REVIEW

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Wilms Tumor Management: A Systematic Review Comparing SIOP and NWTS/COG Protocols in Diagnosis, Treatment, and Outcome

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Abstract

Introduction: Wilms tumor is the most common pediatric renal malignancy, with two predominant management approaches creating clinical decision-making challenges. SIOP advocates preoperative chemotherapy to reduce tumor burden, while NWTS/COG prioritizes immediate surgery for histopathological analysis. Evidence-based comparison is essential, particularly in resource-limited settings. Objective: To systematically compare preoperative chemotherapy (SIOP) versus upfront nephrectomy (NWTS/COG) protocols in Wilms tumor management by analyzing diagnostic accuracy, treatment efficacy, and surgical outcomes through direct comparative studies. **Methods:** A PRISMA 2020-guided systematic review was conducted, searching PubMed, ScienceDirect, SpringerLink, and Google Scholar for comparative studies (2015-2024) that directly compared SIOP and NWTS/COG protocols in pediatric Wilms tumor patients. Quality assessment was performed using the ROBINS-I tool. **Results:** Four comparative studies encompassing 226 patients from developing countries (India, Pakistan, Iraq, Vietnam) were included. Diagnostic accuracy varied significantly, with SIOP protocols showing misdiagnosis rates of 17.4-21.7% in resource-limited settings, while NWTS protocols achieved 100% accuracy in the single study reporting this outcome. Surgical outcomes were heterogeneously reported: one Indian study found no intraoperative spillage in SIOP patients (0/23) versus 22.2% in NWTS patients (2/9), though this finding cannot be generalized due to single-center limitations. Postoperative complications varied by setting, with one Pakistani study reporting higher rates in SIOP patients (21% vs. 9.5%). Survival outcomes ranged from 80.9-96.7% across protocols and countries, with no consistent pattern favoring either approach. **Conclusion:** Neither protocol demonstrates consistent superiority across all outcomes. Protocol selection should be individualized based on disease stage, diagnostic capabilities, and healthcare infrastructure. The limited number of comparative studies and heterogeneous reporting highlight the need for standardized outcome measures and larger multicenter trials.

Keywords: Wilms tumor- nephroblastoma- pediatric oncology- comparative protocols

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Introduction

Wilms tumor (nephroblastoma) represents the most common pediatric renal malignancy, accounting for approximately 6-7% of childhood cancers globally, with an annual incidence of 7-10 cases per million children under 15 years of age [1, 2]. Despite achieving >90% survival rates in high-income countries, fundamental philosophical differences persist between the International Society of Paediatric Oncology (SIOP) and National Wilms Tumor Study/Children's Oncology Group (NWTS/COG) approaches, creating ongoing clinical decision-making challenges [3].

SIOP protocols advocate preoperative chemotherapy to reduce tumor size and minimize surgical complications, particularly beneficial for advanced or bilateral disease [3, 4]. This approach enables treatment response assessment and has facilitated specific therapy modifications, such as the successful omission of doxorubicin in intermediate-risk cases [5]. However, neoadjuvant treatment may obscure original tumor histology, potentially complicating molecular risk stratification [6].

Conversely, NWTS/COG protocols prioritize immediate surgical intervention for comprehensive histopathological and molecular analysis [3]. Early identification of high-risk features including anaplastic histology and genetic abnormalities such as 1q gain and TP53 mutations significantly influences treatment intensity and prognosis [7, 8]. While immediate tumor biology access facilitates precise risk stratification, this approach may increase surgical complications in large or bilateral tumors.

Global implementation disparities further complicate protocol selection decisions. Healthcare systems in low-

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and middle-income countries face significant challenges including limited surgical expertise, inadequate diagnostic infrastructure, higher treatment abandonment rates, and delayed presentations, leading to inferior outcomes compared to high-income countries [9]. These disparities have necessitated regional protocol adaptations and international collaborative efforts to improve outcomes in resource-constrained environments [10].

This systematic review synthesizes evidence from direct comparative studies to address critical questions in Wilms tumor management regarding the comparative effectiveness of preoperative chemotherapy versus upfront nephrectomy approaches.

Objective

To compare preoperative chemotherapy (SIOP) versus upfront nephrectomy (NWTS/COG) protocols in Wilms tumor management by systematically analyzing diagnostic methods, treatment efficacy, and outcomes through direct comparative studies, while critically evaluating the generalizability of findings across different healthcare settings.

Materials and Methods

Study Design

This systematic review adhered to the 2020 PRISMA guidelines to ensure methodological integrity and transparency [11, 12].

