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Brief Report

Lost in submission? Investigating publication bias in regional anaesthesia: A pilot case study of the erector spinae plane block

¿Perdido en la presentación? Investigación del sesgo de publicación en anestesia regional: estudio de un caso piloto de bloqueo en el plano del músculo erector de la columna

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ABSTRACT

Background: The Erector Spinae Plane (ESP) block is a regional anaesthesia technique with a growing range of clinical applications due to its short learning curve, low complication rate, and effectiveness. However, publication bias can distort the perceived efficacy of interventions, especially when studies with negative or inconclusive results remain unpublished. The real extent of publication bias in ESP-related clinical research currently remains unclear.

Methods: We searched ClinicalTrials.gov on 2 February 2025 using the terms «Erector Spinae Plane Block» and «ESP block», and obtained 671 records. After excluding duplicates, irrelevant, and ongoing studies, 500 records were eventually included. Study characteristics and publication status were determined using a multi-step search strategy that included PubMed®, Scopus®, Embase®, and Central®. Data were analysed using appropriate statistical tests on R (v3.4.0).

Results: Of the 500 studies included, 361 (72.2%) were complete, 102 (20.4%) had unknown status, and 37 (7.4%) had been suspended, terminated, or withdrawn. Only 211 studies (42.2%) were published, and included data from 14,374 of 32,600 intended patients. Published studies were registered significantly earlier than unpublished ones (median year 2020 vs 2021; $P = .004$). No significant differences were found between published and unpublished studies in terms of main outcome, continent, surgical setting, study design, or sample size.

Conclusions: A substantial proportion of ESP block studies remain unpublished, indicating potential publication bias. Although earlier registration was associated with publication, other study characteristics were not. These findings highlight the need for increased transparency and for clinical trial results to be published regardless of outcome in order to ensure that the evidence base is unbiased.

Palabras clave:
Bibliométrico
Sesgo de publicación
Realización de la anestesia
Bloqueo ESP

RESUMEN

Antecedentes: El bloqueo en el plano del músculo erector de la columna (ESP) es una técnica anestésica regional con un rango creciente de aplicaciones clínicas debido a su corta curva de aprendizaje, baja tasa de complicaciones y efectividad. Sin embargo, el sesgo de publicación puede distorsionar la eficacia percibida de las intervenciones, especialmente cuando los estudios con resultados negativos o no concluyentes siguen sin publicarse. El alcance real del sesgo de publicación en la investigación clínica relacionada con el ESP sigue siendo actualmente incierto.

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Métodos: Realizamos una búsqueda en ClinicalTrials.gov el 2 de febrero de 2025 utilizando los términos «Erector Spinae Plane Block» y «ESP block», obteniendo 671 registros. Tras excluir los estudios duplicados, irrelevantes y en curso, se incluyeron 500 registros eventualmente. Las características del estudio y el estado de la publicación fueron determinados mediante una estrategia de búsqueda de múltiples pasos que incluyó PubMed®, Scopus®, Embase® y Central®. Los datos fueron analizados utilizando pruebas estadísticas adecuadas en R (v3.4.0).
Resultados: De los 500 estudios incluidos, 361 (72,2%) fueron completos, 102 (20,4%) tenían un estado desconocido, y 37 (7,4%) habían sido suspendidos, finalizados o retirados. Sólo 211 estudios (42,2%) fueron publicados, e incluyeron datos de 14.374 a 32.600 pacientes previstos. Los estudios publicados se registraron considerablemente antes que los no publicados (mediana de año 2020 vs 2021; $P = ,004$). No se encontraron diferencias significativas entre estudios publicados y no publicados en términos de resultado principal, continente, contexto quirúrgico, diseño del estudio o tamaño muestral.
Conclusiones: Una parte sustancial de los estudios sobre bloqueo ESP siguen sin estar publicados, lo cual indica un sesgo de publicación potencial. Aunque el registro temprano estuvo asociado a la publicación, otras características de los estudios no lo estuvieron. Estos hallazgos destacan la necesidad de incrementar la transparencia y de que se publiquen los resultados de los ensayos clínicos, independientemente del resultado, a fin de garantizar la imparcialidad de la base de la evidencia.

