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Association of Circulating Tumor DNA (ctDNA) to Monitoring Treatment Response in Urothelial Carcinoma: A Comprehensive Systematic Review

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Abstract. Circulating tumor DNA (ctDNA) has emerged as a promising liquid biopsy biomarker for real-time monitoring of tumor dynamics. In urothelial carcinoma (UC), effective monitoring of treatment response remains a clinical challenge due to the limitations of conventional imaging and invasive procedures. This systematic review aims to synthesize the existing evidence on the association between ctDNA dynamics and treatment response monitoring across various stages and therapeutic settings. A comprehensive systematic review was conducted. We included cohort studies, randomized controlled trials, and meta-analyses that evaluated ctDNA in UC patients undergoing treatment. Data were extracted on patient population, methodology, treatment, sampling strategy, clinical outcomes, and statistical associations. The review encompassed 80 studies. Baseline ctDNA positivity was strongly prognostic, associated with a 4- to 6-fold increased risk of recurrence or death (HR 4.23-6.56). Dynamic ctDNA clearances or significants reduction during treatment, were strongly associated with improved outcomes. Showing hazard ratios for adverse events as low as 0.10-0.31. ctDNA demonstrated time advantages of 53-90 days over radiographic detection. ctDNA is a potent tool for monitoring treatment response in urothelial carcinoma. It provides superior prognostic and offers a significant lead time for detecting treatment failure. Future research must focus on standardizing methodologies and validating ctDNA-guided therapeutic.

Keywords: Bladder Cancer; Liquid Biopsy; Minimal Residual Disease; Treatment Monitoring; Urothelial Carcinoma.

1. INTRODUCTION

Urothelial carcinoma (UC), particularly its muscle-invasive (MIBC) and metastatic forms, poses a significant oncologic challenge due to its high recurrence rates and variable response to systemic therapies (Grosso et al., 2025; Redla et al., 2025; Liu et al., 2024). Traditional methods for monitoring treatment response, such as computed tomography (CT) and cystoscopy, are limited by cost, radiation exposure, invasiveness, and delays in detecting molecular disease progression (Mehrotra et al., 2025; Gao et al., 2025; Ma et al., 2025). There is an urgent need for minimally invasive, real-time biomarkers that can accurately reflect tumor burden and biology to guide therapeutic decisions (Al-Showbaki et al., 2023; Dyrskjøt et al., 2025; Shohdy et al., 2024; Khetrapal et al., 2018). Circulating tumor DNA (ctDNA), fragments of tumor-derived DNA shed into the bloodstream, has emerged as a cornerstone of liquid biopsy, offering a dynamic window into tumor genetics and evolution (Maas et al., 2018; Herranz et al., 2021; Azevedo et al., 2018).

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Despite growing interest, the evidence on ctDNA's utility in UC treatment monitoring remains fragmented. Studies vary widely in design, patient populations (non-muscle invasive vs. muscle-invasive vs. metastatic), treatment modalities (chemotherapy, immunotherapy, targeted therapy), ctDNA detection platforms (Signatera, Guardant360, ddPCR), and definitions of molecular response (clearance vs. reduction) (Suartz et al., 2024; Lindskrog & Dyrskjøt, 2023). A comprehensive synthesis reconciling these disparate results is lacking, creating uncertainty about the optimal clinical application of ctDNA in UC care pathways.

This systematic review addresses this gap by providing a holistic, detailed synthesis of 80 studies. Its novelty lies in its explicit focus on treatment response monitoring (as opposed to solely diagnostic or prognostic use). This review holds significant clinical and research implications. For clinicians, it consolidates evidence to inform the potential integration of ctDNA testing into standard monitoring protocols, moving towards personalized, response-adapted therapy. It can help identify patients at high risk of recurrence who need intensified surveillance or adjuvant treatment, while sparing low-risk patients from overtreatment and toxicity (de Kruijff et al., 2020; Das, 2021). For researchers, it identifies key knowledge gaps, such as the need for standardized response criteria and cost-effectiveness analyses, and highlights promising avenues for future prospective trials, including ctDNA-guided de-escalation studies (St-Laurent et al., 2025; Zhan et al., 2025).

