



Emerging Role of Padeliporfin Vascular-Targeted Photodynamic Therapy In Upper Tract Urothelial Carcinoma: A Comprehensive Systematic Review

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Track Record Article	Abstract
Revised: 31 July 2026 Accepted: 25 September 2026 Published: 30 September 2026 How to cite: Hendri, A. Z., & Pangestu, A. R. (2026). Emerging Role of Padeliporfin Vascular-Targeted Photodynamic Therapy In Upper Tract Urothelial Carcinoma: A Comprehensive Systematic Review. <i>Contagion: Scientific Periodical Journal of Public Health and Coastal Health</i>, 8(3), 728–741.	<i>Upper tract urothelial carcinoma (UTUC) is an uncommon malignancy, accounting for only 5–10% of urothelial tumors, and often presents with invasive disease. Consequently, radical nephroureterectomy remains the standard treatment despite its substantial impact on renal function. Padeliporfin vascular-targeted photodynamic therapy (VTP) is a novel kidney-sparing modality in which intravenously administered padeliporfin is activated by endoluminal near-infrared laser, selectively occlude tumor microvasculature and inducing coagulative necrosis while preserving surrounding tissues. This review synthesizes evidence from a Phase I study and the Phase III ENLIGHTED trial involving adults with low-grade, non-muscle-invasive UTUC suitable for kidney-sparing management, focusing on complete response (CR), durability of response, renal preservation, and safety outcomes. A search of PubMed, the Cochrane Library, and Web of Science identified seven reports arising from these two single-arm study programs. In the Phase I trial, which predominantly included patients with residual or recurrent UTUC following unsuccessful endoscopic treatment, the 30-day CR rate was 50%, increasing to 68% after retreatment of partial responders, with an overall response rate of 94% and preservation of both renal function and kidneys at 6 months. In the ENLIGHTED trial, which enrolled patients with one or two small, biopsy-confirmed low-grade lesions, padeliporfin VTP achieved a CR rate of 73% at first assessment, overall response rates exceeding 86%, and local recurrence rates ranging from 3.2 to 10.8%. Among complete responders, 88% maintained CR for at least 12 months, and the median duration of response was not reached after more than 23.9 months of follow-up. Adverse events were predominantly transient Grade 1–2 urinary or flank symptoms; Grade 3 events were infrequent and short-lived, and no phototoxicity or ureteral strictures were reported. Padeliporfin VTP appears to be a promising kidney-sparing treatment for selected patients with low-grade UTUC, although confirmation in randomized controlled trials is needed.</i> Keywords: <i>Padeliporfin, Photodynamic Therapy, Upper Tract Urothelial Carcinoma, Kidney-Sparing Surgery, Endoscopic Ablation</i>

INTRODUCTION

Upper tract urothelial carcinoma (UTUC) is a rare urothelial malignancy but is clinically significant because it frequently presents as invasive or otherwise high-risk disease, resulting in substantial risks of recurrence, progression, and cancer-specific mortality. Radical nephroureterectomy with bladder cuff excision remains the standard treatment for high-risk UTUC. However, nephrectomy reduces renal reserve, often causes persistent declines in estimated glomerular filtration rate, and may preclude subsequent eligibility for cisplatin-based chemotherapy. Loss of renal function is also associated with adverse long-term outcomes,

including increased overall and cardiovascular mortality (Zhou et al., 2025; Giulioni et al., 2024).

For appropriately selected patients with low-grade, non-muscle-invasive UTUC, kidney-sparing management, including endoscopic laser ablation or resection and chemoablation with mitomycin gel, aims to preserve renal function. Nevertheless, these approaches are limited by high rates of local recurrence, the need for repeated endoscopic interventions, the risk of ureteral stricture formation, and the potential for cumulative tissue injury associated with thermal ablation or repeated instrumentation (Rose & Matin, 2023; Farrow et al., 2021; Wang et al., 2024).

Padeliporfin vascular-targeted photodynamic therapy (VTP) is an investigational non-thermal, organ-preserving modality that uses near-infrared light activation to selectively occlude tumour microvasculature and induce tumour necrosis. Preliminary findings from the ENLIGHTED phase III trial suggest promising response rates and kidney preservation; however, the study is limited by its single-arm design. Comparative trials against established kidney-sparing therapies are needed to determine its relative efficacy in terms of oncological control, durability of response, renal functional preservation, and safety, as well as to define its eventual role in UTUC treatment guidelines. (Azzouzi & Gelet, 2022; Xue et al., 2022; Chien et al., 2022).

