Urachal cancer: a clinical, diagnostic, and therapeutic update

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Purpose of review
To give an overview of the advances in treatment, diagnosis, and epidemiological data of urachal tumors in 2024 and 2025.

Recent findings
The update specifically refers to surgical approaches for localized cancers, drug therapy of advanced cancers, diagnostic criteria and consensus recommendations, diagnostic approaches, and epidemiological data.

Summary
Recommendations for partial cystectomy (if feasible) in localized urachal adenocarcinomas helps to standardize therapeutic approaches. In addition, current clinical trial results and running studies will help to personalize treatment decisions in advanced disease. The ISUP Dublin consensus recommendations will facilitate the diagnostic process and research, as will the summarized, unbiased epidemiological data.

Keywords
update, urachal cancer, urachal tumors

INTRODUCTION

Urachal tumors are rare but hold significant clinical implications as therapeutic strategies differ from urinary bladder tumors [1]. Most cases of urachal tumors are cancers (UrC) with adenocarcinomas (UrAC) being the most common type [2,3]. These cases are subdivided into the more common noncystic and rarer cystic adenocarcinomas, the latter being similar to counterparts in the appendix or ovary.

Recent years have brought profound changes in the molecular and diagnostic understanding of these tumors flanked by advances in therapeutic options and standardization. This review focusses on key developments in urachal tumors over the last 18 months (2024 and 2025).

For the review, PubMed was accessed for articles over the current 18 months period (March 2024 to September 2025). The main topics with new data and relevant publications included surgical approaches for localized cancers, drug therapy of advanced cancers (including clinical trials), diagnostic criteria and consensus recommendations, and epidemiological data.

SURGICAL APPROACHES FOR LOCALIZED CANCERS

It is widely accepted by the majority that localized UrC is usually treated (when feasible) with partial cystectomy including resection of the median umbilical ligament and umbilicus [1]. This recommendation has been underlined for UrAC in a recent review published by Gupta and colleagues from the International Bladder Cancer Group stating the following consensus recommendation: "PC should be offered to patients with urachal adenocarcinomas that are amenable for resection with adequate margins" [4▪]. Another current review supports this notion, inherently also based on prior data [5]. A third review article from Drobot *et al.* [6], including data from their single center experience, focused on "robot-assisted urachal excision and partial cystectomy for urachal pathologies" with 33.8% of the 145 cases being malignant. The authors conclude that both

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Curr Opin Urol 2026, 36:155–160
DOI:10.1097/MOU.0000000000001360

KEY POINTS

- Guideline recommendations and international consensus statements facilitate therapeutic decision-making in localized therapy and streamline the diagnostic pathological process in and of urachal tumors.
- Advanced and metastatic cases of urachal cancer are increasingly integrated into prospective clinical trials thus paving the way to more personalized treatment decisions.
- Recent registry-based epidemiological data strengthen the data foundation of urachal cancer for health policy decisions, clinical trial planning, and research.

open and laparoscopic approaches are potential surgical options in this setting and that the robot-assisted urachal excision might have potential advantages [6]. However, other groups have raised some concerns, for example regarding the presence of port-site recurrences in laparoscopic approaches [7]. Therefore, the type of surgical approach is under debate.

In conclusion, in the reviewed time period, more support and recommendations are available for partial cystectomy.

DRUG THERAPY OF ADVANCED CANCERS

For UrC diagnosed in advanced or metastatic stages, survival rates are low and systemic therapy is often administered [1]. Classically, the chemotherapy regimes were oriented at urothelial bladder cancer. However, due to histological and clinical similarities, regimes parallel to ones used in colorectal cancer, such as FOLFOX or FOLFIRINOX, are being used. This was underlined in the currently largest meta-analysis of 74 UrC cases using retrospective data [1].