Introduction

The Erector Spinae Plane (ESP) block is a regional anaesthesia technique that was first described by Forero in 2016. It involves injecting local anaesthetic deep to the erector spinae muscle, near the transverse processes of the vertebrae. This results in the spread of anaesthesia along the paravertebral space and provides both somatic and visceral pain relief.[1] The technique has been widely adopted and experts consider it to be a valuable approach[2] due to its short learning curve,[3] low complication rate,[4] and favourable clinical effect on a broad range of clinical applications.[5] Previous research in other fields has shown that up to 85% of biomedical studies are never published,[6] leading to a significant loss of funding, effort, and valuable data. Failure to publish research findings undermines the reliability of scientific evidence, and can result in overestimation of an intervention's effectiveness, particularly when studies remain unpublished due to statistically non-significant results—a phenomenon known as publication bias.[7] Understanding the incidence of publication bias in a technique with promising but as yet debated efficacy compared to other techniques may be important to critically assess the available data. However, the rate of publication bias in regional anaesthesia has yet to be determined.

The primary aim of this study is to assess the rate of discontinuation and non-publication of studies in which the ESP block was one of the comparators. Secondary aims include identifying differences among characteristics of published and unpublished studies.

Methods

On 2 February 2025, we queried the *ClinicalTrials.gov* registry to identify studies analysing the ESP block using the following search terms: "Erector Spinae Plane Block" and "ESP block" which include the following synonyms: erector spinae; Erector spinae muscle; block; blocks; Blockade. Results from both searches were merged and duplicate entries were removed, leaving a total of 671 records. The retrieved studies were independently reviewed by two authors who excluded those not relevant to the ESP block (4 studies). Next, 167 studies labelled as ongoing were excluded ("Recruiting", "Active, not recruiting", "Not yet recruiting" or "Enrolling by invitation") leaving a total of 500 studies labelled "Suspended", "Withdrawn", "Completed", "Terminated" or "Unknown" for inclusion.

In the ClinicalTrials.gov database, a study is labelled "Unknown" when its recruitment status has not been verified for more than two years, meaning its progress or completion remains uncertain. We verified the publication status of each study and extracted the following variables from the record: year, country, main objective, surgery involved, study design (RCT vs nonRCT), and total number of patients. The following strategies were used to verify publication status: first, we checked the ClinicalTrials.gov record for the 'Published' label; second, we searched PubMed, Scopus, EMBASE, and CENTRAL using the ClinicalTrials.gov identifier as the search term; third, we reviewed the publication history of the researcher associated with the ClinicalTrials.gov record from the date of record publication to March 1, 2025. Normality of distribution was tested with the Shapiro-Wilk test; descriptive statistics were reported as mean ± standard deviation or median (first and third quartile) for normally in the case of non-normally distributed continuous variables, respectively, and as absolute numbers (percentages) in the case of categorical variables. Normally distributed variables were compared using the *t*-student test, non-normally distributed variables were compared using the Wilcoxon test, while the variables presented as percentage were compared between groups using the Chi-square test or the Fisher exact test, as appropriate. All statistical analyses were performed using R version 3.4.0 (2017-04-21). *P*-values $< .05$ were considered statistically significant.

Results

The 500 studies included were labelled as follows: completed (361, 72.2%), unknown (102, 20.4%), terminated (21, 4.2%), withdrawn (15, 3.0%), and suspended (1, 0.2%). Only a relatively small number of studies were published (211, 42.2%). This is particularly noteworthy considering that the studies initially planned to include a total of 32,600 patients, yet data from only 14,374 patients were ultimately published.

It is important to bear in mind that there is usually a time gap between study completion and data publication. Our data reflect this, as published studies were registered earlier than unpublished ones 2020 (2019–2022) vs 2021 (2019–2022) $P = .004$). We found no significant differences between groups in terms of the main outcome analysed ($P = .914$), the researcher's continent of origin ($P = .283$), the surgical setting ($P = .548$), the study design ($P = .527$), or the total number of patients per study ($P = .166$) (Table 1).

Discussion

Our study aligns with broader concerns in biomedical research,[6,7] where a substantial proportion of studies remain unpublished, leading to potential publication bias and overestimation of treatment efficacy. While we identified a time lag between study completion and publication, no other significant factors, such as study design, research setting, or sample size, were associated with non-publication.