METHODS

This systematic review synthesized the available clinical evidence on padeliporfin vascular-targeted photodynamic therapy (VTP) for adults with low-grade, non-muscle-invasive upper tract urothelial carcinoma (UTUC) undergoing kidney-sparing treatment. Following contemporary systematic review standards, the authors formulated a predefined research question and eligibility criteria, conducted comprehensive searches across multiple databases, and used standardized data extraction methods. Because all included studies were single-arm and differed in design and outcome measures, the findings were synthesized narratively.

Studies were eligible if they included adults with histologically confirmed UTUC, predominantly low-grade and non-muscle-invasive disease (or reported this subgroup separately), evaluated endoluminal padeliporfin VTP as the primary intervention, and reported at least one clinically meaningful outcome, such as treatment response, recurrence, progression, kidney preservation, or safety. Studies involving high-grade, muscle-invasive, or metastatic disease, those that did not evaluate padeliporfin VTP, and those lacking usable outcome data

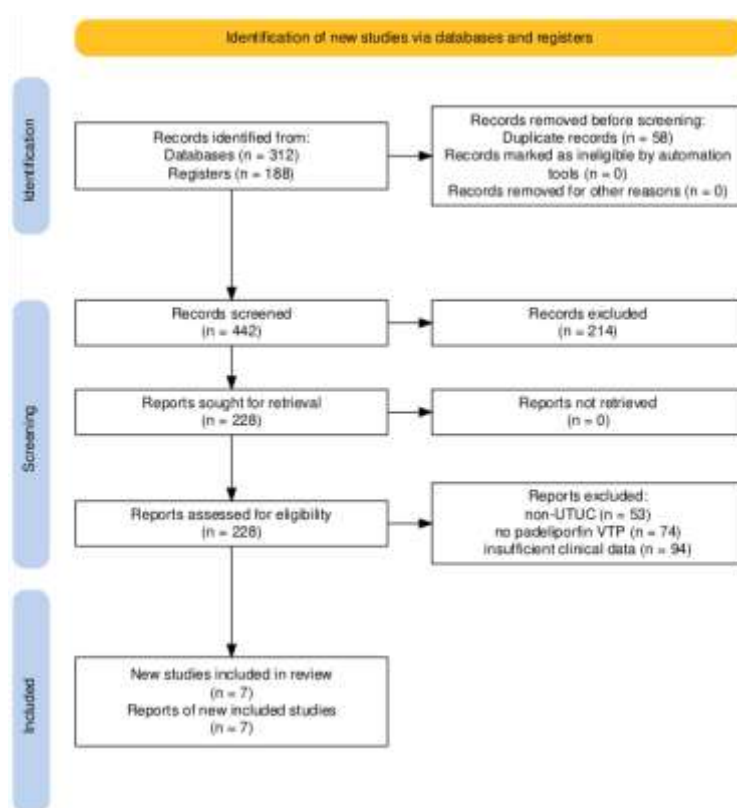
were excluded. Multiple publications arising from the same clinical trial were considered part of a single study program.

PubMed, the Cochrane Library, and Web of Science were searched without language or date restrictions, yielding 500 records. Two reviewers independently screened them after deduplication, excluding 493. Seven reports remained, drawn from a Phase I dose-escalation trial (NCT03617003) and the Phase 3 ENLIGHTED study (NCT04620239).

RESULTS

The initial search identified 500 records across PubMed, the Cochrane Library, Web of Science, and relevant clinical trial registers. After the removal of 58 duplicate records, 442 unique records remained for title and abstract screening. Of these, 214 records were excluded as clearly ineligible, leaving 228 reports for full-text or expanded-abstract assessment. During full-text review, 53 reports were excluded because they involved non-UTUC populations, 74 because they did not evaluate padeiporfin VTP, and 94 because they lacked extractable clinical outcome data, resulting in 7 reports that met all eligibility criteria and were included in the final synthesis. Overall, the PRISMA flow diagram illustrates the study selection process from 500 initially identified records to 7 included studies.

Figure 1. PRISMA 2020 flow diagram for identification, screening, eligibility assessment, and inclusion of studies in the primary synthesis



Padeliporfin VTP for UTUC is supported in this review by seven single-arm publications derived from one Phase I dose-escalation trial (NCT03617003) and the Phase III ENLIGHTED trial (NCT04620239). Collectively, these studies provide evidence regarding treatment efficacy, durability of response, kidney preservation potential, and safety in adults with predominantly low-grade, non-muscle-invasive UTUC selected for kidney-sparing management.

