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Abstract 46

Impact of the antibiotic intake before BCG immunotherapy in non-muscle-invasive bladder cancer patients

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Introduction: Intravesical immunotherapy with Bacillus Calmette-Guérin (BCG) is the standard treatment for non-muscle-invasive bladder cancer (NMIBC) patients. Unfortunately, 40% of patients do not respond to this treatment. Recent studies have highlighted the importance of gut microbiome and the deleterious effect of antibiotics (ATB) on the efficacy of various immunotherapies. However, the impact of ATB intake before BCG treatment initiation is unclear.

Methods: This is a single-center retrospective study of 622 NMIBC patients who received BCG immunotherapy following transurethral resection of a bladder tumor at CHU de Québec from 2009–2019. We evaluated ATB intake based on prescriptions and medical records. ATB was evaluated up to 12 months before BCG initiation. The impact of ATB use on BCG response was determined as the rate of bladder cancer recurrence after BCG treatment. Additionally, to explore the impact of ATB on BCG efficacy *in vivo* in a preclinical bladder cancer model, C3H mice were subjected to a broad-spectrum ATB regimen. One group received ATB for only one week, while the other group continued the ATB treatment throughout the entire experiment. Mice were subcutaneously injected with MBT-2 bladder cancer cells and received weekly intra-tumor BCG treatments starting on day three post-tumor implantation.

Results: Of the 622 NMIBC patients, 77 (12%) were exposed to ATB within three months before their BCG treatment, while 545 patients (88%) were not. The use of ATB within this three-month window was associated with the first occurrence following BCG treatment (p=0.01) and showed a notable increase in the recurrence rate two years post-BCG (p<0.0001). Conversely, no significant difference in recurrence rates was observed between patients with or without ATB between 3–12 months before initiating the BCG therapy. Finally, mice with MBT-2 tumors undergoing BCG immunotherapy showed a negatively impacted antitumor effect of BCG when treated with a long-duration ATB regimen compared to controls, suggesting biological importance of the gut microbiota in response to BCG.

Conclusions: This study represents the first large single-site retrospective study to evaluate the detrimental effects of ATB use before BCG treatment in NMIBC patients. Our findings support that antibiotic treatment within three months before BCG treatment antagonizes its antitumor activity. This suggests that gut microbiota may play a role in the efficacy of BCG therapy in NMIBC patients.

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Abstract 47

Preoperative circulating basophils as a prognostic biomarker for muscle-invasive bladder cancer

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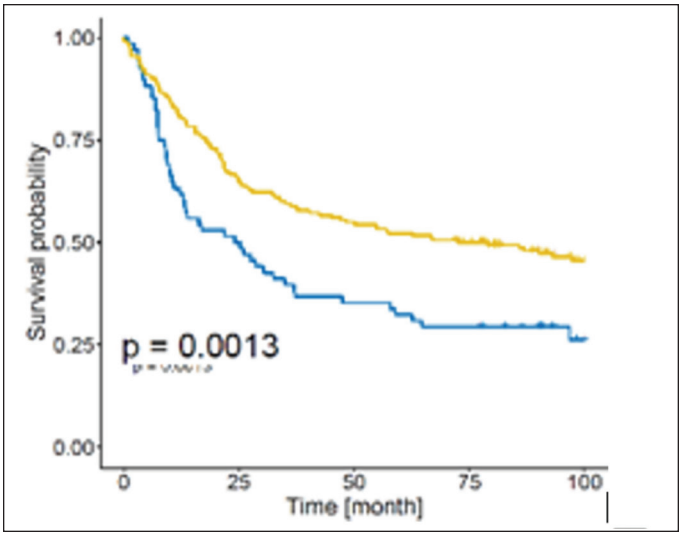
Introduction: Immunological biomarkers from the complete blood count are accessible, inexpensive, and have previously proven to have prognostic utility in bladder cancer. Following our previous work finding that preoperative absolute basophil counts predict progression and recurrence in non-muscle-invasive bladder cancer, we sought here to evaluate its prognostic importance in our institutional cohort of patients undergoing radical cystectomy.