In 2025, Park *et al.* [8▪▪] added important and confirmatory data reporting the first prospective results in the ULTIMA trial. This Korean "multicenter phase II study of modified FOLFIRINOX for first-line treatment for advanced urachal cancer" was a single-arm and open-label study. Patients with recurrent or metastatic UrC received a modified FOLFIRINOX regime plus prophylactic pegteograstim every 2 weeks for up to 12 cycles, or until disease progression or unacceptable toxicity. The overall response rate (ORR) was the primary, and progression-free survival (PFS), overall survival (OS), and the incidence of febrile neutropenia were the secondary endpoints. Twenty-one patients from five centers were enrolled with typical clinicopathological characteristics. The ORR was 61.9% (two complete and 11 partial responses) with the remaining patients showing stable disease. Therefore, no progression was noted in this first phase of the trial. After a median follow-up period of 23.4 months, the median OS was 19.7 months (95% CI, 14.3–25.1), the median PFS was 9.3 months (95% CI, 6.7–11.9), and no unexpected adverse events including no febrile neutropenia or grade 4 adverse events were noted. Although the final survival and molecular data have to be awaited, the ULTIMA trial results underline the effectiveness of chemotherapeutic regimes addressing adenocarcinoma histology especially being the first prospective trial data in this setting.

When translating these data to the clinic, however, one has to keep in mind the small cohort size, the good performance status (ECOG 0–1) and young median age (50 years) of the patients. Therefore, results in elderly and/or comorbid patients might differ. In addition, no information are currently available for histological subtypes of UrAC, which might influence the efficacy of treatment.

Another noteworthy approach was published in a patient with metastatic UrAC. Urushibara and colleagues achieved favorable survival of more than 5 years through repeated cytoreductive surgery combined with S-1/Cisplatin-based chemotherapy at each event of disease progression in the 74-year-old female patient [9].

In current years, also immune checkpoint inhibition (ICI) and targeted therapeutic approaches including antibody-drug conjugates (ADCs) are being explored in UrAC.

Apolo and colleagues reported the results of a phase I trial of "cabozantinib and nivolumab alone or with ipilimumab for advanced/metastatic genitourinary tumors" including 15 cases of bladder adenocarcinomas/urachal carcinomas [10▪]. The trial included 120 patients of whom 108 were available for further evaluation. However, the subgroup of bladder adenocarcinoma/urachal tumors were not further separated into primary urinary bladder adenocarcinomas and UrAC, thus limiting the significance of the findings for UrAC. In the subgroup of bladder adenocarcinoma/urachal tumors the ORR was 20% (95% CI, 4.3–48.1), the disease control rate (DCR) was 80% (95% CI, 51.9–95.7), the median PFS was 10.1 months (95% CI, 1.8–16.5), and the median OS was 18.0 months (95% CI, 5.8–28.2).

Regarding ADCs, the expression of ADC-related protein markers was analyzed by immunohistochemistry (IHC) and correlated with prognosis in a Chinese study by Han *et al.* [11]. In a cohort of 41 UrC (39 adenocarcinomas, two non-adenocarcinomas) with typical clinico-pathological characteristics, the authors stained for expression levels of HER2, Nectin-4, Claudin18.2, Trop2, Mesothelin, and PD-L1. A tissue micro-array (TMA) based approach was used,

thus evaluating the staining in representative punch biopsies of the tumors. In line with previous publications, HER2- and PD-L1 expression levels were low, while TROP2 showed the highest expression levels. High TROP2 expression was additionally associated with significantly shorter OS, also in multivariable analyses but not after an additional sensitivity analysis. Figure 1 shows one case of mucinous UrAC from our own cohort displaying similar biomarker characteristics.

Such ADC-biomarker-expression studies become more important as UrAC are included in clinical trials such as the SMART [12▪▪] (NCT06161532) and the E-VIRTUE [13▪▪] (NCT06041503) studies. While the SMART trial since August 2024 is active and recruiting, the E-VIRTUE trial is not yet recruiting (as of October 2025). Both are located in Bethesda, Maryland, United States at the National Institutes of Health Clinical Center. For the SMART trial, it is likely that "this study will open at three to four additional cancer centers in the U.S" [12▪▪].