Table 1. Characteristics of included studies

Study (first author, year)	Study type/phase	Trial registration	Planned/analysed sample	Population and key inclusion criteria	Geographic setting	Primary endpoint / main objective
Nogueira 2021	Single-arm dose-escalation	NCT03617003	18 patients	Residual or recurrent UTUC, low- and high-grade, any size, after failed endoscopic therapy or not suitable for radical surgery.	Single centre (not specified)	Maximally tolerated laser light fluence rate (dose-limiting toxicity and safety).
Yip 2022	Single-arm Phase I	NCT03617003	19 patients	Residual or recurrent UTUC failing prior endoscopic treatment; mixed grades and sizes.	Not specified	Maximum tolerated dose (MTD) / maximally tolerated laser fluence; safety and feasibility.
Yip 2023	Single-arm Phase I (final)	NCT03617003	19 patients	Same Phase I cohort: residual or recurrent UTUC of any grade/size after failed endoscopic therapy.	Not specified	Final determination of maximally tolerated laser light fluence and early efficacy (CR, ORR) at 30 days.
Coleman 2023	Phase 3 design description	NCT04620239	100 planned; 3 enrolled	Up to 2 biopsy-proven low-grade UTUC lesions, 5–15 mm, in calyces, renal pelvis or	Multicentre (USA, EU, Israel)	Efficacy and durability of padeliporfin VTP (CR and maintenance of response)

Study (first author, year)	Study type/phase	Trial registration	Planned/analysed sample	Population and key inclusion criteria	Geographic setting	Primary endpoint / main objective
				ureter; kidney-sparing candidates.		over long-term follow-up).
Coleman 2024	Phase 3 preliminary results	NCT04620239	100 planned; 12 treated	Up to 2 biopsy-confirmed low-grade UTUC lesions, ≤ 15 mm in kidney and ≤ 20 mm in ureter; negative high-grade cytology.	Multicentre (USA, EU, Israel)	Complete response (CR) on endoscopic evaluation and selective cytology after induction treatment phase.
Margulies 2025	Phase 3 interim analysis	NCT04620239	100 planned; 50 evaluable	Up to 2 biopsy-proven low-grade UTUC, ≤ 15 mm kidney, ≤ 20 mm ureter; treatment-naïve or previously treated; kidney-sparing candidates.	Multicentre (USA, EU, Israel)	CR on endoscopic evaluation plus negative instrumental cytology at 28 ± 3 days post-induction.
Margulies 2026	Phase 3 updated results	NCT04620239	100 planned; 78 enrolled; 63 completed induction	Up to 2 biopsy-confirmed low-grade lesions, 5–15 mm in kidney, 5–20 mm in ureter; treatment-naïve or previously treated; non-muscle-invasive.	Multicentre (US, EU, Israel)	CR at primary response evaluation 28 ± 3 days after last induction treatment; durability and safety up to 48 months.

The Phase I program establishes dose, feasibility, and early signals of efficacy in a more challenging cohort (including high-grade and previously failed endoscopic therapy), whereas the Phase III ENLIGHTED trial targets strictly low-grade, small UTUC lesions in a kidney-sparing setting, with long-term follow-up to assess durability and organ preservation.