Methods: Retrospectively, patients were identified who underwent radical cystectomy at our institution between 2009 and 2023. Patients included had a diagnosis of urothelial carcinoma. Preoperative complete blood count within 30 days prior to surgery was used to assay preoperative absolute basophil counts. Survival analysis was performed using the Kaplan-Meier method, with log-rank test.

Results: A total of 904 patients were included in our study cohort. The mean age was 69.48 (±9.0) and the median followup was 31.49 years. Preoperatively, 454 patients had detectable basophil counts and 450 patients had undetectable basophil counts. Overall survival was significantly poorer among patients with detectable basophil counts (p=0.0013).

Conclusions: We report for the first time that preoperative basophil counts are a significant prognostic biomarker among patients undergoing radical cystectomy for urothelial carcinoma. Further research is required to understand both the biological reasons for this and how this biomarker can be incorporated with other known prognostic inflammatory biomarkers.

Funding: N/A



Abstract 47. Figure 1. Survival probability in months.

Abstract 48

Analysis of genitourinary rhabdomyosarcoma in phase 3 clinical trials

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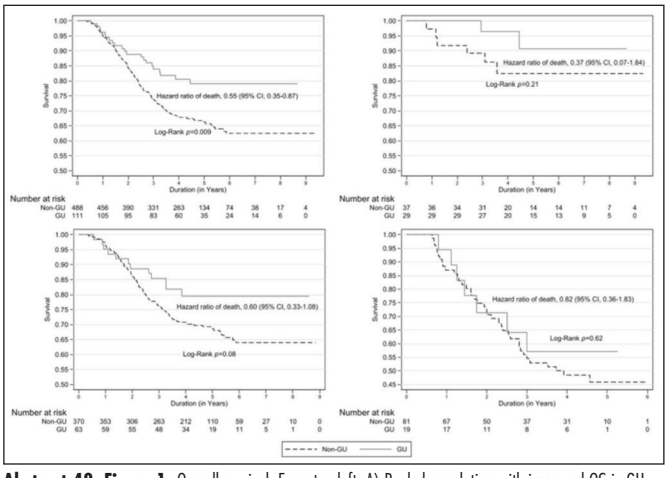
Introduction: Rhabdomyosarcoma (RMS) is a rare, morbid, and often lethal condition. Given its rarity, there are limited data on genitourinary (GU) RMS, and it is unclear whether GU sites (bladder, prostate, paratesticular, female GU) have outcomes distinct from non-GU sites. This study pools primary data from three phase 3 clinical trials involving RMS to pursue this question.

Methods: Primary data were pooled from three Children's Oncology Group trials (ARST0331, ARST0431, ARST0531) evaluating low- (L-R), intermediate- (I-R), and high-risk (H-R) RMS, separating GU primary sites from non-GU primary sites. Survival analysis was performed using the Kaplan-Meier method. Overall survival was defined as time to death. Event-free survival (EFS) was defined as time to relapse, ± progression, second malignancy, or death (whichever occurred first). Statistical analysis was performed using STATA.