Our analysis shows that studies registered earlier had a significantly higher publication rate compared to those registered more recently. While this finding likely reflects the expected time lag between study completion and publication, as supported by the median registration years (2020 vs 2021, $P = .004$), earlier studies may have benefited from

Table 1
Characteristics of the Studies.

Variable	Category	Published (n = 211)	Unpublished (n = 289)	p-value
Continent	Africa	70 (33.1%)	88 (30.4%)	0.283
	North America	17(8.0%)	38 (13.1%)	
	Asia	95 (45.0%)	133 (46.0%)	
	Europe	27 (12.8%)	26 (9.0%)	
	South America	2 (0.9%)	4 (1.4%)	
Main Outcome	Opioid and non-opioid analgesics	96 (45.5%)	143 (49.4%)	0.914
	Block extension	13 (6.2%)	14 (4.8%)	
	Hemodynamic	3 (1.4%)	3 (1.0%)	
	Other	9 (4.3%)	11 (3.8%)	
	Pain	87 (41.2%)	112 (38.8%)	
	Respiratory parameters	3 (1.4%)	6 (2.1%)	
Surgical Setting	Cardio/Thoracic and vascular surgery	45 (21.3%)	66 (22.8%)	0.548
	Chronic nonsurgical pain	8 (3.8%)	10 (3.5%)	
	General	61 (28.9%)	81 (28.0%)	
	Healthy	5 (2.4%)	6 (2.1%)	
	Hepatobiliary	4 (1.9%)	2 (0.7%)	
	Obstetrics/Gynecology	16 (7.6%)	18 (6.2%)	
	Orthopedics/Vertebral	53 (25.1%)	67 (23.2%)	
	Pediatrics	3 (1.4%)	5 (1.7%)	
	Transplantation	0 (0%)	7 (2.4%)	
	Urology	16 (7.6%)	27 (9.3%)	
Type of Study	Observational	17 (8.0%)	19 (6.6%)	0.527
	RCTs	194 (92.0%)	270 (93.4%)	
Year	Median (IQR)	2020(2019-2022)	2021(2019-2022)	0.004*
Enrolled Patients	Mean ± SD	68.1 ± 37.5	63.0 ± 43.8	0.166

RCT = Randomized Controlled Trial.
* Statistically significant.

less competition and novelty saturation in the field of research into the ESP block, making them more attractive for publication, while later studies might have been more difficult to publish due to the existing volume of literature on the subject and possibly stricter editorial scrutiny. Other factors such as funding, study design quality, or editorial preferences may also influence the decision to publish, although these were beyond the scope of our data. Given these limitations, further research is needed to fully clarify the barriers to publication in this domain.

We also observed a slight, non-significant trend toward higher publication rates in studies originating from Africa and Asia. This difference may be attributable to regional variations in research infrastructure, access to publication, or prioritization of local clinical issues. However, our data do not allow us to draw definitive conclusions, and we recommend that future studies explore geographic disparities in publication practices in regional anaesthesia research.

Another important limitation of our study is that we only included studies registered in ClinicalTrials.gov, which, while comprehensive and widely used, is not the sole clinical trial registry. Other registries, such as the Chinese Clinical Trial Registry, the Clinical Trials Registry - India and others may contain relevant studies not captured in our analysis. Inclusion of data from these additional sources could potentially alter the observed publication rates and patterns, especially considering the growing volume of clinical research taking place in these countries. Future research should aim to incorporate multiple registries to provide a more global, representative overview of publication bias in ESP block studies.

Our findings underscore the need for greater transparency and accountability in clinical trial reporting to ensure that evidence-based practice is guided by a complete and unbiased dataset. Further efforts should focus on improving publication rates and addressing barriers that prevent the dissemination of clinical trial results, particularly in the case of studies yielding negative or inconclusive findings.

Our study has certain limitations that warrant discussion. First, we only searched *ClinicalTrials.gov,* which, while one of the most recognized databases, is not the only one. Examining multiple registries could have provided a more comprehensive overview of our research question. Second, some of the included studies may still be under peer review or may have been published after our search, and this could affect our findings.

CRediT authorship contribution statement

ADC and BD agreed on the idea, all the authors gathered the data, wrote the first borrador of the article, and edited and approved the final borrador of the article.

Informed consent

Not applicable.

Special considerations

Not applicable.

Declaration of Generative AI and AI-assisted technologies in the writing process

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