The SMART study [12▪▪] itself is an "open-label, nonrandomized, phase 2 trial of sacituzumab govitecan monotherapy or concomitant sacituzumab govitecan plus atezolizumab in locally advanced or metastatic cancers", including UrAC. Two cohorts are open with ICI-treated patients in cohort A (sacituzumab govitecan monotherapy) and ICI-naive patients in cohort B (sacituzumab govitecan plus atezolizumab). UrAC patients can be enrolled in both arms. The primary endpoint in both cohorts is ORR, and "secondary objectives are safety, PFS, OS, duration of response" [12▪▪]. The study will also feature translational research including TROP2-expression analyses by IHC, evaluation of mutational status (DNA/RNA), and changes in circulating tumor cells and tumor DNA. Up to 60 evaluable patients across both cohorts and both stages will be enrolled; the study is thought to be completed 2–3 years after study begin.

The E-VIRTUE study [13▪▪] is an "open-label, nonrandomized, dual-arm, phase 2 trial enrolling patients with locally advanced or metastatic urinary tract adenocarcinoma (Cohort A1: immune checkpoint inhibitor-treated, Cohort A2: immune checkpoint inhibitor- naïve)" and other rare genitourinary cancers for therapy with enfortumab vedotin with or without pembrolizumab. The primary endpoint is ORR, and secondary objectives include safety, PFS, OS, duration of response, and one additional parameter. This study will also feature a translational arm with analysis of nectin-4 expression, evaluation of mutational status (DNA/RNA), changes in circulating tumor cells and tumor DNA, urine tumor DNA analysis, and analysis of the immune tumor microenvironment. Up to 68 evaluable participants are required.

These trials will provide new prospective data on the efficacy of chemotherapy, ICI, and/or ADC-treatment, offering – for the first time – higher-level evidence to support personalized clinical decision-making in advanced cases of UrAC. Table 1 gives an overview of all current clinical trials involving urachal cancer.

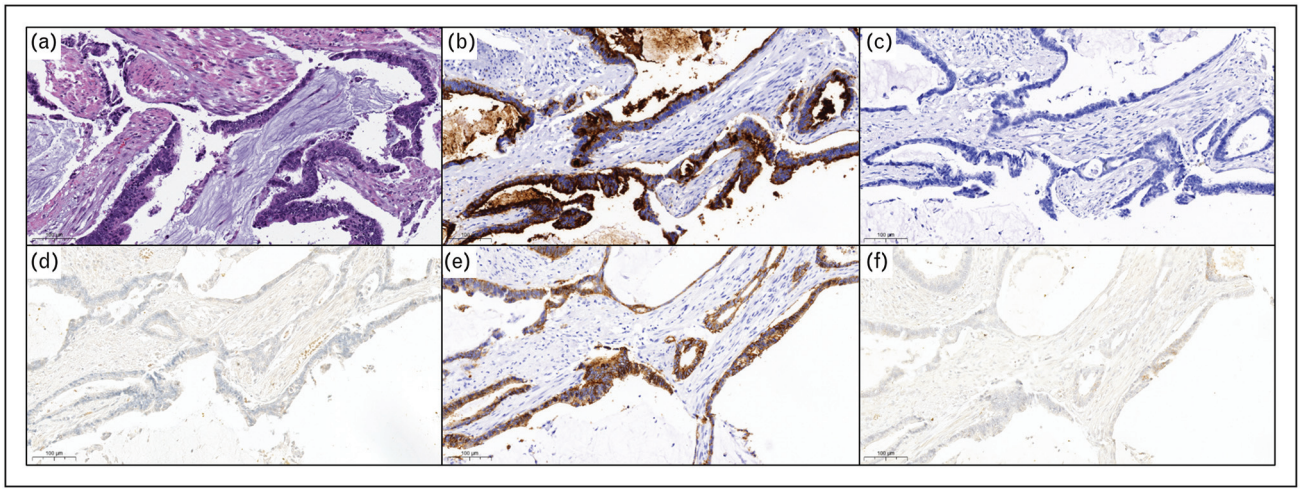

FIGURE 1. A representative case of a mucinous urachal adenocarcinoma with protein biomarker stainings (IHC) from the author's cohort. (a) H&E staining showing atpyical pseudostratified epithelia with extracellular mucin prodcution and invasion of urinary bladder detrusor muscle. (b) Strong expression of cancer embryonic antigen (CEA)/carcinoembryonic antigen-related cell adhesion molecule 5 (CEACAM5). (c) negative stainings for HER2/neu (score: 0, negative) and in (d) for Nectin4. (e) Tumor cells exhibiting moderate to strong TROP2 staining and in (f) few tumor cells with weak expression of Claudin 18.2. All microphotographs taken at 200x magnification.