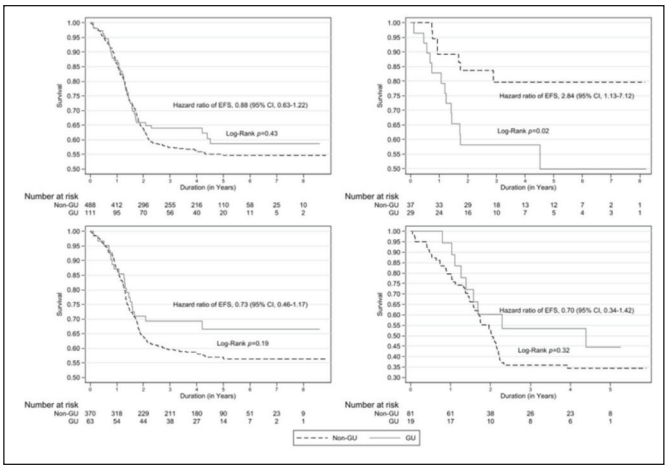
Results: A total of 599 subject records were analyzed (111 GU RMS, 488 non-GU RMS). ARST0331 (L-R) included 66 complete subject records, 29 of which were GU primary site (43.9%). ARST0531 (I-R) included 433 complete subject records, 63 of which were of GU primary site (14.5%). ARST0431 (H-R) included 100 total HR records, 19 of which were GU primary site (19%). For 111 subjects with GU RMS, OS was superior to non-GU RMS (HR 0.55, 95% CI 0.35–0.87, p=0.009). In this same group, EFS superiority was not statistically significant compared to non-GU RMS (HR 0.88, 95% CI 0.63–1.22, p=0.43). In the L-R population, GU primary site was associated with improved OS that was not statistically significant (HR 0.37, 95% CI 0.07–1.84, p=0.21) and less favorable EFS (HR 2.84, 95% CI 1.13–7.12, p=0.02). In the I-R population, GU primary site was associated with improved OS that was not statistically significant (HR 0.60, 95% CI 0.33–1.08, p=0.06) and improved EFS that was not statistically significant (HR 0.73, 95% CI 0.46–1.17, p=0.19). In the HR population, GU primary site was associated with improved OS that was not statistically significant (HR 0.82, 95% CI 0.36–1.83, p=0.62) and improved EFS that was not statistically significant (HR 0.70, 95% CI, 0.34–1.42, p=0.32).

Conclusions: GU primary site is associated with improved OS compared to non-GU primary site. EFS did not appear to mimic OS patterns, calling into question its validity as a surrogate predictor of OS.

Funding: N/A



Abstract 48. Figure 1. Overall survival. From top left: A) Pooled population with improved OS in GU RMS compared with non-GU RMS (p=0.009). B) Low-risk population with improved OS in GU RMS compared with non-GU RMS. C) Intermediate-risk population with improved OS in GU RMS compared with non-GU RMS. D) High-risk population with improved OS in GU RMS compared with non-GU RMS. CI: confidence interval; GU: genitourinary; OS: overall survival; RMS: rhabdomyosarcoma.



Abstract 48. Figure 2. Event-free survival. From top left: A) Pooled population GU RMS had improved EFS compared with non-GU RMS. B) Low-risk non-GU RMS had improved EFS compared with GU RMS (p=0.02). C) Intermediate-risk GU RMS had improved EFS compared with non-GU RMS. D) High-risk GU RMS had improved EFS compared with non-GU RMS. CI: confidence interval; EFS: event-free survival; GU: genitourinary; RMS: rhabdomyosarcoma.

Abstract 49

Disparities in the management of small renal masses: A disaggregated analysis by race/ethnicity

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Introduction: There is increasing recognition of racial disparities in kidney cancer care. However, most studies use aggregated groups of races, which may mask disparities among race/ethnic subgroups. Disaggregated analyses can offer more granular information and are essential to characterize disparities in cancer care. Therefore, the objective of this study was to perform a disaggregated race/ethnic analysis to evaluate potential disparities in the management of small renal masses.

Methods: We used the National Cancer Database to identify patients diagnosed with clinically localized kidney cancer and tumor size ≤4 cm. We studied 16 predefined racial/ethnic subgroups and compared 1) the use of surveillance for tumors <2 cm, and 2) the use of radical nephrectomy for tumors ≤4 cm. We used multivariable logistic regression to evaluate the independent association of race/ethnicity with management, adjusting for baseline characteristics. We compared our disaggregated analyses to aggregate analysis using the six National Institute of Health race categories.

