was applied, and the four significance tests are reported as exploratory with exact p-values. The alpha level was 0.05. The sensitivity of the percutaneous-versus-surgical contrast to the ten registrations whose recruitment country was not recorded was evaluated by enumerating every assignment of those records to a modality that is consistent with the modality margins of the not-recorded-as-China group and reporting the resulting range of the odds ratio and of the two-sided Fisher exact p-value. Analyses were performed in Python 3.13 with NumPy 2.3, SciPy 1.18, pandas 3.0 and Matplotlib 3.11; the dataset build and analysis scripts accompany this manuscript.

One sensitivity analysis was performed. The eligibility rule was relaxed so that registrations whose study population undergoes septal reduction were retained even where the evaluated intervention was peri-procedural care, and the headline proportions and tests were recomputed on that broader set. A finding was treated as robust only if the direction of the estimate was unchanged and the two-sided Fisher exact p-value remained below the 0.05 threshold.

2.7 Ethics approval

Not applicable. The study analysed publicly available trial-registration records and involved no human or animal participants, no biological material and no individual-level or identifiable data.

3. Results

3.1 Retrieval, screening and final sample

The nine searches returned 210 result rows representing 92 unique registrations after deduplication by main identifier. Nineteen registrations were excluded: 16 named no septal-reduction modality in the intervention field or the title, and three evaluated peri-procedural care, comprising anaesthetic management for transapical beating-heart septal myectomy and two studies of postoperative blood-pressure management after percutaneous intramyocardial septal radiofrequency ablation. The excluded registrations were dominated by catheter ablation of atrial fibrillation or ventricular tachycardia in patients with hypertrophic cardiomyopathy, myosin-inhibitor trials in patients eligible for septal reduction, and genetic or prognostic studies in postoperative populations. The record-level decision for

every retrieved registration, with its registry identifier and its reason, is given in the screening log (Supplementary Table S1). Seventy-three registrations were eligible and formed the analysis set (Fig. 1).

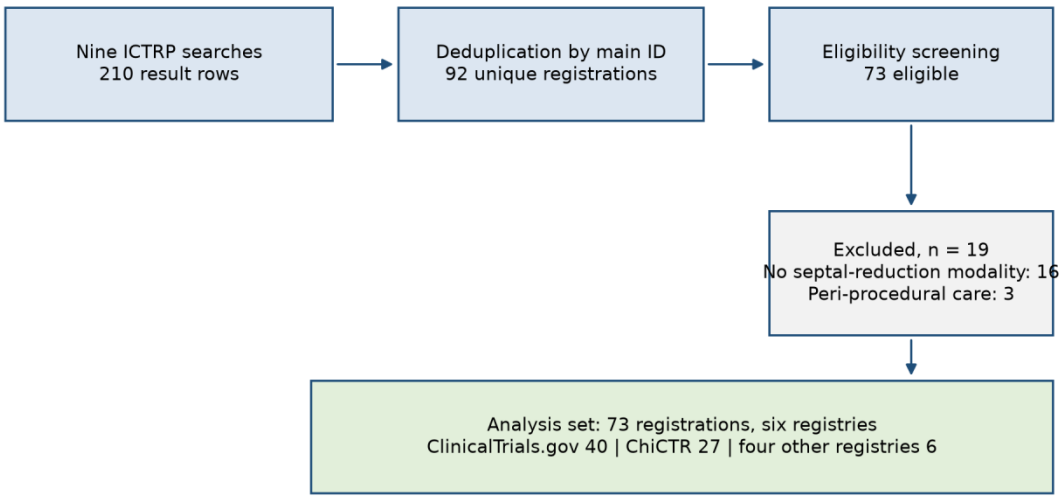


Fig. 1. Study flow. Identification, deduplication, screening and inclusion of septal-reduction registrations retrieved from the WHO International Clinical Trials Registry Platform on 9 October 2026. The nine pre-specified searches returned 210 result rows, which represented 92 unique registrations after deduplication by main identifier. Nineteen registrations were excluded: 16 named no septal-reduction modality in the WHO Trial Registration Data Set intervention field or in the registered title, and three evaluated peri-procedural care rather than septal reduction. The remaining 73 registrations formed the analysis set. ID, identifier; ICTRP, International Clinical Trials Registry Platform.

3.2 Cross-registry coverage and temporal distribution

The 73 eligible registrations were contributed by six registries. ClinicalTrials.gov accounted for 40 registrations (54.8%) and ChiCTR for 27 (37.0%); the remaining six came from the Netherlands Trial Register (OMON, 3), the Japan Primary Registries Network (JPRN, 1), the Clinical Research Information Service of the Republic of Korea (KCT, 1) and the Brazilian Registry of Clinical Trials (REBEC, 1). JPRN is a network of Japanese registries rather than a single registry. No registration listed more than one country of recruitment, and a recruitment country was recorded for 63 registrations (86.3%); the field was empty or unassignable in the remaining ten. Two trial pairs were registered in two registries at once. ChiCTR2000031936 and NCT04355260 described the same echocardiography-guided radiofrequency ablation study and carried identical normalised titles. NCT04684290 and NL-OMON56423 both described the AMARONE trial of surgical septal myectomy versus alcohol septal ablation, but their registered titles differed in the use of "vs" and "versus" and in a trailing acronym, so the exact-title rule did not flag them; this pair was identified by inspection of the extracted titles. Because each pair contributed two registrations, the 73 registrations analysed here represent 71 distinct trials (Table 1, Table 2).