2. METHODS

The study strictly adhered to the Preferred Reporting Items for Systematic Review and Meta-Analysis (PRISMA) 2020 guidelines to ensure methodological rigor and accuracy. This systematic review aims to evaluate the Association of Circulating Tumor DNA (ctDNA) to Monitoring Treatment Response in Urothelial Carcinoma. The review protocol was registered on PROSPERO (CRD420261298275).

PubMed, Semantic Scholar, Wiley Online Library, and Google Scholar were searched for all relevant publications from January 1, 2016 to February 2026. The Boolean MeSH keywords inputted on databases for this research are: (“Urothelial carcinoma” OR “Bladder cancer” OR “Upper tract urothelial cancer” OR “Transitional cell carcinoma”) AND (“Circulating tumor DNA” OR “ctDNA” OR “Liquid biopsy” OR “Cell-free DNA”) AND (“Response assessment” OR “Therapeutic monitoring” OR “Treatment monitoring” OR “Treatment efficacy”).

Four review authors independently screened the titles and abstracts of identified studies for eligibility and extracted outcome data, with disagreements resolved by discussion. The population included patients diagnosed with urothelial carcinoma at any stage. The intervention involved measurement of circulating tumor DNA in blood samples using any detection method, with ctDNA assessed at multiple time points or by comparing pre- and post-treatment levels. Treatment response assessment was based on imaging, clinical assessment, or pathological response correlated with ctDNA levels.

The primary outcome was the association between ctDNA dynamics and treatment outcomes, including pathological response, recurrence-free survival, and overall survival. A secondary outcome was to elucidate methodological and clinical factors contributing to heterogeneity. Risk of bias was assessed using the JBI Critical Appraisal tool. The study selection process is described in Figure 1. Identified for screened 4352, of which 749 underwent a comprehensive full-text critical. After screening 80 studies were included.

3. RESULTS

This systematic review encompasses 80 sources evaluating the association between circulating tumor DNA (ctDNA) and treatment response monitoring in urothelial carcinoma. The included studies span multiple treatment settings, disease stages, and ctDNA methodologies.

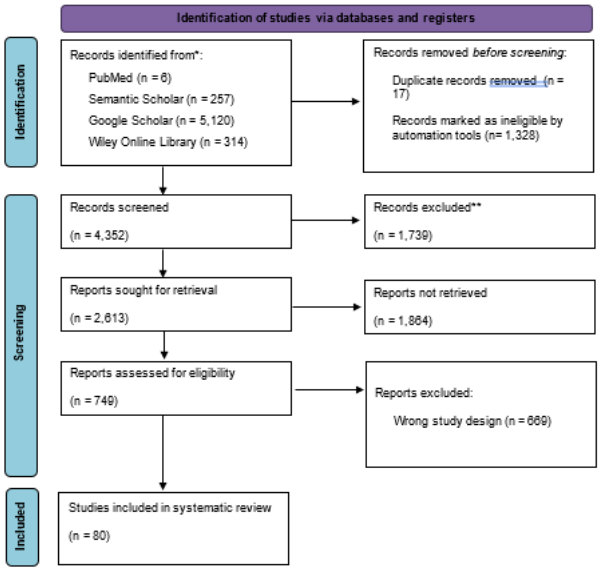

Figure 1. Article search flowchart by Preferred Reporting Items for Systematic Review and Meta-Analyses (PRISMA) for Study Selection.

Table 1. Characteristics of Included Studies.