Results: We identified 549 845 patients that met inclusion criteria. For tumors <2 cm, Black non-Hispanic (aOR 1.43, p<0.001) and Mexican patients (aOR 1.29, p=0.03) were significantly more likely to undergo surveillance, compared to White patients (Figure 1a). For tumors ≤4 cm, Black non-Hispanic (aOR 1.43, p<0.001), Filipino (aOR 1.28, p=0.002), Japanese (aOR 1.28, p=0.023), Mexican (aOR 1.32, p<0.001), and Native Indian patients (aOR 1.15, p=0.016) were significantly more likely to undergo radical nephrectomy compared to White patients (Figure 2A). When comparing our disaggregated analysis to the NIH categories, we found that many disaggregated race/ethnic subgroups had associations with a management strategy that was not represented by their aggregated group (Figures 1B and 2B).

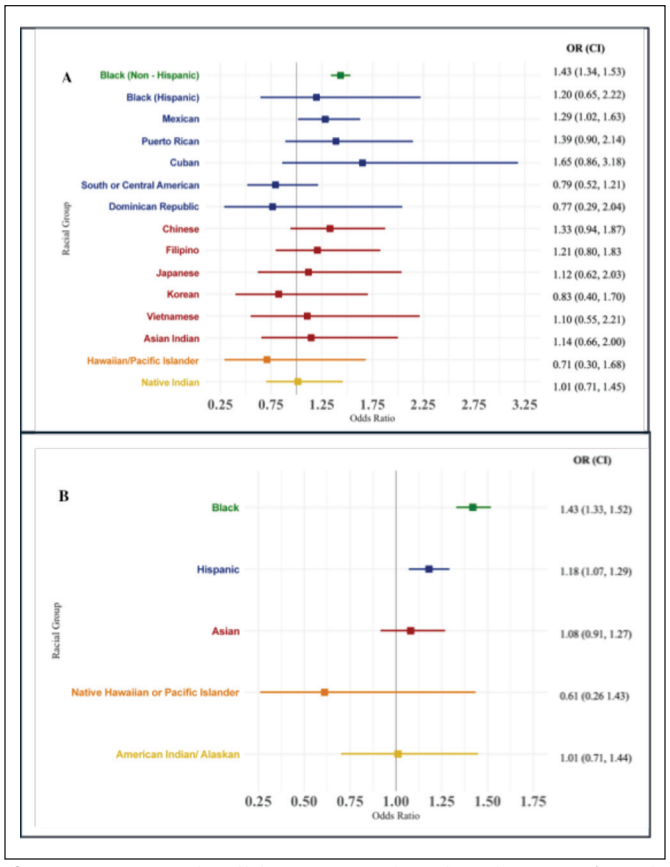
Conclusions: We used a large, national cancer database to characterize disparities in the management of small renal masses and found that the use of surveillance for tumors <2 cm and radical nephrectomy for tumors ≤4 cm varied significantly among certain race/ethnic subgroups. Our disaggregated approach provides information on particular subgroups that warrant further study to determine the potential sources of disparities and optimize kidney cancer care for all patients.