Eligibility Criteria

Studies directly comparing SIOP and NWTS/COG protocols within the same population, pediatric populations (0-18 years) with confirmed or suspected Wilms tumor, comparative outcome data on survival, complication, or treatment completion, were published in English between 2015-2024, and had follow-up periods of at least 12 months were included in this systematic review. Single-protocol studies without direct comparison, case report ot case series with <10 patients, studies focusing exclusively on bilateral tumors or syndromic patients, conference abstracts without full-text availability, studies with unclear protocol definitions, mixed tumor types without separate wilms tumor analysis, and studies without extractable comparative data were excluded from this study.

Search Strategy

Comprehensive searches were conducted in PubMed, ScienceDirect, SpringerLink, and Google Scholar using following terms: ("Wilms tumor" OR "nephroblastoma") AND ("SIOP" OR "International Society of Pediatric Oncology") AND ("NWTS" OR "COG" OR "Children's Oncology Group") AND ("comparison" OR "versus" OR "compare") AND ("protocol" OR "treatment" OR "outcome").

Study Selection

Search results were compiled in management software with duplicate removal. Reviewers independently screened titles and abstracts, then full texts of potentially eligible articles. Disagreements were resolved through discussion or third-party consultation. From 435 initially identified studies, duplicates were removed (n=127), leaving 308 unique records. Title and abstract screening excluded 289 studies for the following reasons, single protocol studies (n=156), not Wilms tumor specific (n=78), review articles or editorials (n=32), and non comparative design (n=23). 19 full text articles were assessed for eligibility. Fifteen studies were excluded because insufficient comparative data (n=8), mixed populations without separate analysis (n=4), follow-up <12 months (n=2), and protocol definitions unclear (n=1). Four studies met all inclusion criteria and were included in the final analysis (Figure 1).

Data Extraction

Standardized data extraction forms captured: study characteristics (author, year, country, design, setting), patient demographics, sample sizes, comparative protocol details, diagnostic strategies, treatment regimens, surgical outcomes, survival data, treatment completion rates, complications, and follow-up duration. Data extraction was performed independently with discrepancies resolved through consensus.

Risk of Bias Assessment

The ROBINS-I tool assessed bias risk across seven domains: confounding, participant selection, intervention classification, deviations from intended interventions, missing data, outcome measurement, and selective reporting [13]. Each domain was rated as low, moderate, serious, or critical risk, with overall study quality determined by the highest individual domain rating.

Data Synthesis

Due to substantial clinical and methodological heterogeneity across studies (different healthcare settings, varying protocol implementations, diverse outcome definitions, and different study designs), quantitative meta-analysis was deemed inappropriate. Qualitative synthesis employed narrative analysis with tabular presentation of key findings from individual studies.

Results

Four comparative studies encompassing 226 pediatric patients with Wilms tumor treated under SIOP (preoperative chemotherapy) and NWTS/COG (upfront nephrectomy) protocols in developing countries were included (Table 1). Studies originated from India [14], Pakistan [15], Iraq [16], and Vietnam [17], representing diverse lower-middle-income healthcare settings .

Study Characteristics and Patient Demographics

The Singhai study from India included 32 patients with 23 receiving SIOP protocols and 9 treated according to NWTS guidelines, demonstrating a comparative cohort design with moderate risk of bias. [14] The Pakistani investigation by Halepota analyzed 49 patients retrospectively, with 28 in the SIOP group and 21 in the NWTS group, reporting extended follow-up periods of 119 months for SIOP and 114 months for NWTS patients

Table 1. Characteristics of Included Studies

Study (First Author, Year)	Country	Study Design	Sample Size	SIOP Group (n)	NWTS Group (n)	Key Comparative Outcomes	Follow-up	Recurrence rate
Singhai et al. (2018)	India	Comparative Cohort	32	23	9	Surgical outcomes, tumor response	Not specified	SIOP: Not reported; NWTS: not reported
Halepota et al. (2018)	Pakistan	Comparative Retrospective	49	28	21	Stage-specific survival, surgical complications	SIOP: 119 months, NWTS: 114 months	SIOP: 14% (4/28 patients); NWTS: 10% (2/21 patients)
Al-Jumaily et al. (2024)	Iraq	Comparative Cohort	54	31	23	Treatment approach, EFS, OS	0-5.9 years	Overall: Not stratified by protocol
Tran et al. (2019)	Vietnam	Sequential Comparative	91	58	33	Protocol-specific outcomes, diagnostic accuracy	SIOP: 27 months, NWTS: 30.4 months	SIOP: 22.4% (13/58 patients); NWTS: 9.1% (3/33 patients)

[15]. Al-Jumaily's Iraqi study examined 54 patients, including 31 SIOP and 23 NWTS cases, with follow-up ranging from 0 to 5.9 years [16]. The Vietnamese study by Tran represented the largest cohort with 91 patients, comprising 58 SIOP and 33 NWTS cases, employing a sequential comparative design [17].