Registration dates spanned 1999 to 2026, with a median year of 2022. Sixty-five registrations (89.0%) were entered in 2019 or later, and the annual count rose from single figures before 2019 to a peak of 13 in 2024 (Fig. 2). The cumulative curve shows that ChiCTR registrations accumulated entirely after 2019, whereas ClinicalTrials.gov registrations began in 1999 (Fig. 3).

Table 1. Characteristics of the 73 eligible septal-reduction registrations retrieved from the WHO International Clinical Trials

Registry Platform on 9 October 2026.

Characteristic	Registrations
Total, n	73
Registry	
ClinicalTrials.gov	40 (54.8)
ChiCTR	27 (37.0)
Four other registries	6 (8.2)
Registration year, median (range)	2022 (1999-2026)
Registered in 2019 or later	65 (89.0)
Country of recruitment	
China	48 (65.8)
Outside China, country recorded	15 (20.5)
Country not recorded	10 (13.7)
Procedure modality	
Surgical septal myectomy	33 (45.2)
Percutaneous or endocardial septal ablation	32 (43.8)
Alcohol septal ablation	6 (8.2)
Septal radiation ablation	2 (2.7)
Study type	
Interventional	49 (67.1)
Observational	24 (32.9)
Registration transparency	
Prospectively registered	40 (54.8)
Portal-visible results information recorded	1 (1.4)
Metadata completeness	
Target sample size stated	71 (97.3)
Target sample size, median (IQR)	64 (30-136)
Primary outcome recorded	71 (97.3)
Key secondary outcomes recorded	57 (78.1)
Secondary identifiers present	43 (58.9)
Substantive funder named	31 (42.5)
Completion date populated	0 (0.0)
First-publication date populated	0 (0.0)
Record currency	
Days since portal last refreshed the record, median (IQR)	1005 (472-2033)
Records not refreshed for more than two years	46 (63.0)

Percentages are of the 73 eligible registrations unless otherwise stated. Two dual-registered pairs were identified, so the 73 registrations represent 71 distinct trials. A recruitment country was recorded for 63 registrations; the field was empty or unassignable in the remaining ten. Completion date and first-publication date are elements of the WHO Trial Registration Data Set that the portal displays for every record, and no retrieved record populated either. ChiCTR, Chinese Clinical Trial Registry; IQR, interquartile range; WHO, World Health Organization.

Table 2. Cross-registry coverage of septal-reduction registrations, by source registry.

Registry	Registrations	Prospective	Results	Interventional	China	Median size	Median refresh
ClinicalTrials.gov	40 (54.8)	15 (37.5)	1 (2.5)	28 (70.0)	21 (52.5)	70	1019
ChiCTR	27 (37.0)	21 (77.8)	0 (0.0)	19 (70.4)	27 (100.0)	64	1243
OMON	3 (4.1)	3 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	30	389
JPRN	1 (1.4)	1 (100.0)	0 (0.0)	1 (100.0)	0 (0.0)	20	102
KCT	1 (1.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	100	1145
REBEC	1 (1.4)	0 (0.0)	0 (0.0)	1 (100.0)	0 (0.0)	-	347

The registration count is a percentage of all 73 registrations; every other percentage is a percentage of the registrations held by that registry, and each median is within that registry. All values are n (%) unless stated. Procedure modality was not tabulated by registry in the table body and is therefore given here: percutaneous or endocardial septal ablation accounted for 15 of 40 ClinicalTrials.gov registrations (37.5%) and 16 of 27 ChiCTR registrations (59.3%), while surgical septal myectomy accounted for 21 of 40 (52.5%) and 8 of 27 (29.6%) respectively; the remaining registrations in each of those two registries used alcohol or radiation ablation. The dash in the REBEC row indicates that no target sample size was recorded for that registration. ChiCTR, Chinese Clinical Trial Registry; JPRN, Japan Primary Registries Network; KCT, Clinical Research Information Service of the Republic of Korea; OMON, Netherlands Trial Register; REBEC, Brazilian Registry of Clinical Trials.

