Discrepancies Between Published Randomized Controlled Trials and Their Registry Entries: A 6-Year Analysis of Top General Orthopaedic Journals

Amir Human Hoveidaei, Sean Tabaie

INTRODUCTION:

The integrity of clinical research is essential for advancing orthopaedic practice and ensuring optimal patient care. Randomized controlled trials (RCTs) are considered the gold standard of clinical evidence, but their effectiveness depends on strict reporting and transparent methodology. Registering RCTs in advance is crucial to avoid selective reporting and bias research. This study aimed to comprehensively examine the alignment between registered protocols and the published reports of RCTs in prominent orthopaedic journals from 2019 to 2025.

METHODS:

A comprehensive review was conducted of RCTs published in the five highest-ranked general orthopaedic journals, as determined by the 2022 Scientific Journal Rankings. A systematic PubMed search identified 620 candidate publications, of which 337 RCTs met specific inclusion criteria. For each trial, nine key items from the 24-item WHO Minimum Data Set were extracted and compared between the published article and its corresponding trial registry entry, with particular attention to health condition, intervention, sample size, outcomes, and eligibility criteria.

RESULTS:

Among the 337 RCTs analyzed, 72.7% (245 studies) were conducted outside the United States, and 65% (219 studies) were registered on ClinicalTrials.gov. Alarmingly, 7.4% (25 studies) lacked any registry entry, while 1% reported incorrect registration codes. Nearly half (47.5%, 160 studies) focused on joint reconstruction, and 86.9% (293 studies) employed a double-arm design. Additionally, our analysis of registered studies (N=312) revealed considerable discrepancies: 38.2% (119 studies) failed to report the sample size in either the registry or publication. Moreover, 27.2% (85 studies) altered their primary outcome between registration and publication, 62.2% (194 studies) modified key secondary outcomes, 35.3% (110 studies) changed the inclusion criteria, 55.8% (174 studies) changed exclusion criteria, and 88.8% (277 studies) did not submit results to the registry prior to publication.

DISCUSSION AND CONCLUSION:

These findings highlight substantial and widespread inconsistencies between registered protocols and published reports in orthopaedic RCTs. Such lapses in transparency and reporting integrity not only compromise the reliability of the scientific record but also threaten the foundation of evidence-based orthopaedic practice. The failure to adhere to registered protocols undermines clinical decision-making, erodes trust in published research, and ultimately jeopardizes patient outcomes. Therefore, it's crucial for the orthopaedic research community—including investigators, peer reviewers, and journal editors—to adopt more stringent standards for trial registration, reporting, and enforcement.

Table 1. Characteristics of included studies

Items	Characteristic	No. (%) of RCTs
Orthopedic subspecialties	Oncology	3 (0.9%)
	Joint reconstruction	160 (47.5%)
	Sport and arthroscopy	17 (5%)
	Spine	16 (4.7%)
	Foot and ankle	17 (5%)
	Trauma	44 (13.1%)
	Upper extremity	47 (13.9%)
	Pediatrics	7 (2.1%)
	General	26 (7.7%)
Journal	J Bone Joint Surg Am	123 (36.5%)
	Clin Orthop Relat Res	55 (16.3%)
	Acta Orthop	42 (12.5%)
	Bone Joint J	96 (28.5%)
	J Am Acad Orthop Surg	21 (6.2%)
Publication year	2019	65 (19.3%)
	2020	62 (18.4%)
	2021	54 (16%)
	2022	55 (16.3%)
	2023	44 (13.1%)
	2024	48 (14.2%)
	2025 (Until February)	9 (2.7%)
Study Location	US	81 (24%)
	Non-US	245 (72.7%)
	Multicenter (US and non-US)	11 (3.3%)
Clinical Trial Registry	Clinicaltrials.gov	219 (65%)
	ISRCTN.com	20 (5.9%)
	Netherlands Trial Register	18 (5.3%)
	Other	55 (16.3%)
	No registry found	22 (6.5%)
	No registry found despite of reporting code in article	3 (1%)
Number of Arms	2	293 (86.9%)
	3	32 (9.5%)
	4	11 (3.3%)
	>4	1 (0.3%)

Table 2. Registry and Publication Discrepancies in the Included Studies

		Same	Whole different or missing in registry or article		
1	**Condition**	310 (99.4%)	2 (0.6%)		
2	**Intervention**	301 (96.5%)	11 (3.5%)		
3	**Study Type**	307 (98.4%)	5 (1.6%)		
4	**Sample Size**	193 (61.8%)	119 (38.2%)		
5	**Primary Outcome**	Same	Added/Removed	Not defined in article or registry	Changed from secondary
		227 (72.8%)	41 (13.1%)	33 (10.6%)	11 (3.5%)
6	**Secondary Outcome**	Same	Added/Removed	Not defined in article or registry	Changed from primary
		118 (37.8%)	96 (30.8%)	79 (25.3%)	19 (6.1%)
7	**Inclusion Criteria**	Same	Added/Removed	Not defined in article or registry	
		202 (64.7%)	97 (31.1%)	13 (4.2%)	
8	**Exclusion Criteria**	Same	Added/Removed	Not defined in article or registry	
		138 (44.2%)	154 (49.4%)	20 (6.4%)	
9	**Summary Results *Before* Publication**	Yes	No		
		35 (11.2%)	277 (88.8%)		