Table 1. Current clinical trials involving cases of urachal cancer

NCT Number	Study title	Study status	Sponsor	Phases	Enrollment (*n*)	Study type	Start Date	Completion date
NCT00082706	Fluorouracil, Leucovorin, Gemcitabine, and Cisplatin in Treating Patients With Metastatic or Unresectable Adenocarcinoma of the Urothelium or Urachal Remnant	Active, not recruiting	M.D. Anderson Cancer Center	II	46	interventional	4/23/2003	12/31/2025
NCT04923178	A Multi-Center Natural History of Urothelial Cancer and Rare Genitourinary Tract Malignancies	recruiting	National Cancer Institute (NCI)		1100	observational	10/24/2022	12/1/2042
NCT04611724	A Multicenter Prospective Phase II Study of Modified FOLFIRINOX for 1st Line Treatment for Advanced Urachus Cancer	unknown	Asan Medical Center	II	35	interventional	12/1/2020	9/30/2024
NCT06684327	Multicohort, Single-arm Phase II Study of Albumin-paclitaxel, Ifosfamide, and Cisplatin in the Treatment of Rare Advanced Tumors	recruiting	Fudan University	II	100	interventional	11/30/2024	12/30/2027
NCT06683846	Ivonescimab in the Treatment of Multiple Advanced Tumors	recruiting	Fudan University	II	400	interventional	11/20/2024	11/30/2027
NCT07046650	Multicohort, Single-arm, Phase II Study of the Efficacy and Side Effects of Cisplatin Plus Gemcitabine in the Treatment of PD1 Failure or Intensive Treatment of Some Rare Tumors	recruiting	Sheng Zhang	II	84	interventional	1/1/2025	7/31/2028
NCT06638931	Agnostic Therapy in Rare Solid Tumors	Active, not recruiting	Instituto do Cancer do Estado de São Paulo	II	28	interventional	7/1/2024	5/1/2028
NCT03866382	Testing the Effectiveness of Two Immunotherapy Drugs (Nivolumab and Ipilimumab) With One Anticancer Targeted Drug (Cabozantinib) for Rare Genitourinary Tumors	recruiting	National Cancer Institute (NCI)	II	314	interventional	5/13/2019	2/28/2026
NCT05756569	Enfortumab Vedotin Plus Pembrolizumab for the Treatment of Locally Advanced or Metastatic Bladder Cancer of Variant Histology	recruiting	Emory University	II	25	interventional	9/26/2023	12/16/2027
NCT06161532	Sacituzumab Govitecan With or Without Atezolizumab Immunotherapy in Rare Genitourinary Tumors (SMART) Such as High Grade Neuroendocrine Carcinomas, Adenocarcinoma, and Squamous Cell Bladder/ Urinary Tract Cancer, Renal Medullary Carcinoma and Penile C...	recruiting	National Cancer Institute (NCI)	II	60	interventional	8/1/2024	11/1/2028
NCT06041503	Enfortumab Vedotin With or Without Pembrolizumab in Rare Genitourinary Tumors (E-VIRTUE)	not yet recruiting	National Cancer Institute (NCI)	II	68	interventional	11/2/2025	10/1/2028

Source: Clinicaltrials.gov, https://clinicaltrials.gov/, [Accessed 28 October 2025].