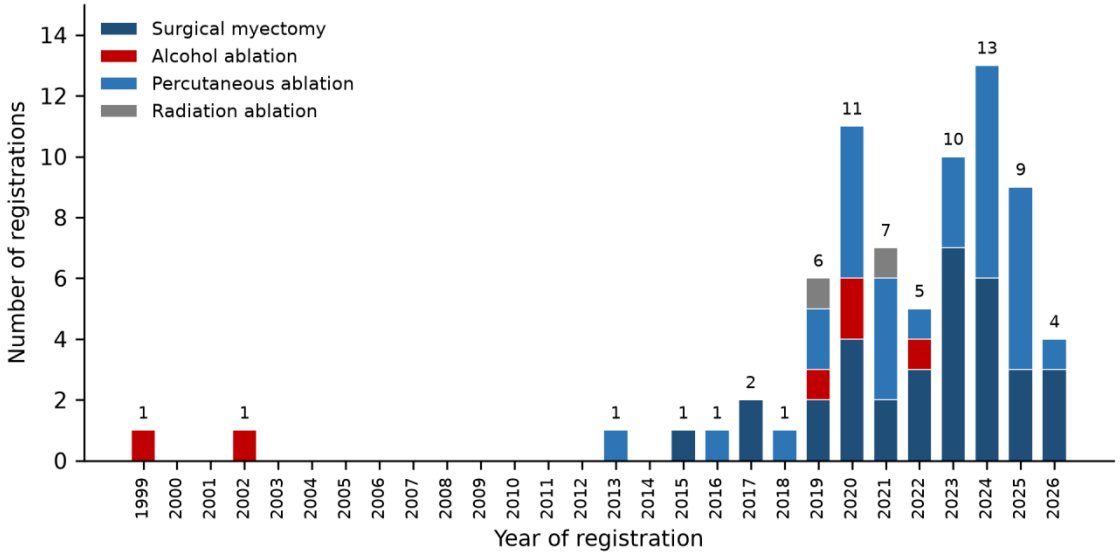


Fig. 2. Annual septal-reduction registrations by procedure modality, 1999-2026. Bars are stacked by modality, and the number above each bar is the total number of registrations entered in that year. Registration activity before 2019 was sparse (8 of 73 registrations, 11.0%); 65 registrations (89.0%) were entered in 2019 or later and the annual count peaked at 13 in 2024. The bar for 2026 covers registrations entered up to the retrieval date (9 October 2026) and is therefore a partial year. Modality groups are mutually exclusive as defined in the Methods.

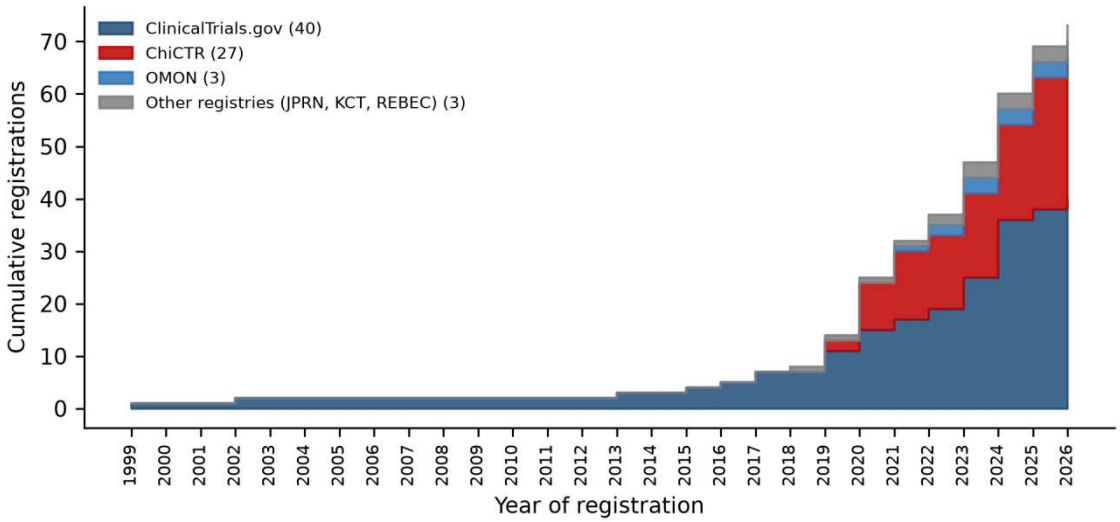


Fig. 3. Cumulative septal-reduction registrations by source registry, 1999-2026. Areas are stacked, so the height of the shaded region is the cumulative number of registrations in the analysis set and each band is the share contributed by one group of registries; the legend gives the number of registrations held by each group. The three registries that contributed the most registrations are shown separately (ClinicalTrials.gov, n = 40; ChiCTR, n = 27; Netherlands Trial Register, OMON, n = 3) and the remaining three registries, which contributed one registration each (JPRN, KCT and REBEC), are pooled. ClinicalTrials.gov registrations begin in 1999 and accumulate steadily, whereas ChiCTR registrations accumulate entirely after 2019. JPRN, Japan Primary Registries Network; KCT, Clinical Research Information Service of the Republic of Korea; OMON, Netherlands Trial Register; REBEC, Brazilian Registry of Clinical Trials.

3.3 Procedure mix and geographic distribution

Surgical septal myectomy was the most frequent modality with 33 registrations (45.2%), followed closely by percutaneous or endocardial septal ablation with 32 (43.8%), then alcohol septal ablation with six (8.2%) and septal radiation ablation with two (2.7%). The two modalities were distributed differently between registries: percutaneous ablation accounted for 16 of 27 ChiCTR registrations (59.3%) and 15 of 40 ClinicalTrials.gov registrations (37.5%), while surgical myectomy accounted for 21 of 40 ClinicalTrials.gov registrations (52.5%) and 8 of 27 ChiCTR registrations (29.6%) (Table 2).