Diagnostic Methods

Diagnostic performance varied markedly between protocols and settings. In resource-limited environments, SIOP protocols demonstrated significant diagnostic challenges. In Indian study, among 23 patient treat with SIOP protocols based on clinical radiological assessment, subsequent histopatology revealed that 4 cases (17.4%) were non-Wilms tumor (2 clear cell sarcomas, 1 neuroblastoma, 1 rhabdoid tumor). In contrast, all 9 NWTS patients had confirmed nephroblastoma on histopathology [14]. Vietnamese study similarly, showed that among patients managed with SIOP protocols, only 78.3% with preoperative imaging diagnosis of Wilms tumor were confirmed on final pathology, with 21.7% ultimately diagnosed as non Wilms tumor [17]. This discrepancy highlights the challenge of relying solely on imaging and clinical assessment for diagnosis in settings where the spectrum of pediatric renal tumors is broader and radiology expertise may be limited [14]. The Pakistani and Iraqi studies did not specifically report diagnostic discordance rates, limiting comparative analysis. But both

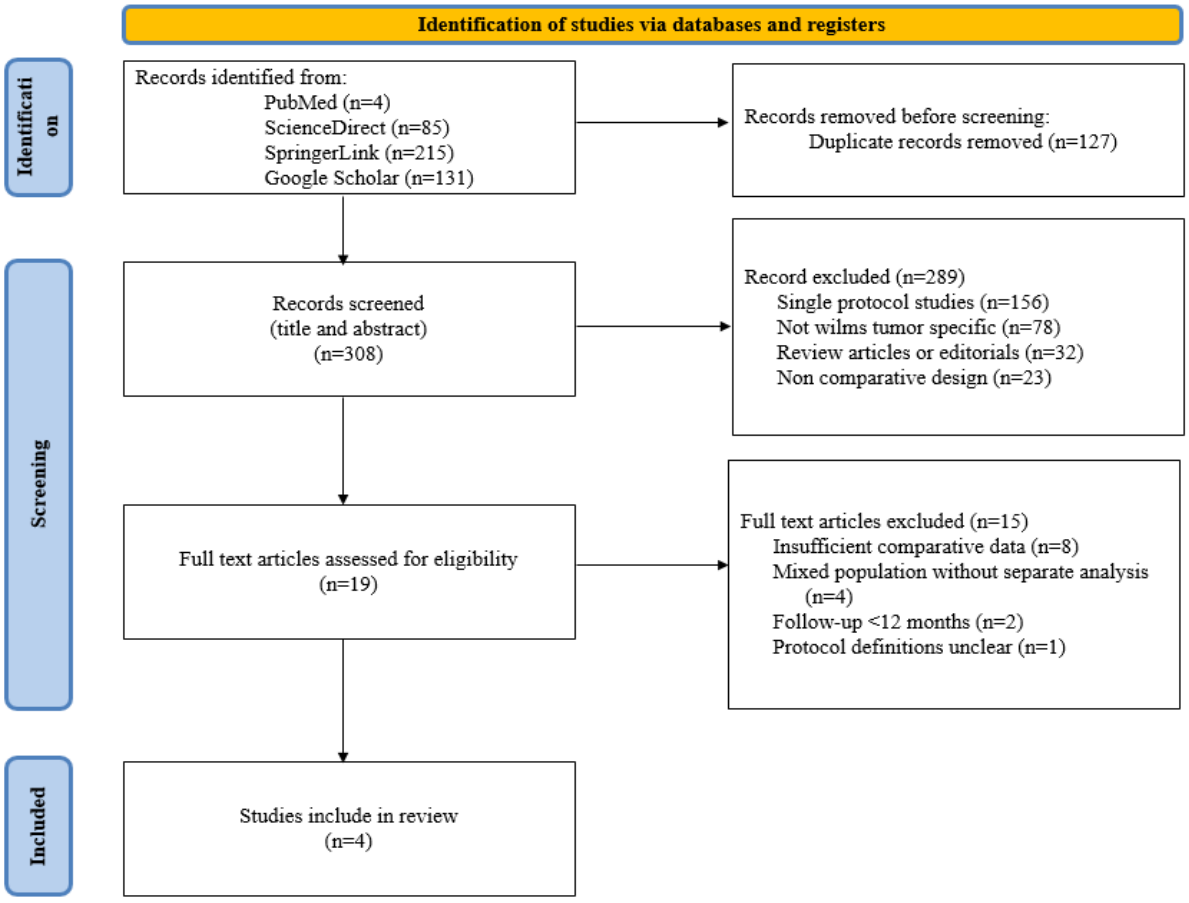

Figure 1. PRISMA Chart Workflow

Table 2. Clinical Decision-Making Framework for Protocol Selection

SIOP protocols are preferable when:	NWTS/COG protocols are preferable when:
- Advanced disease (Stage III-IV) presentation, particularly with large tumor size (>10 cm) (Singhai et al., 2018; van den Heuvel-Eibrink et al., 2017)	- Early-stage disease (Stage I-II) with favorable clinical presentation (Dome et al., 2015; Hau Duc & Ba X, 2019)
- Bilateral disease requiring nephron-sparing approaches (Charlton et al., 2017)	- Comprehensive molecular diagnostic capabilities readily available (Chagtai et al., 2016; Dome et al., 2015)
- Limited pediatric surgical expertise or high-volume cancer centers unavailable (Halepota et al., 2018)	- Immediate histopathological characterization crucial for treatment planning (Hau Duc & Ba X, 2019)
- Resource constraints affecting treatment completion or follow-up (Al-Jumaily et al., 2024; Atun et al., 2020)	- Specialized pediatric surgical expertise and infrastructure accessible (Dome et al., 2015)
- Patient/family concerns about treatment tolerability and hospitalization burden (Halepota et al., 2018)	- Research protocols requiring detailed tumor biology assessment for risk stratification (Chagtai et al., 2016)

described the use of imaging (primarily CT) and, in the Iraqi cohort, pretreatment biopsy in selected cases [15, 16].

Surgical and Treatment Comparison