Funding: N/A

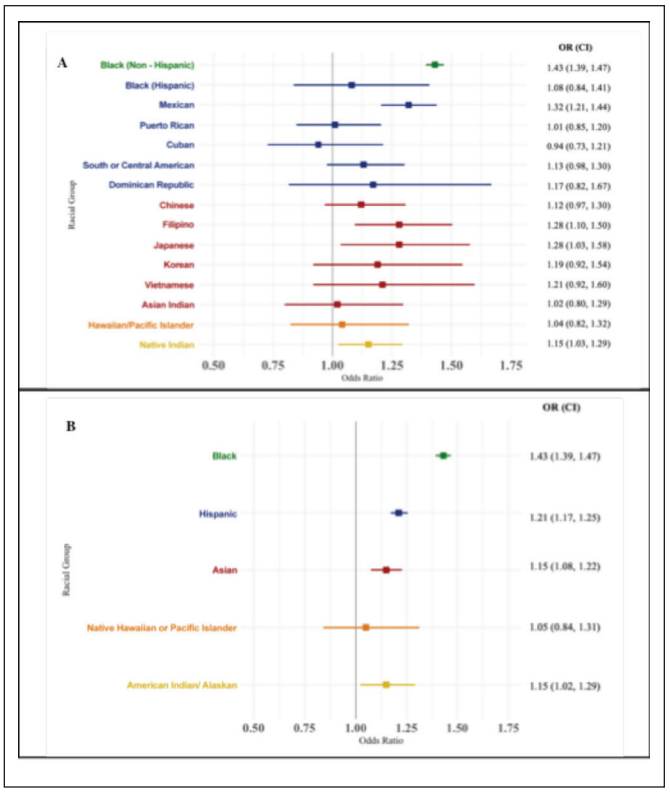
Abstract 48. Table 1. Characteristics of patients with newly diagnosed RMS

	Total (N=599, 100%)							Low-Risk (LR) (n=66, 11.02%)							Intermediate-Risk (IR) (n=433, 72.29%)							High-Risk (HR) (n=100, 16.69%)						
	Total (n=599, 100%)		Total GU (n=111, 18.53%)		Total Non-GU (n=488, 81.47%)		p-value	Total LR (n=66, 100%)		GU LR (n=29, 43.94%)		Non-GU LR(n=37, 56.06%)		p-value	Total IR (n=433, 100%)		GU IR (n=63, 14.55%)		Non-GU IR (n=370, 85.45%)		p-value	Total HR (n=100, 100%)		GU HR (n=19, 19.00%)		Non-GU HR (n=81, 81.00%)		p-value
	n	%/SE	n	%/SE	n	%/SE		n	%/SE	n	%/SE	n	%/SE		n	%/SE	n	%/SE	n	%/SE		n	%/SE	n	%/SE	n	%/SE	
Age, n (%)																												
< =9 y.o.	385	64.27	82	73.87	29	26.13	0.02	54	81.82	24	82.76	30	81.08	0.86	295	68.13	54	85.71	241	65.14	0.001	36	36.00	4	21.05	32	39.51	0.13
>9 y.o.	214	35.73	303	62.09	185	37.91		12	18.18	5	17.24	7	18.92		138	31.87	9	14.29	129	34.86		64	64.00	15	78.95	49	60.49	
Sex, n (%)																												
Male	309	51.59	65	58.56	46	41.44	0.10	22	33.33	5	17.24	17	45.95	0.01	199	45.96	17	26.98	182	49.19	0.001	47	47.00	5	26.32	14	73.68	0.045
Female	290	48.41	244	50.00	244	50		44	66.67	24	82.76	20	54.05		234	54.04	46	73.02	188	50.81		53	53.00	14	51.85	39	48.15	
Stage, n (%)																												
1	83	13.86	27	24.32	56	11.48	0.004	45	68.18	24	82.76	21	56.76	0.02	38	8.78	3	4.76	35	9.46	0.45	n/a	n/a	n/a	n/a	n/a	n/a	n/a
2	131	21.87	21	18.92	110	22.54		0	0.00	0	0.00	0	0.00		131	30.25	21	33.33	110	29.73		n/a	n/a	n/a	n/a	n/a	n/a	
3	285	47.58	44	39.64	241	49.39		21	31.82	5	17.24	16	43.24		264	60.97	39	61.90	225	60.81		n/a	n/a	n/a	n/a	n/a	n/a	
4	100	16.69	19	17.12	81	16.60		n/a	n/a	n/a	n/a	n/a	n/a		n/a	n/a	n/a	n/a	n/a	n/a		100	100.00	19	100.00	81	100.00	
Groups, n (%)																												
I	22	3.67	3	2.70	19	3.89	0.90	7	10.61	1	3.45	6	16.22	0.07	15	3.46	2	3.17	13	3.51	0.92	n/a	n/a	n/a	n/a	n/a	n/a	n/a
IIA, IIB	61	10.18	10	9.01	51	10.45		14	21.21	4	13.79	10	27.03		47	10.85	6	9.52	41	11.08		n/a	n/a	n/a	n/a	n/a	n/a	
III	416	69.45	79	71.17	337	69.06		45	68.18	24	82.76	21	56.76		371	85.68	55	87.30	316	85.41		n/a	n/a	n/a	n/a	n/a	n/a	
IV	100	16.69	19	17.12	81	16.60		n/a	n/a	n/a	n/a	n/a	n/a		n/a	n/a	n/a	n/a	n/a	n/a		100	100.00	19	100.00	81	100.00	
Histology subtypes, n (%)																												
ARMS	260	43.41	13	11.71	247	50.61	<0.001	n/a	n/a	n/a	n/a	n/a	n/a	<0.001	196	45.27	8	12.7	188	50.81	<0.001	64	64.00	5	26.32	14	73.68	<0.001
Botryoid	58	9.68	37	33.33	21	4.30		21	31.82	16	55.17	5	13.51		37	8.55	21	33.33	16	4.32		n/a	n/a	n/a	n/a	n/a	n/a	
Embryonal	260	43.41	59	53.15	201	41.19		38	57.58	13	44.83	25	67.57		186	42.96	32	50.79	154	41.62		36	36.00	14	72.84	22	27.16	
Spindle cell	21	3.51	2	1.80	19	3.89		7	10.61	0	0.00	7	18.92		14	3.23	2	3.17	12	3.24		n/a	n/a	n/a	n/a	n/a	n/a	
Event-free survival (EFS) time, mean (SE) in years	3.32	0.09	3.19	0.20	3.34	0.10	0.49	3.37	0.27	2.93	0.42	3.72	0.34	0.14	3.52	0.11	3.48	0.26	3.52	0.12	0.88	2.40	0.17	2.62	0.39	2.35	0.19	0.55
Overall survival (OS) time, mean (SE) in years	4.07	0.08	4.32	0.20	4.01	0.09	0.15	5.27	0.29	5.60	0.37	5.01	0.42	0.30	4.16	0.09	4.20	0.23	4.15	0.10	0.83	2.91	0.17	2.75	0.38	2.95	0.19	0.63