China was recorded as a country of recruitment in 48 of the 73 registrations (65.8%). Among the 15 registrations that recorded any other country, the largest regions were the Americas (7 registrations), Europe (6) and Asia excluding China (2); the remaining ten registrations (13.7%) carried no country that could be assigned in the aggregated record, and the modality composition of those ten cannot be recovered from the aggregated data (Table 3).

Procedure route differed between the two country groups. Among registrations recorded as recruiting in China, percutaneous or endocardial septal ablation accounted for 29 of the 45 registrations that used that technique or surgical myectomy (64.4%); among registrations not recorded as China the corresponding proportion was 3 of 20 (15.0%), giving an odds ratio of 10.3 (95% CI 2.6-40.4; two-sided Fisher exact p = 0.0003) (Table 3). Because ten registrations carried no recorded country, this estimate is bounded rather than exact, as the sensitivity analysis in Section 3.7 shows. No registration evaluated percutaneous or endocardial septal ablation against surgical myectomy; the only registration that compared a catheter-based ablative technique with surgery was AMARONE (NCT04684290), which compared alcohol septal ablation with surgical septal myectomy.

Table 3. Procedure modality, prospective registration and target sample size, by recruitment region.

Recruitment group (n)	Myectomy	Alcohol	Percutaneous	Radiation	Prospective	Median size
China (48)	16 (33.3)	2 (4.2)	29 (60.4)	1 (2.1)	28 (58.3)	100
Outside China (25)	17 (68.0)	4 (16.0)	3 (12.0)	1 (4.0)	12 (48.0)	40

Values are n (%) of the registrations in that group, except median size, which is the median target sample size in participants. Percentages are row percentages. Recruitment country was taken from the WHO Trial Registration Data Set countries-of-recruitment field: registrations were classified as China when that field listed China and as not China otherwise, so the not-China group includes the ten registrations in which the field was empty or unassignable (a country was recorded for 15 of those 25 registrations). Percutaneous ablation includes percutaneous and endocardial septal radiofrequency ablation, transcatheter myocardial ablation, transthoracic radiofrequency or laser ablation, cryoablation of the septum and pulsed field ablation of the septum. The comparison of percutaneous ablation with surgical myectomy between country groups gave an odds ratio of 10.3 (95% CI 2.6-40.4; two-sided Fisher exact p = 0.0003); across the 24 admissible modality assignments of the ten registrations without a recorded country the odds ratio ranged from 4.2 to 25.4, and the two-sided Fisher exact p-value was 0.075 in the most conservative assignment. The four-category comparison was not tested because the minimum expected cell count was 0.68.

3.4 Registration transparency

Prospective registration was recorded for 40 of 73 registrations (54.8%, 95% CI 43.4-65.7); the remaining 33 (45.2%) were registered retrospectively, that is, after the stated date of first enrolment. The proportion differed between the two dominant registries: 21 of 27 ChiCTR registrations were prospective (77.8%) compared with 15 of 40 ClinicalTrials.gov registrations (37.5%), giving an odds ratio of 5.8 (95% CI 1.9-17.7; two-sided Fisher exact p = 0.0014) (Table 2, Fig. 4). When registrations were grouped by recorded recruitment country rather than by registry, the difference was not statistically significant: 28 of 48 registrations recorded as China were prospective (58.3%) compared with 12 of 25 registrations not recorded as China (48.0%; Fisher exact p = 0.46). The two groupings are not independent, because every ChiCTR registration in this set is also a China-recruited registration, and no adjusted analysis was attempted; the data therefore do not establish which of registry administration, recruitment country, registration year or study type accounts for the difference.