Study	Disease Stage	Treatment Setting	Sample Size
Matthew Young et al., 2024	Muscle-invasive	Neoadjuvant	40
L. Dyrskjøt et al., 2025	MIBC (cT2-4aN0-1M0)	Neoadjuvant + Adjuvant	179
T. Powles et al., 2024	Advanced/Metastatic	First-line metastatic	263
A. C. Redla et al., 2025	Mixed (NMIBC/MIBC)	Adjuvant	581
T. Powles et al., 2025	MIBC (cT2-T4aN0/1M0)	Neoadjuvant + Adjuvant	462
Thomas Powles et al., 2025	Muscle-invasive	Adjuvant	761
Kevin R. Reyes et al., 2025	Advanced	Metastatic	36
T. Powles et al., 2024a	Metastatic	First-line metastatic	260
Qingping Ma et al., 2025	Mixed	ICI therapy	862
Haoyang Liu et al., 2024	Mixed	Multiple settings	1725
J. Zang et al., 2023	Metastatic	Refractory	27
L. Haoyang et al., 2023	Mixed	Multiple settings	1844
M. Aslanova et al., 2025	Locally advanced/Metastatic	Systemic therapy	47
J. van Dorp et al., 2022	Stage III	Neoadjuvant	24
T. Powles et al., 2023	Muscle-invasive	Adjuvant	581
T. Powles et al., 2020	Muscle-invasive	Neoadjuvant	40
E. Crupi et al., 2023	MIBC (T2-T4a)	Perioperative	Not specified
Xindong Gao et al., 2025	Muscle-invasive	Multiple settings	1170
C. Suartz et al., 2024	Muscle-invasive	Neoadjuvant	780
Yi-Tsung Lu et al., 2023	MIBC (cT2-T4aN0M0)	Neoadjuvant	72
Dibash Kumar Das et al., 2021	Muscle-invasive	Adjuvant	581
Valentina Tateo et al., 2025	Muscle-invasive	Neoadjuvant	29
Danielle Carroll et al., 2019	Metastatic	First-line metastatic	149
Andrew B. Katims et al., 2023	N+ MIBC	Neoadjuvant	9
Yongle Zhan et al., 2025	Muscle-invasive (pT2-4a)	Adjuvant	20
Yi-Tsung Lu et al., 2022	Muscle-invasive	Neoadjuvant	73
Y. Salhi et al., 2023	Metastatic	Second-line	74
Ruiyun Zhang et al., 2022	Muscle-invasive	Neoadjuvant	20
F. Jackson-Spence et al., 2023	Advanced	First-line metastatic	Not specified
F. Jackson-Spence et al., 2023a	Muscle-invasive	Adjuvant	Not specified
J. van Dorp et al., 2023	Stage III	Neoadjuvant	30
N. Sundahl et al., 2019	Metastatic	First-line metastatic	18
G. G. Galarza Fortuna et al., 2024	Non-metastatic	Adjuvant	28
Marie-Pier St-Laurent et al., 2025	MIBC (≥T2, N0M0)	Neoadjuvant	72-688
G. G. Galarza Fortuna et al., 2025	Muscle-invasive	Adjuvant	28
G. Vandekerkhove et al., 2019	Metastatic	First-line metastatic	18
Andrea Necchi et al., 2024	MIBC (T2-T4N0M0)	Neoadjuvant	30
S. Lindskrog et al., 2023	Muscle-invasive	Adjuvant	581
A. Siefker-Radtke et al., 2020	Locally advanced/Metastatic	First-line metastatic	82
T. Powles et al., 2021	Muscle-invasive	Adjuvant	Not specified
B. Guercio et al., 2025	Metastatic	First-line metastatic	201
Jingwen Zhao et al., 2024	Not specified	Not specified	Not specified
M. D. Galsky et al., 2025	Muscle-invasive	Adjuvant	133
Xiatong Huang et al., 2025	Muscle-invasive	Adjuvant	Not specified