Table 2. Main synthesized outcomes from included studies

Study (phase)	Patients analyzed	Key efficacy outcomes	Durability of response	Kidney preservation data	Safety profile (main points)	Notable limitations
Nogueira 2021 (Phase I)	18	CR 67% at 30 days; disease recurrence reported around 28% at 30 days; other response parameters sparsely reported.	Only short-term (30-day) data; no 12-month durability reported.	Kidney and renal function preserved at early follow-up; no ureteral strictures reported.	High rates of flank pain and hematuria; dose-limiting flank pain at highest light fluence; no phototoxicity or strictures.	Single-centre early-phase study; mixed low- and high-grade disease; limited follow-up and incomplete long-term outcomes.
Yip 2022 / 2023 (Phase I)	19	30-day CR 50% after first session, rising to 68% after a second VTP session in partial responders; PR ~44%; overall response rate 94% at 30 days.	Follow-up to 6 months; no formal 12-month CR maintenance or long-term recurrence data reported.	All patients maintained kidneys and stable renal function at 6 months; no ureteral strictures detected.	Flank pain 79% and hematuria 84% in Phase I; one dose-limiting toxicity cluster at 200 mW/cm ² ; AEs mostly Grade 1–2 and transient.	Small sample; broader inclusion (any grade/size, prior endoscopic failures); one-arm design with no comparator; durability data limited.
Coleman 2024 (Phase 3 preliminary)	9 completed induction	CR 67%, PR 33%, overall response 100% after induction treatment in early cohort.	Long-term follow-up planned up to 48 months but not yet mature at time of report.	Report emphasizes organ-sparing intent, but quantitative kidney survival / nephroureterectomy-free rates not yet detailed.	Adverse events mainly flank pain, hematuria, and procedure-related symptoms; Grade 3 events (e.g., renal colic) rare and resolved quickly.	Very small early cohort; preliminary results; incomplete durability and kidney function data; abstract-level reporting.
Margulis 2025 (Phase 3 interim)	50 evaluable	CR 73%; PR 13.5%; overall response 86.5%; disease recurrence 10.8%;	Durability beyond primary 28±3-day evaluation not fully reported; focus on early	Organ-sparing paradigm described conceptually; detailed kidney function and surgery-avoidance endpoints still immature.	AEs predominantly Grade 1–2 (flank pain, hematuria, GI symptoms, dysuria, fatigue); Grade 3 SAEs (renal	Interim analysis; one-arm design; durability and kidney survival not yet fully characterized

Study (phase)	Patients analyzed	Key efficacy outcomes	Durability of response	Kidney preservation data	Safety profile (main points)	Notable limitations
		progression 2.7% in early follow-up.	response metrics.		colic/flank pain) ~9.2% of SAEs, resolving within 2 days; no phototoxicity or strictures reported.	; reliance on abstract reports.
Margulis 2026 (Phase 3 updated)	63 completed induction	CR 73%; PR 17.7%; overall response 90.7%; recurrence in treated area 3.2%; progression 4.8% at updated follow-up.	Among patients achieving CR, 88.2% maintained CR in the treated area for at least 12 months; median duration of response not reached at ≥ 23.9 months.	Early data suggest preserved kidneys and acceptable renal function, but formal kidney survival, eGFR, and nephroureterectomy-free rates remain incompletely reported.	AEs mostly Grade 1–2 flank pain, hematuria, nausea, dysuria, fatigue; median AE duration about 5 days; Grade 3 events (renal colic, flank pain, hypertension) infrequent and self-limited; no phototoxicity or ureteral strictures observed.	Still single-arm, no randomized comparison versus endoscopic laser or chemoablation; long-term kidney outcomes and comparative effectiveness not yet definitive.

Padeliporfin vascular-targeted photodynamic therapy (VTP) has demonstrated promising activity in selected patients with upper tract urothelial carcinoma (UTUC), with complete response rates of approximately 68%–73% and overall response rates approaching or exceeding 90%. Early-phase studies, which included patients with residual, recurrent, and some high-grade disease, demonstrated improved complete response rates following repeat treatment, while preserving renal function, avoiding nephroureterectomy during the 6-month follow-up period, and showing no reported cases of ureteral strictures. In the phase III ENLIGHTED trial involving patients with biopsy-confirmed low-grade UTUC, complete response rates reached 73% after up to three induction treatment sessions, and most complete responders maintained their response for at least 12 months. Treatment-related adverse events were generally transient and low grade, with the most commonly reported events including flank pain, hematuria, and mild urinary or gastrointestinal symptoms. However, interpretation of these findings is limited by the single-arm designs of all included studies, the small sample sizes of the early-phase cohorts, reliance on abstract-based reporting for some outcomes, and

limited data on long-term renal function and kidney preservation. Randomized controlled trials comparing VTP with established kidney-sparing approaches, including endoscopic ablation and chemoablation, are needed to determine its relative efficacy, durability of response, functional benefits, and role in clinical practice.