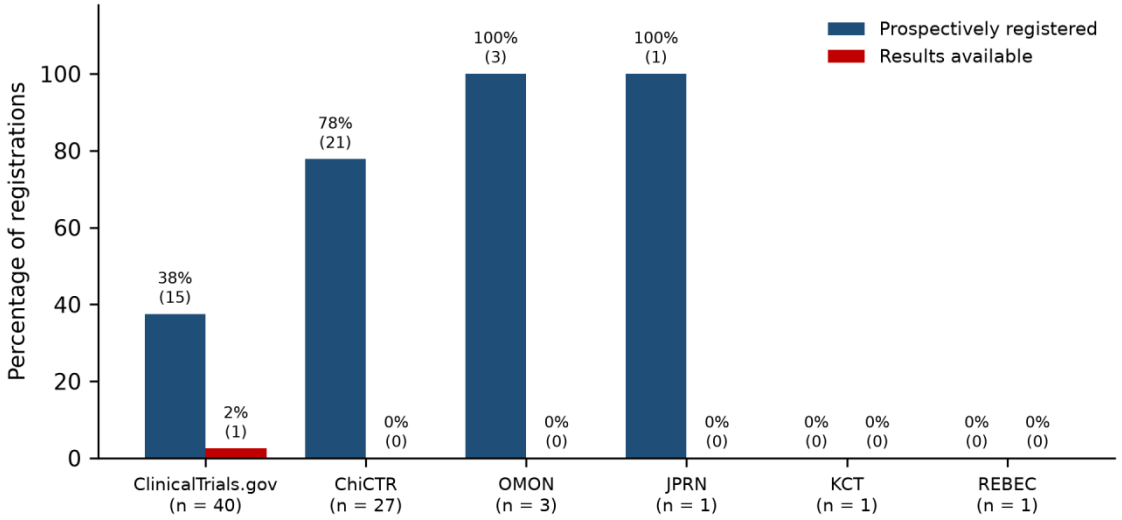


Fig. 4. Registration transparency by source registry. Bars show the percentage of registrations in each registry that were prospectively registered and the percentage for which the portal displayed results information; the number in parentheses is the numerator. Prospective registration was recorded for 21 of 27 ChiCTR registrations (77.8%) and 15 of 40 ClinicalTrials.gov registrations (37.5%) (two-sided Fisher exact p = 0.0014). Portal-visible results information was recorded for a single registration overall. ChiCTR, Chinese Clinical Trial Registry; JPRN, Japan Primary Registries Network; KCT, Clinical Research Information Service of the Republic of Korea; OMON, Netherlands Trial Register; REBEC, Brazilian Registry of Clinical Trials.

3.5 Results information and record currency

The portal displayed results information for 1 of the 73 registrations (1.4%, 95% CI 0.2-7.4), an early feasibility study of transcatheter myotomy; the remaining 72 records carried no results-availability entry. The portal also carried no completion date and no first-publication date for any of the 73 registrations, so the interval between completion and dissemination could not be measured from this source (Table 2, Fig. 4). These statements describe what the aggregated record displayed, not whether the underlying studies reported. The distinction is not hypothetical: the transapical beating-heart septal myectomy registration NCT05332691 satisfies the eligibility rule applied here, carries no results entry in the aggregated record, and yet corresponds to published first-in-human and post-learning-curve outcome reports [19, 20].

The median interval since the portal last refreshed a record was 1005 days (IQR 472-2033), and 46 records (63.0%) had not been refreshed for more than two years (Fig. 5). Median staleness was 1243 days for ChiCTR records

(n = 27) and 1019 days for ClinicalTrials.gov records (n = 40); the difference was not statistically significant (Mann-Whitney U = 585.0, p = 0.57). Among the four remaining registries the median intervals ranged from 102 days (JPRN) to 1145 days (KCT). Inspection of the extracted text revealed transcription defects in the aggregated Chinese records, including a target sample size field rendered as "diofrequency ablation:40;Alcohol Ablation:40" and an intervention field truncated to "The Septal myectom".

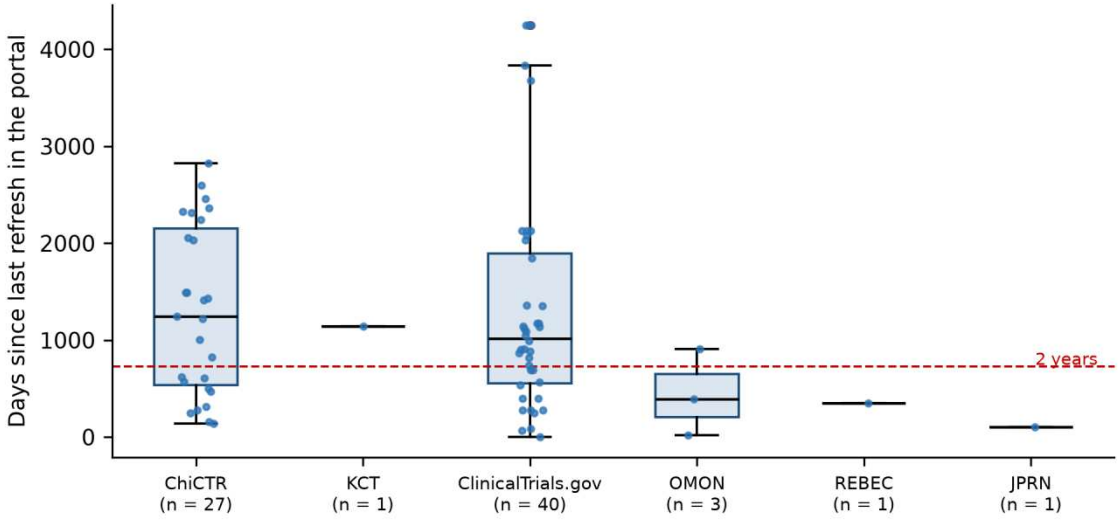


Fig. 5. Currency of the aggregated registry record at the retrieval date. Boxes show the distribution of days between the date the portal last refreshed each record and 9 October 2026, with individual registrations overlaid and the dashed line marking two years. The four registries that contributed three or fewer registrations are also shown, but their distributions rest on one to three records and are not interpretable as registry-level estimates. Registries are ordered from left to right by decreasing median interval since the last refresh. The median interval was 1005 days overall (IQR 472-2033) and 46 of 73 records (63.0%) had not been refreshed for more than two years. Median staleness was 1243 days for ChiCTR records and 1019 days for ClinicalTrials.gov records (Mann-Whitney U = 585.0, p = 0.57). ChiCTR, Chinese Clinical Trial Registry; IQR, interquartile range; JPRN, Japan Primary Registries Network; KCT, Clinical Research Information Service of the Republic of Korea; OMON, Netherlands Trial Register; REBEC, Brazilian Registry of Clinical Trials.