I. D. de Kruijff et al., 2020	Muscle-invasive	Perioperative	Not specified
S. Mehrotra et al., 2025	Metastatic	Not specified	289
M. Gögenur et al., 2022	Nonmetastatic	Neoadjuvant	727
A. Andrea Grosso et al., 2025	Muscle-invasive	Perioperative	Not specified
J. Goodall et al., 2020	N/A	N/A	N/A
M. Hellmann et al., 2019	Mixed solid tumors	ICI therapy	Not specified
R. Herranz et al., 2021	Mixed (MIBC, NMIBC, metastatic)	Multiple settings	Not specified
A. Forschner et al., 2019	N/A	N/A	N/A
M. Gögenur et al., 2022a	Nonmetastatic	Neoadjuvant	Not specified
J. Bachet et al., 2020	N/A	N/A	N/A
L. Al-Showbaki et al., 2022	Advanced solid tumors	ICI therapy	Not specified
S. Wildsmith et al., 2020	Locally advanced/Metastatic	First-line	536
Jeeyun Lee et al., 2016	Mixed solid tumors	Not specified	Not specified
D. Geynisman et al., 2021	Muscle-invasive	Neoadjuvant	Not specified
D. Geynisman et al., 2018	Muscle-invasive (cT2-T3N0M0)	Neoadjuvant	Not specified
Ryota Ogura et al., 2023	Metastatic	First-line metastatic	Not specified
E. Grande et al., 2019	Muscle-invasive (T2-T4/N+)	Neoadjuvant	66
Yu Lu et al., 2025	Mixed	Not specified	9 studies
Jiaxin Zhou et al., 2023	Not specified	Neoadjuvant	Not specified
P. Khetrapal et al., 2018	Mixed	Multiple settings	Not specified
E. Laukhtina et al., 2021	Not specified	Neoadjuvant	Not specified
L. Siu et al., 2020	Mixed solid tumors	ICI therapy	94
K. Shohdy et al., 2024	Mixed solid tumors	Phase I trials	34
Maya Kansara et al., 2022	Mixed solid tumors	ICI therapy	40
A. Apolo et al., 2019	Metastatic GU tumors	Combination therapy	52
R. Azevedo et al., 2018	Mixed	Not specified	Not specified
L. Al-Showbaki et al., 2023	Advanced solid tumors	ICI therapy	18 trials
C. Valenza et al., 2025	Mixed solid tumors	Neoadjuvant ICI	380
M. Maas et al., 2018	NMIBC	Not specified	Not specified
Andy Zulfiqqar et al., 2024	NMIBC (T1)	Post-TURBT	5 studies
Aaron Li et al., 2025	Not specified	Multiple settings	Simulated
Aaron Li et al., 2024	Not specified	Multiple settings	Simulated
Giorgio Calleris et al., 2023	Non-metastatic UTUC	Neoadjuvant	Not specified
A. Mittal et al., 2023	Mixed solid tumors	Curative intent	1924
Sam S. Chang et al., 2016	Locally advanced/Metastatic	Refractory	Not specified
P. Eastman et al., 2023	Not specified	Not specified	Not specified

The majority of primary studies focused on muscle-invasive bladder cancer, predominantly in perioperative and neoadjuvant settings, with additional representation from metastatic disease treated using systemic therapies. Despite methodological variation in ctDNA, consistent patterns emerged demonstrating the prognostic relevance of ctDNA detection at baseline, post-treatment, and during longitudinal monitoring. Detectable ctDNA was consistently associated with inferior disease-free and overall survival outcomes. These associations were supporting its role as a marker of minimal residual disease. Dynamic monitoring further strengthened prognostic accuracy, as ctDNA clearance correlated with improved clinical outcomes.

Table 2. ctDNA and Pathological Response.

Study	Setting	ctDNA Metric	Pathological Response	Association
T. Powles et al., 2025	Perioperative	Pre-RC ctDNA+	Non-pCR	97% non-pCR in ctDNA+
Matthew Young et al., 2024	Neoadjuvant	ctDNA clearance	pCR	All patients with clearance achieved pCR
J. van Dorp et al., 2022	Neoadjuvant	Plasma ctDNA-	pCR	76% pCR in ctDNA-
Valentina Tateo et al., 2025	Neoadjuvant	Post-treatment ctDNA-	pCR	72.7% pCR if ctDNA-
Andrew B. Katims et al., 2023	Neoadjuvant	ctDNA clearance	pCR	70% clearance rate
Ruiyun Zhang et al., 2022	Neoadjuvant	utDNA clearance	pCR	Associated with objective responses
C. Suartz et al., 2024	Neoadjuvant	cfDNA	pCR prediction	79-100% accuracy (plasma)

Studies demonstrated that ctDNA negativity or clearance prior to surgery was strongly associated with pathological complete response, whereas persistent ctDNA detection was linked to residual disease. Treatment-specific analyses indicated that ctDNA also holds predictive value in immunotherapy settings. In contrast, chemotherapy-induced ctDNA changes demonstrated less consistent associations with long-term outcomes, suggesting modality-specific differences in ctDNA utility.