Table 3. JBI-style appraisal of primary-synthesis padeliporfin VTP studies

Study (year)	Clear inclusion criteria	Population & setting well described	Outcome measurement valid & reliable	Follow-up length	Confounders identified	Appropriate statistical analysis	Transparency (registration, reporting)
Nogueira 2021 (Phase I)	Yes – residual/recurrent UTUC after failed endoscopy; adult patients.	Partial – UTUC grade/recurrence described; setting single centre, limited detail.	Yes – CR at 30 days based on endoscopic assessment; standard definitions.	Partial – only 30-day data; no 12-month outcomes.	Unclear/No – mixed grades and prior treatments; no formal confounder analysis.	Partial – descriptive statistics; no comparative or adjusted analyses.	Yes – registered trial (NCT03617003), primary dose-finding endpoint reported but mostly as early report.
Yip 2022 (Phase I)	Yes – residual/recurrent UTUC failing prior endoscopic therapy; adult patients.	Partial – basic clinical characteristics given; setting not fully described.	Yes – CR, PR, ORR at 30 days via endoscopy; response definitions stated.	Partial – follow-up to 6 months; durability beyond 6 months not reported.	Unclear/No – heterogeneous disease; no explicit adjustment for confounding.	Partial – appropriate descriptive analysis for single-arm dose-escalation; no advanced modeling.	Yes – linked to NCT03617003, results reported in line with dose-finding objectives.
Yip 2023 (Phase I final)	Yes – same defined cohort as earlier Phase I report.	Partial – population clarified (any grade/size, failed endoscopy) but limited setting description.	Yes – CR increase from 50% to 68% after second session; ORR 94% at 30 days, with clear definitions.	Partial – 6-month renal function and kidney preservation reported; no long-term recurrence data.	Unclear/No – high-grade lesions and prior therapies not analytically separated.	Partial – descriptive efficacy and safety; no time-to-event or multivariable analyses.	Yes – registered study with consistent endpoint reporting; still limited depth due to early phase design.
Coleman 2023 (Phase I)	Yes – up to two biopsy-proven	Yes – clear description of lesion size, grade,	Yes – planned CR assessment	Partial – long-term follow-up (up to 48	Partial – key eligibility criteria	Yes (for design stage) – prespecified	Yes – trial registered (NCT04620239),

Study (year)	Clear inclusion criteria	Population & setting well described	Outcome measurement valid & reliable	Follow-up length	Confounders identified	Appropriate statistical analysis	Transparency (registration, reporting)
3 design)	low-grade UTUC lesions, 5–15 mm, kidney-sparing candidates.	anatomical sites, and multicentre setting (USA/EU/Israel).	nt via endoscopy and cytology; standardized schedule.	months) planned; no results yet in design paper.	limit confounding (low-grade, size, non-muscle-invasive), but no formal adjustment strategy.	ed endpoints and analysis plan; detailed in protocol.	design and objectives transparently described.
Coleman 2024 (Phase 3 preliminary)	Yes – same strict low-grade, size-limited inclusion criteria; negative high-grade cytology.	Yes – early treated cohort characteristics are outlined (lesion number, size, location).	Yes – CR and PR defined on endoscopic evaluation and selective cytology after induction.	Partial – only early post-induction outcomes; durability and complete follow-up not yet mature.	Partial – selection criteria reduce confounding, but no comparative arm or adjustment.	Partial – simple proportions for CR/PR/ORR; no advanced time-to-event analysis yet.	Yes – registered trial with preliminary results reported according to protocol, though mostly as abstract-level data.
Margulis 2025 (Phase 3 interim)	Yes – up to two biopsy-proven low-grade UTUC lesions, 15 mm kidney/20 mm ureter; well-defined criteria.	Yes – multicentre cohort, lesion characteristics, and eligibility well described.	Yes – CR, PR, ORR, recurrence and progression defined using endoscopy and cytology at 28±3 days.	Partial – focus on early primary response; full long-term durability and loss-to-follow-up not yet reported.	Partial – strict low-grade selection limits heterogeneity, but no comparator or confounder modeling.	Partial – appropriate descriptive statistics; limited inferential analysis.	Yes – interim results from NCT04620239 reported with clear endpoints; sponsor involvement acknowledged.
Margulis 2026 (Phase 3 updated)	Yes – biopsy-confirmed low-grade lesions, defined size ranges, non-muscle-invasive, treatment-naïve or	Yes – 78 enrolled, 63 completing induction; setting and lesion characteristics clearly described.	Yes – CR 73%, PR 17.7%, ORR 90.7% with recurrence and progression outcomes; CR durability	Partial/Yes – 88.2% of CR responders maintain CR ≥12 months; median duration not reached at ≥23.9 months, but full	Partial – rigorous eligibility reduces confounding; still no randomization or adjusted comparative analyses.	Partial – descriptive and time-based durability reporting; limited advanced modeling or sensitivity analyses.	Yes – updated findings from registered Phase 3 trial, with clear safety and efficacy reporting, though still

Study (year)	Clear inclusion criteria	Population & setting well described	Outcome measurement valid & reliable	Follow-up length	Confounders identified	Appropriate statistical analysis	Transparency (registration, reporting)
	previously treated.		assessed ≥ 12 months.	48-month data pending.			abstract-heavy.