DIAGNOSTIC CRITERIA AND CONSENSUS RECOMMENDATIONS

In addition to formerly lacking prospective clinical trial data, no consented recommendations were available for diagnostic aspects of urachal tumors. Therefore, an international consensus meeting was organized under the auspices of the International Society of Urological Pathology (ISUP) in 2023 prior to the European Congress of Pathology in Dublin, Ireland. The results were published by the organizers in 2025 in two separate papers [14▪,15▪]. Regarding urachal tumors, the most important consensus decisions were UrC is a combination diagnosis of gross, histologic, clinical, and imaging findings; metastatic disease from a primary elsewhere should be excluded; the 2022 WHO criteria should be applied in the diagnosis of UrAC and other types of UrC; recommendations regarding grossing, sampling, and use of diagnostic IHC (optional) were made; a decision against the current threshold for the extent of intraepithelial carcinoma in urachal mucinous cystic tumor of low malignant potential was reached; recommendation for a new staging approach on UrC was formulated; modification of the current TNM/AJCC staging system for urinary bladder cancer for UrC was recommended; [14▪] molecular analysis [. . .] should be performed only in advanced [. . .] UrAC for targetable therapy [15▪].

These reports from the Dublin ISUP consensus conference are the first consented recommendations from an international committee of pathologists, urologists, oncologists, radiologists, and other specialists and will serve as a best practice recommendation and guide further research.

DIAGNOSTIC APPROACHES

Apart from typical calcifications in mucinous UrAC, no typical radiological signs in UrC are known [1]. Two recent case reports highlight the usefulness of ^{99m}Tc-FAPI 46 scintigraphy and contrast-enhanced CT [16] and ^{18}F-PSMA-1007 PET/CT [17] in the diagnosis of metastases of colorectal and prostate adenocarcinomas to the urachus. It might be useful in such special circumstances to keep these data in mind.

EPIDEMIOLOGICAL DATA

As UrC is a rare cancer that can be difficult to diagnose, epidemiological data are scarce. A current systematic review and meta-analysis by Olah and colleagues from the Academia Europaea Translational Medicine Working Group identified 4748 publications, from which only six met the criteria to be selected for final analysis [18▪]. These unbiased data from six countries on three continents show incidence ranges from 0.022 to 0.060/100 000 person-years with highest figures in Japan and lowest in Canada. The overall incidence rate was calculated to be 0.04 (95% CI: 0.03–0.05)/100 000 person-years. The survival rate at 5 years of all 1123 patients was 51.0% (95% CI: 45.2–57.4) with no significant differences between world regions. The median survival time was reported to be 62.9 months (95% CI: 52.0–-82.8). At first diagnosis, median age was 60 years and the female to male ratio was 40%/60%. Distant and lymph node metastases were present in 14% and 9% of cases. Partial cystectomy was conducted in 69% of cases and positive resection margins were reported in 13% of all resected patients (including radical cystectomies). UrAC histology accounted for 86%, followed by urothelial carcinoma (12%) and squamous cell carcinoma (2%) [18▪].

Shortly after, Akhtar *et al.* [19] reported data of 43 UrC patients from a nationwide multicenter cohort study in Norway between 1997 and 2022 from the population-based Cancer Registry of Norway (CRN). The group reported similar findings with a median age of 59.5 years (IQR 49–73), more affected patients being male (57%), and OS rates of 93%, 61%, and 46% at 1, 3, and 5 years, respectively. Interestingly, only the Mayo staging system showed significant OS differences between stages. This provides more data for the staging-based discussion mentioned in the diagnostic criteria and consensus recommendations section.

Orsini *et al.* [20] reported further data from 2475 UrC patients during the period of 2010–2022 based on the PearlDiver Mariner database covering 150 Mio persons in the U.S. These data, however, derive from TURBT or bladder biopsy specimen, which can be difficult to render a definitive diagnosis of UrC, and therefore have to be interpreted with caution when compared to the other epidemiological studies. This study put emphasis on the following treatment of partial cystectomy versus radical cystectomy in the U.S. UrC patients who received partial cystectomy (n = 330) were younger compared to those who received radical cystectomy (n = 407) (60.55 ± 12.92 versus 66.74 ± 8.13 years) and the use of radical cystectomies decreased over time [20]. The latter is in line with general recommendations to prioritize the use of partial cystectomy in UrC when feasible as discussed in the surgical approaches for localized cancers section.