3.6 Design, sample size and metadata completeness

Forty-nine registrations (67.1%) were interventional and 24 (32.9%) were observational, including two designated patient registries; several of the observational entries describe patients undergoing a septal-reduction procedure rather than evaluating the procedure itself. The unit of this audit is the registration, and the portfolio described here therefore contains both interventional and observational studies. A target sample size was stated for 71 registrations (97.3%); the median was 64 participants (IQR 30-136, range 1-1300). Primary outcome measures were recorded for 71 registrations (97.3%) and secondary outcome measures for 57 (78.1%). Secondary identifiers were present for 43 registrations (58.9%). The source-of-monetary-support field was populated for all 73 records, but 42 (57.5%) carried only generic wording directing readers to consult the primary and secondary sponsors, leaving 31 registrations (42.5%) with a substantively named funder. An ethics review status was populated for 32 registrations (43.8%): 30 were recorded as approved, one as submitted for approval and one as not approved. The remaining 41 records carried no ethics entry, so the completeness of this field varied between registries rather than within them.

3.7 Sensitivity analysis

Relaxing the eligibility rule to retain registrations whose study population undergoes septal reduction, even where the evaluated intervention was peri-procedural care, added three registrations: one study of anaesthetic management during transapical beating-heart septal myectomy and two studies of postoperative blood-pressure management after percutaneous intramyocardial septal radiofrequency ablation, all recruiting in China. The analysis set increased from 73 to 76 registrations, and no headline finding changed in direction or significance. Prospective registration was recorded for 55.3% of the broader set compared with 54.8% of the primary set; portal-visible results information was 1.3% compared with 1.4%; China recruitment was 67.1% compared with 65.8%; percutaneous ablation accounted for 64.6% of China-recruited ablative or surgical registrations compared with 64.4% (Fisher exact $p = 0.0004$); and prospective registration was recorded for 79.3% of ChiCTR registrations compared with 77.8% (versus 36.6% of ClinicalTrials.gov registrations, $p = 0.0006$). Median record staleness fell from 1005 days to 949 days. The largest change in any headline proportion was 1.4 percentage points. This analysis relocates the eligibility boundary; it does not resolve the ten registrations whose recruitment country was not recorded.

Two further sensitivity analyses addressed classification decisions that the aggregated records do not settle. First, the ten registrations that carried no recorded recruitment country were retained in the not-China group throughout. Because the modality margins of that group are fixed by Table 3, every admissible assignment of those ten records to a modality can be enumerated. Across the 24 admissible assignments the odds ratio for the percutaneous-versus-surgical contrast ranged from 4.2 to 25.4, six assignments left a zero cell in which the odds ratio is undefined, and the two-sided Fisher exact p-value was 0.075 under the most conservative assignment. The contrast is therefore robust in direction but not in statistical significance, and the ten records must be resolved against the source registries before the contrast is reported as significant. Second, the two registrations of the single alcohol-versus-surgery comparison (AMARONE, NCT04684290 and NL-OMON56423) were each assigned to one modality group; assigning both to alcohol septal ablation instead of surgery moves the odds ratio from 10.3 (95% CI 2.6-40.4) to 9.1 (95% CI 2.3-36.1) without changing the direction of the contrast.

4. Discussion

This audit found that the septal-reduction portfolio retrieved from the WHO International Clinical Trials Registry Platform is small, recent and concentrated. Seventy-three registrations were retrieved, nearly nine in ten of them entered since 2019, and almost all of them held by two registries. Procedure route was distributed unevenly between the country groups: percutaneous or endocardial septal ablation accounted for 64.4% of the China-recruited registrations that used that technique or surgery, compared with 15.0% of the registrations not recorded as China, although the size of that difference depends on ten registrations whose recruitment country the aggregated record did not supply. Prospective registration was more common in ChiCTR than in ClinicalTrials.gov, and the portal displayed results information for a single registration.

The concentration of the portfolio is the most consequential finding for anyone attempting to synthesise this evidence. A reviewer searching ClinicalTrials.gov alone would miss 33 of the 73 registrations, including 17 of the 32 registrations of percutaneous or endocardial septal ablation, and a reviewer searching ChiCTR alone would miss 25 of the 33 registrations of surgical septal myectomy. This is consistent with the rationale for the WHO International Clinical Trials Registry Platform, which exists precisely to bridge registrations held by different primary registries [27], and with evidence that searching a single registry under-identifies eligible studies [28]. Registry choice therefore determines which procedures a synthesis can see.