Phase I and ENLIGHTED trials applied well-defined eligibility criteria, particularly for patients with biopsy-confirmed, low-grade, small UTUC lesions suitable for kidney-sparing management. Standardized endoscopic and cytological assessments supported the reliable evaluation of treatment response and recurrence. The ENLIGHTED trial further enhanced methodological rigor through prospective registration, prespecified endpoints, extended follow-up, and multinational, multicentre enrollment.

Methodological limitations and risk of bias

Under JBI critical appraisal framework, key limitations include the single-arm study design, the absence of comparator groups such as laser ablation or chemoablation, and limited control of potential confounding factors. Participant selection procedures are inadequately reported, follow-up duration varies across studies, and long-term renal outcomes remain insufficiently characterized. Analyses are largely descriptive, and reliance on conference abstracts and interim reports reduces reporting transparency, consequently, the confounding and follow-up domains were rated as partial or unclear.

DISCUSSION

Main findings

This systematic review suggests that padeliporfin VTP offers promising tumour control and kidney preservation in selected adults with low-grade, non-muscle-invasive UTUC. Across Phase I and ENLIGHTED studies, response rates were high, renal function remained stable, and treatment-related adverse events were predominantly transient and low grade, supporting the potential of VTP as a non-thermal, kidney-sparing therapeutic option.

Limitations and potential biases

Current evidence is derived from uncontrolled Phase I and III studies, creating potential for selection bias, confounding, and overestimation of treatment benefit relative to established kidney-sparing therapies. Restrictive eligibility criteria, small sample sizes, imprecise effect estimates, heterogeneous populations, limited follow-up duration, and sparse reporting of renal function outcomes further limit generalizability and confidence in long-term effectiveness and safety.

Comparison with existing literature

Reported response rates with padeliporfin VTP appear comparable with the favorable outcomes reported in laser ablation and chemoablation series, although direct comparisons across studies are limited by differences in patient populations, and study designs, and follow-up duration. Its non-thermal mechanism of action may reduce the risk of structural injury associated with conventional ablative techniques. However, VTP cannot currently be considered a substitute for radical nephroureterectomy in patients who require definitive surgical management.

External validity and confounders

Trials were conducted in specialized, high-volume centres under standardized protocols; therefore, the findings are primarily generalizable to patients with small, low-grade UTUC who have access to expert endourological care and intensive surveillance. The single-arm design of the included studies leaves the reported outcomes vulnerable to both measured and unmeasured confounding factors, including tumour biology, prior treatment history, lesion-mapping accuracy, and institutional experience, making it difficult to attribute observed effects solely to VTP.

Overall interpretation and cost

Padeliporfin VTP is a promising emerging kidney-sparing treatment option that should currently be integrated alongside, rather than replace, established endoscopic and chemoablative strategies. Although the upfront costs associated with the drug, laser equipment, and specialist expertise may be substantial, these costs could potentially be offset in selected patients if durable kidney preservation reduces the incidence of chronic kidney disease (CKD), the need for dialysis, and long-term renal-related expenditures. However, formal cost-effectiveness studies in UTUC are still required.

CONCLUSION

Padeliporfin vascular-targeted photodynamic therapy (VTP) demonstrates promising early tumour control in selected patients with low-grade, non-muscle-invasive UTUC, with complete response rates ranging from 50%–73%, high overall response rates, preserved renal function, and predominantly mild, transient adverse events. However, the current evidence is limited to small, single-arm studies lacking randomized comparators and mature long-term data on renal and survival outcomes. Consequently, its comparative benefit relative to laser ablation or chemoablation remains uncertain. Future randomized controlled trials should evaluate oncological control, durability, of response, kidney preservation, renal function trajectories,

nephroureterectomy-free survival, and patient-reported outcomes. Until such evidence becomes available, VTP should remain an investigational kidney-sparing treatment option within experienced centres.

Author Contributions

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Data curation: Ahmad Zulfan Hendri.

Writing – original draft: Ahmad Zulfan Hendri.

Writing – review & editing: Aldy Ridho Pangestu.

Visualization: Ahmad Zulfan Hendri.

Conflict of Interest

The authors report no commercial or financial relationships that might present a conflict of interest for this systematic review of padeliporfin vascular-targeted photodynamic therapy in upper tract urothelial carcinoma. The work relied solely on publicly available Phase I and Phase 3 ENLIGHTED data, and no sponsor or pharmaceutical company influenced any stage of the manuscript.

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