Overall, these new registry-based epidemiological data improve the data basis of UrC. This will facilitate the validity of health policy decisions regarding UrC as well as clinical trial planning and research.

CONCLUSION

The present article gives an update on specific aspects of UrC. Partial cystectomy (when feasible) as the

therapy of choice is strengthened by new consented recommendations and data. In addition, for the first time, consensus recommendations are available for histopathological, immunohistochemical and molecular analyses in the diagnostic process of UrC, which will help to streamline diagnosis and facilitate further research. UrC and especially UrAC are increasingly integrated into clinical trials, including studies on chemotherapy, ICI, and ADC-treatment efficacy, paving the way to more personalized treatment decisions.

Acknowledgements

None.

Financial support and sponsorship

This work was supported by the K139059 grant of the Ministry for Innovation and Technology from the source of the National Research Development and Innovation Fund.

Conflicts of interest

Henning Reis received consulting fees and/or lecture fees and/or travel support from Astellas, Astra-Zeneca, Bristol-Myers Squibb, Boehringer-Ingelheim, CHOP GmbH, Diaceutics, Evidia, GlaxoSmithKline, HUeG e.V., Janssen-Cilag, Klinikum Wolfsburg, Lilly, MCI, Menarini Stemline, Merck / MSD, Novartis, Philips, Roche, Sanofi, and Takeda, and received grants from Bristol-Myers Squibb.

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- ■ of special interest
- ■■ of outstanding interest

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This study summarizes the consensus recommendations from the International Bladder Cancer Group including a recommendation for the use of partial cystectomy in UrAC when feasible.

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This study reports the first prospective clinical trial results (ULTIMA trial) in UrC. It was a "multicenter phase II study of modified FOLFIRINOX for first-line treatment for advanced urachal cancer" that recruited in Korea (single-arm & open-label). The results underlined the effectiveness of chemotherapeutic regimes addressing adenocarcinoma histology, but final data are to be awaited.

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This study reports the results of a phase I trial of "cabozantinib and nivolumab alone or with ipilimumab for advanced/metastatic genitourinary tumors" including 15 cases of bladder adenocarcinomas/urachal carcinomas with ORR of 20%, DCR of 80%, median PFS of 10.1 months, and median OS of 18.0 months. However, the subgroup of bladder adenocarcinoma/urachal tumors were not further separated into primary urinary bladder adenocarcinomas and UrAC, thus limiting the significance of the findings for UrAC.

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As one of the two ongoing, targeted ADC-based clinical trials including UrAC, the SMART study is an "open-label, nonrandomized, phase 2 trial of sacituzumab govitecan monotherapy or concomitant sacituzumab govitecan plus atezolizumab in locally advanced or metastatic cancers". Two cohorts are open with ICI-treated patients in cohort A (sacituzumab govitecan monotherapy) and ICI-naive patients in cohort B (sacituzumab govitecan plus atezolizumab). The primary endpoint in both cohorts is ORR. The study will also feature translational research. It is thought to be completed 2–3 years after study begin.

13. ■■ Chandran EBA, Atiq S, Simon N, *et al.* E-VIRTUE: a study of enfortumab vedotin with or without pembrolizumab in rare genitourinary tumors-design and rationale. Future Oncol 2025; 21:1625–1630.

As the second of the two targeted ADC-based clinical trials including UrAC, the E-VIRTUE study is an "open-label, nonrandomized, dual-arm, phase 2 trial enrolling patients with locally advanced or metastatic urinary tract adenocarcinoma (Cohort A1: immune checkpoint inhibitor-treated, Cohort A2: immune checkpoint inhibitor-naïve)" and other rare genitourinary cancers for therapy with enfortumab vedotin with or without pembrolizumab. The primary endpoint is ORR. This study will also feature a translational arm. It is not yet recruiting (as of October 2025).

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This study is the first of two reports summarizing the results of the Dublin ISUP Consensus Conference in 2023, mainly focused on urachal tumors. Together with the second study, it reports the first consented recommendations from an international committee, will serve as a best practice recommendation and guide further research.

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