Only one study (Indian study) provided detailed intraoperative spillage data. In this single-center experience, no spillage occurred in SIOP patients (0/23) compared to 22.2% spillage in NWTS patients (2/9), both involving advanced-stage disease. This finding cannot be generalized due to the small sample size and single-center nature of the observation. The Indian study documented significant tumor size reduction with SIOP protocols (mean decrease from 11.65 cm to 10.03 cm, $p<0.001$), enabling nephron-sparing surgery in 2 cases. The Vietnamese study noted similar downstaging effects.The Pakistani study reported higher postoperative complications in SIOP patients (21% vs 9.5% in NWTS), attributed to chemotherapy-induced immunosuppression in resource-limited settings. The authors attributed this difference to the immunosuppressive effects of preoperative chemotherapy, which may increase the risk of infection and delay recovery in resource-limited environments. Other studies did not provide detailed complication data for comparison [14]. Other studies did not report detailed intraoperative complication data for comparative analysis. The Vietnamese study also noted that preoperative chemotherapy had a "down-staging" effect, resulting in a higher proportion of patients presenting with lower-stage disease at the time of surgery [17].

Outcome and Survival

Survival outcomes varied by protocol and country, reflecting differences in health system capacity, patient population, and protocol adherence. In the Vietnamese cohort, five-year overall survival was markedly higher for NWTS patients (96.7%) than for those treated under the SIOP protocol (80.9%). When analysis was restricted to SIOP patients with Stage I–III disease, the five-year overall survival improved to 84.1%, but still lagged behind the NWTS group [17]. The Pakistani study found no significant difference in five-year survival between the two protocols, with both groups exceeding 80% survival. Recurrence and mortality rates were slightly higher in the SIOP group (14% recurrence, 7% mortality) compared to the NWTS group (10% recurrence, 5% mortality), but the differences were not statistically significant [15].

The Iraqi study demonstrated a dramatic improvement in outcomes over time, with overall survival rising from 40% in the initial study period (2014–2017) to 76% in the extended period (2014–2021), a change attributed to improved protocol standardization and the introduction of multidisciplinary care, including pediatric oncology expertise [16]. The three-year event-free survival in this cohort was 64%, and the study highlighted that survival was significantly better for patients with early-stage disease. In the Indian study, while long-term survival data were not the primary focus, the authors concluded that SIOP protocols provided a clear advantage in reducing viable tumor burden and facilitating risk-adapted management, especially for mixed and focally anaplastic nephroblastoma [14].