The geographic split in procedure route reflects the origin of the competing technologies. Surgical myectomy and alcohol septal ablation were developed and evaluated in North American and European centres and dominate the

comparator literature [7–15]. Percutaneous intramyocardial septal radiofrequency ablation and transapical beating-heart septal myectomy were developed in Chinese centres and reported first in Chinese cohorts [16–20]. The registrations analysed here show the same tendency rather than a clean division: percutaneous or endocardial septal ablation accounted for 64.4% of the China-recruited registrations that used that technique or surgical myectomy, but 16 of the 48 registrations recorded as China (33.3%) were surgical, and 3 of the 20 registrations not recorded as China (15.0%) were percutaneous. The registered portfolio therefore tracks the geography of procedural innovation rather than a shared assessment of comparative effectiveness. Because percutaneous or endocardial septal ablation has not been compared with surgical myectomy in any registration in this dataset, and because centre volume is strongly associated with outcome for both procedures [15], the absence of a head-to-head registration for the percutaneous route is a substantive evidence gap rather than a bookkeeping detail.

The difference in prospective registration between the two registries is large, but the registries differ in composition as well as in administration, and these data cannot separate the two. All ChiCTR records in this set were China-recruited and all were entered after 2019, whereas ClinicalTrials.gov contributed records from 1999 onwards, including observational and device-related studies; published descriptions of the accumulated ChiCTR holdings [29, 30] provide background but are not evidence about this sample. Grouping by recorded recruitment country did not reproduce the difference (58.3% versus 48.0%, $p = 0.46$), but because every ChiCTR registration is also a China-recruited registration the two variables are collinear, and an unadjusted comparison of either grouping cannot attribute the difference to one factor. A larger set, or an adjusted model, would be needed to separate registry administration from recruitment country, registration year and study type.

The absence of results information has the clearest practical consequence, and it must be stated precisely. This audit measured what the aggregated record displayed: 1 of 73 registrations carried a results entry, and none carried a completion date or a first-publication date. That is not the same as showing that the studies never reported. Completion date and summary results form part of the WHO Trial Registration Data Set, and the summary-results element is designed to carry the date of first posting, the date of first journal publication and links to the results; the retrieved records displayed these elements without populating them. The underlying studies may therefore have reported in the source registry, in the literature, or not at all, and this audit cannot distinguish those cases. One observation bounds the possibilities: registrations in this set do correspond to published outcome reports — for example NCT05332691, a transapical beating-heart septal myectomy registration that satisfies the eligibility rule applied here, carries no results entry yet has published first-in-human and post-learning-curve outcomes [19, 20]. At the same time, the source record for that registration carried no results module either, so the empty field is not merely a transmission artefact. The practical consequence stands: a reader consulting the aggregated record alone cannot tell whether a study has finished, has reported, or has done neither. The wider literature on selective reporting [35, 36] and on non-publication of registered trials [37], together with the difficulties of evaluating surgical and device innovation [38], indicates that such ambiguity is common after procedural interventions; that is an argument for verifying each record against its source registry and the literature, not an inference about the conduct of any individual study in this set.

Record currency compounds the problem. The median registration had not been refreshed in the portal for 1005 days (IQR 472-2033), and 46 of the 73 records (63.0%) had not been refreshed for more than two years. The interval was numerically longer for ChiCTR records than for ClinicalTrials.gov records (medians 1243 and 1019 days), but the difference was not statistically significant (Mann-Whitney $U = 585.0$, $p = 0.57$), so these data do not identify a single contributor as the source of the lag. Two transcription defects were observed in the aggregated records — a target sample size field retaining an arm label and a misspelt, truncated intervention string. These are minor individually and material collectively, because the aggregator is the interface used for most record retrieval, and a truncated intervention field is exactly the field on which this study's eligibility rule depends. A researcher applying

the same rule to the portal's rendered text, rather than to the source registry record, would misclassify such a registration.

The study has several limitations, each with a defined direction of bias. Eligibility was decided by a mechanical rule applied to the intervention field and, secondarily, the registered title; registrations that studied a named procedure without naming it in either field would have been missed, which biases the sample size downward, and the rule could not be validated against the source registry records, which biases the modality classification toward the aggregator's wording. One registration that combined mavacamten with a generically described radiofrequency ablation was excluded because the record did not identify the ablation as septal; if that procedure was in fact septal ablation, the percutaneous count is understated by one. Alcohol septal ablation is itself a catheter-based technique and was more frequent outside China, so the contrast measured here is specific to the percutaneous or endocardial route and would be attenuated if all catheter-based techniques were pooled. Nine keyword combinations cannot exhaust the vocabulary of procedure naming, so the retrieval is a defined but not exhaustive search, and registrations titled only in Chinese and indexed without an English procedure term would be missed. Record staleness was measured against the portal's last-refresh date, which reflects the aggregator's import schedule as much as the source registry's update behaviour, so the staleness estimates are an upper bound on true registry currency. Four further limitations concern the classification decisions themselves. Ten registrations carried no recruitment country in the aggregated record and were retained in the not-China group; reassigning them within the constraints set by the published margins moves the odds ratio for the percutaneous-versus-surgical contrast between 4.2 and 25.4 and raises the two-sided Fisher exact p-value as high as 0.075, so the direction of that contrast is robust but its significance is not, and if any of those ten were in fact China-recruited the estimate would move again. Two registrations of a single alcohol-versus-surgery comparison had to be assigned to one modality each. Duplicate identification combined exact matching of normalised titles with inspection of the extracted titles, so an unquantified number of further dual registrations may remain, which affects trial-level but not registration-level counts. No independent duplicate screening or inter-rater agreement was recorded, so records that the eligibility rule does not settle mechanically are not fully reproducible from the published description. Finally, the four significance tests reported here were exploratory and unadjusted, and the numbers are small enough that the confidence interval for portal-visible results information (0.2% to 7.4%) is wide; the descriptive counts, not the p-values, should carry the interpretation.