Table 3. Lead Time Advantage of ctDNA Detection.

Study	Lead Time	Clinical Context
L. Dyrskjøt et al., 2025	90 days (median)	Prior to CT-detected metastases
E. Crupi et al., 2023	101-932 days	Before radiological progression
K. Shohdy et al., 2024	53 days (mean)	Prior to radiological progression
Maya Kansara et al., 2022	11.5 months (median)	ctDNA clearance identified CRs ahead of imaging

Multiple studies demonstrated that changes in ctDNA status preceded radiographic progression, underscoring its potential role in earlier detection of disease recurrence. These findings collectively support ctDNA as a clinically meaningful biomarker across multiple disease stages and treatment contexts.

4. DISCUSSION

This comprehensive systematic review of 80 studies provides compelling evidence that ctDNA is a powerful biomarker for monitoring treatment response in urothelial carcinoma. The discussion synthesizes the key findings and explores their clinical implications.

The most consistent finding across studies is the strong prognostic value of ctDNA. Baseline or post-treatment ctDNA positivity confers a markedly increased risk of recurrence and death, with pooled hazard ratios for disease-free survival ranging from 4.23 to 6.56 (Liu et

al., 2024; Gao et al., 2025; Haoyang et al., 2023). This establishes ctDNA as a highly reliable indicator of minimal residual disease (MRD) and aggressive tumor biology. More importantly, dynamic ctDNA changes showed superior predictive value. A decrease or clearance of ctDNA during therapy was associated with a 74–90% reduction in the risk of adverse outcomes, with hazard ratios as low as 0.10–0.31 (Ma et al., 2025; Al-Showbaki et al., 2023; Crupi et al., 2023).

The predictive utility of ctDNA is context-dependent. In the perioperative setting, evidence is particularly robust and clinically actionable. Landmark trials such as IMvigor011 and CheckMate 274 demonstrated that adjuvant immunotherapy (atezolizumab, nivolumab) provides significant benefit predominantly or exclusively to patients with detectable ctDNA after surgery, whereas patients with undetectable ctDNA experienced excellent outcomes with observation alone (Powles et al., 2025; Galsky et al., 2025; Jackson-Spence et al., 2023). In contrast, in the metastatic setting, ctDNA dynamics remained prognostic but offered limited independent predictive value beyond radiographic assessment, as observed in the KEYNOTE-361 trial (Powles et al., 2024).

Significant heterogeneity across studies represents a major challenge for clinical implementation. Tumor-informed assays consistently demonstrated higher sensitivity for MRD detection and stronger associations with outcomes than tumor-agnostic platforms (van Dorp et al., 2022; Katims et al., 2023). Definitions of ctDNA response also varied; complete clearance was rare but highly specific for pathological complete response and durable benefit, whereas partial reductions were more common but less consistently predictive (Suartz et al., 2024; Young et al., 2024). Sampling timing influenced prognostic performance, with post-surgical and early on-treatment assessments providing more informative results than baseline measurements alone (Laukhtina et al., 2021; Li et al., 2025). A key practical advantage of ctDNA is its lead time over conventional imaging. Several studies reported that ctDNA changes preceded radiographic progression by a median of 53–90 days (Dyrskjøt et al., 2025; Shohdy et al., 2024; Crupi et al., 2023).

Despite its promise, important limitations remain. A proportion of ctDNA-negative patients still experienced relapse, indicating incomplete sensitivity for detecting micrometastatic disease (Mittal et al., 2023).

5. CONCLUSION

ctDNA has emerged as a cornerstone biomarker for monitoring treatment response in urothelial carcinoma. Its ability to provide dynamic and biologically relevant information supports its integration into clinical decision-making, particularly in the perioperative setting.

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