Common challenges identified across all four studies, are limited pathology expertise affecting diagnostic accuracy, delayed presentations with advanced disease, infrastructure constraints affecting treatment delivery, and higher rates of treatment abandonment, which reported in 2/4 studies. Studies varied in their adherence to standard protocols, with local adaptations based on resource availability and institutional expertise (Supplementary File 1).

Discussion

The inclusion of only four studies from 435 screened reflects the paucity of direct comparative research in Wilms tumor management. Most published literature consists of single-protocol case series or registry studies that do not provide head-to-head comparisons within the same population. The restrictive inclusion criteria, while necessary for ensuring comparability, significantly limited the available evidence base. The findings of this systematic review underscore the complex and context-dependent nature of Wilms tumor management in low-middle-income countries (LMICs). By examining data from India, Pakistan, Iraq, and Vietnam, and comparing these results to recent studies from both LMICs and high-income countries (HICs), a clearer picture emerges regarding the strengths and limitations of SIOP and NWTS/COG protocols in diverse healthcare environments.

The diagnostic challenges observe in SIOP protocols

appear specifically related to resource-limited settings with suboptimal imaging and pathology infrastructure. In the high-income countries, centralized pathology rebiew and advanced imaging typically reduce misdiagnosis rates to approximately 5% [18]. The 17.4%-21.7% misdiagnosis rates observed in this review cannor be attributedsolely to the SIOP approach but rather reflect the interaction between protocol choice and healthcare infrastructure limitation [14, 17].

The conclusion regarding intraoperative spillage must be interpreted with extreme caution. The single-center Indian study finding of reduced spillage in SIOP patients is based on a small sample (32 total patients) and may reflect center-specific expertise, patient selection bias, or chance variation rather than a true protocol effect. The 95% confidence interval for the spillage difference would likely include null effect, though this was not reported.

Moving from diagnosis to treatment, the comparison of surgical and treatment outcomes reveals further trade-offs between protocols. In India, the SIOP protocol was associated with no intraoperative tumor spillage and enabled nephron-sparing surgery in select cases, whereas 22.2% of total NWTS patients experienced tumor spillage, a complication known to increase recurrence risk [14, 17]. These advantages are echoed in recent Brazilian study [19], where SIOP protocols have enabled safer surgery and reduced the need for radiotherapy in advanced cases. However, it is important to note that the Pakistani study found a higher rate of postoperative complications among SIOP-treated patients (21% vs. 9.5% in NWTS), likely due to chemotherapy-induced immunosuppression and infection risk in resource-limited settings [15]. This observation aligns with recent data from Kenya, where infection and treatment abandonment are major contributors to poor outcomes despite protocol adherence [20].

Survival outcomes varied considerably across studies, likely reflecting differences in healthcare infrastructure and multidisciplinary care availability, patient presentation patterns (stage distribution, nutritional status), treatment adherence and completion rates, and follow-up intensity and duration. The superior survival observed with NWTS protocols in Vietnam may reflect instutional factors rather than protocol superiority, as the Pakistani study showed equivalent outcomes between protocols. In Vietnam, NWTS protocols achieved a five-year Overall Survival (OS) of 96.7%, compared to 80.9% for SIOP, despite the latter's advantage in tumor downstaging [17]. This survival gap is similar to recent findings from China, where NWTS-based management has produced OS rates above 85% even in high-risk populations [21]. On the other hand, the Pakistani cohort reported equivalent five-year survival rates above 80% for both protocols, suggesting that institutional experience and multidisciplinary care can be as important as protocol choice [15]. The Iraqi study further demonstrated a remarkable improvement in OS from 40% to 76% over seven years, attributed to the introduction of pediatric oncology expertise and standardized protocols [16]. These improvements approach the survival rates reported in HICs such as UK and Japan, where Wilms tumor survival now exceeds 90–95% [18].

It is also instructive to compare these findings with other recent LMIC studies. For example, in Nigeria and Kenya, survival remains low due to late presentation, high rates of treatment abandonment, and limited access to radiotherapy and chemotherapy, with five-year OS rates below 50% in some series [20, 22]. Conversely, centers in Brazil and South India that have successfully adapted SIOP or NWTS protocols to local conditions and invested in multidisciplinary care have reported survival rates approaching those of high-income countries [19, 23]. These successes are often linked to investments in pathology training, centralized care, and international collaboration, as well as the elimination of financial barriers to treatment.