The broad-eligibility sensitivity analysis bounds the first of these concerns. Adding all registrations whose population undergoes septal reduction moved no headline proportion by more than 1.4 percentage points and left both tests below the 0.05 threshold (route $p = 0.0004$; registry $p = 0.0006$), so the principal contrasts in this audit are not artifacts of where the eligibility line was drawn. The concerns the sensitivity analysis cannot address are the two that depend on data the aggregator does not carry: the procedure route of registrations whose intervention is described generically, and the results status of trials that have finished but have not posted.

Three implications follow. For evidence synthesis, the minimum standard for a review of septal reduction in hypertrophic cardiomyopathy is a search of the aggregator plus each registry relevant to the population, because single-registry searching excludes the registrations held elsewhere. For research priority setting, the absence of any registered comparison of the percutaneous or endocardial route with surgical myectomy is the clearest gap in the portfolio, and it is a gap that registry data can identify but cannot close. For registries and sponsors, the finding that no retrieved record carried a completion date, and that one carried results information, is not an argument for adding fields that the data set already contains: completion date and summary results are elements of the WHO Trial Registration Data Set. The task is to populate those elements completely and in time, to transmit them intact from the source registry to the aggregator, and to make what the portal displays verifiable against the source record.

5. Conclusions

The septal-reduction portfolio retrieved from the WHO International Clinical Trials Registry Platform consists of 73 registrations held by six registries, nearly nine in ten of them entered since 2019 and almost all of them concentrated in ClinicalTrials.gov and ChiCTR. Procedure route was distributed unevenly between the country groups: percutaneous or endocardial septal ablation accounted for 64.4% of the registrations recorded as recruiting in China that used that technique or surgery, compared with 15.0% of those not recorded as China, although the contrast loses statistical significance under the most conservative assignment of the ten registrations whose country was not recorded ($p = 0.075$). No registration compared the percutaneous route with surgical myectomy. Portal-visible results information was present for 1 of 73 registrations and no registration carried a completion or first-publication date, so the aggregated record cannot yet support judgements about procedure performance, although studies registered in this set have published their findings and the two elements that would close the gap, completion date and summary results, already form part of the WHO Trial Registration Data Set. Populating those elements completely, verifying their transmission to the aggregator, and searching all relevant registries rather than one would make the portfolio usable for the decisions it is meant to inform.

Declarations

Availability of Data and Materials

All source records are publicly available from the WHO International Clinical Trials Registry Platform search portal (https://trialsearch.who.int/), retrieved on 9 October 2026 under the WHO ICTRP Terms and Conditions for Use of WHO ICTRP Data. The extracted record set (analysis_dataset.csv, reported as Supplementary Table S2), the record-level screening log (screening_log.csv, reported as Supplementary Table S1), the dataset build script (build_dataset.py), the analysis script (analysis.py), the sensitivity analysis script (sensitivity_analysis.py) and the five figures are provided as Supplementary Material. No restricted or individual-level data were used.

Author Contributions

Yulong Sui: Conceptualization, Data curation, Formal analysis, Writing – original draft. Xiaoqian Nie: Methodology, Validation, Investigation, Writing – review & editing. Jiaxiang Tang: Data curation, Formal analysis, Visualization, Writing – review & editing. Quansheng Xing: Conceptualization, Supervision, Project administration, Writing – review & editing.

Ethics Approval and Consent to Participate

Not applicable. This study analysed publicly available trial-registration records and did not involve human or animal participants, biological material, or identifiable individual data, so ethics approval and participant consent were not required.

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Conflicts of Interest

The authors declare no conflicts of interest.

Declaration of AI and AI-assisted Technologies

AI-assisted software was used solely to edit the language of the manuscript. The authors reviewed and approved the final text and take full responsibility for the study design, data analysis, code, keyword lexicons, results, references, and interpretation.

Supplementary Material

Table S1, the record-level screening log (screening_log.csv), gives the registry identifier, the registered title, the source registry, the intervention field, the inclusion decision and the reason for every retrieved registration, including the records excluded as pharmacological-only or peri-procedural care. Table S2, the extracted dataset (analysis_dataset.csv), gives one row per eligible registration with the fields used in this analysis. The dataset build script (build_dataset.py), the analysis script (analysis.py), the sensitivity analysis script (sensitivity_analysis.py) and the five figure files are also provided.

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