Taken together, the evidence from this review and recent literature suggests that neither SIOP nor NWTS protocols are universally superior. Instead, their effectiveness is closely tied to local diagnostic capabilities, surgical expertise, and health system infrastructure. For instance, SIOP protocols may be preferable for advanced or inoperable tumors, where preoperative chemotherapy can downstage disease and facilitate safer surgery. Conversely, NWTS protocols, with their emphasis on immediate histopathological confirmation, may be optimal in settings with reliable pathology services and early-stage presentation. Hybrid approaches, such as those employed in Iraq and recommended by recent global guidelines, may offer the best outcomes by combining the strengths of both protocols using upfront nephrectomy for operable tumors and preoperative chemotherapy for inoperable or advanced cases.

Clinical Decision-Making Framework

Based on our analysis and existing literature, we propose the following evidence-based framework for protocol selection (Table 2).

Several limitations must be acknowledged in interpreting our findings. All studies were retrospective, with potential preferential assignment of advanced cases to SIOP protocols and early stage cases to NWTS protocols. Incomplete medical records likely contributed to underreporting of complications and missing survival data. The vietnamese sequential dessign may reflect institutional learning effects rather than protocol differences. Incosistent outcome definition across studies limit comparative interpretation. Missing data on critical outcomes (treatment completion rates, detailed surgical complications), and lack of standardized staging and histologic classification was reported. Differences in patient presentation between protocol groups not adequately controleed. Varying institutinal expertise and resources bertween study periods and different supportive care standards affecting outcomes.

Future Research Priorities

Our systematic review identifies several critical research priorities for advancing Wilms tumor management globally. Multicenter randomized controlled trials comparing protocols across diverse healthcare settings are urgently needed to provide definitive evidence for protocol

selection. Long-term survivorship studies examining late effects, quality of life, and functional outcomes across both protocols remain limited, particularly in developing countries. Future comparative studies should employ standardized definitions and consistent reporting of surgical outcomes, including intraoperative complications, to enable meaningful meta-analyses and evidence synthesis.

Economic evaluations comparing cost-effectiveness of both approaches in different healthcare systems would inform policy decisions and resource allocation. Additionally, development of evidence-based guidelines for protocol selection incorporating disease characteristics, healthcare infrastructure, and patient-specific factors would facilitate optimal individualized care.

Limitations and Future Implications

This systematic review has several important limitation that affect the interpretation and feneralizability of findings. There are evidence base limitations, methodological limitations, and outcome reporting limitations. Only four comparative studies were identified, reflecting the limited direct comparative research in this field. All studies originated from lower-middle-income countries, limiting generalizability to high-income healthcare settings. Inconsistent outcome definitions and missing data precluded quantitative synthesis. All included studies were retrospective, introducing potential selection and information bias. Surgical complication conclusions are based on one small study and cannot be generalized. Sequential study design may reflect institutinal learning rather than protocol effects. Most studies lacked detailed intra-operative and post-operative complication reposting. Different follow-up periods and outcome definitions limited comparative analysis. None of the studies provide comprehensive treatment adherence data. These limitations necessitate cautious interpretation of findings and highlight the urgent need for prospective comparative research with standardized outcome measures.

Conclusion and Recommendation

This systematic review reveals that neither SIOP nor NWTS/COG protocols demonstrate consistent superiority across all outcomes in lower-middle-income healthcare settings. The paucity of direct comparative studies and heterogeneous outcome reporting highlight critical evidence gaps in Wilms tumor management. Protocol selection should be individualized based on disease stage, institutional capabilities, and healthcare infrastructure rather than assuming universal protocol superiority. Future research priorities include multicenter randomized controlled trials with standardized outcome measures, economic evaluations across different healthcare settings, and implementation science research to optimize protocol adaptation in resource-limited environments.

Author Contribution Statement

TNB, KPS, and AARD made significant contributions to the conceptualization or design of the research, including the acquisition, analysis, or interpretation of data pertinent to the study. TNB, KPS, and AARD participated in the preparation of the manuscript, engaging in drafting or critically revising it to enhance its intellectual substance. TNB, KPS, and AARD provided final approval for the version intended for publication and accepted responsibility for all facets of the research, ensuring that any inquiries regarding the accuracy or integrity of any component of the study are thoroughly examined and addressed.

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Ethical permission and study approval

Since it is a systematic review, no ethical permission was required for the study. This study is not for a student thesis.

Conflict of Interest

There were no conflict of interest.

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