ARMS: alveolar rhabdomyosarcoma; CI: confidence interval; EFS: event-free survival; GU: genitourinary; OS: overall survival; RMS: rhabdomyosarcoma.



Abstract 49. Figure 1. Multivariable logistic regression analysis evaluating the association of race with the use of active surveillance for renal masses less than 2 cm. CI: confidence interval; OR: odds ratio.



Abstract 49. Figure 2. Multivariable logistic regression analysis evaluating the association of race with the use of radical nephrectomy for renal masses up to 4 cm. CI: confidence interval; OR: odds ratio.

Abstract 50

Comprehensive scoring system predicts guideline-based management of adrenal incidentalomas

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Introduction: The objective of this study is to develop a precision scoring system to aid in the management of adrenal masses. Treatment decisions were congruent with the most recent American Urological Association (AUA)-endorsed guideline for the management of incidental adrenal masses.

Methods: An adrenal risk stratification model was developed by allocating points based on Hounsfield units (HU) (0 or 10 points for tumors with <10 HU and >10 HU, respectively), functionality (0, T, or 80 points for non-functional, indeterminate, or functional lesions, respectively), size (0 or 10 points for tumors <4 cm or >4 cm, respectively), and characteristics of second-line testing (0, 20, 50, or 80 points for tumors with features on second-line imaging suggestive of benign, metastatic, other, or adrenocortical carcinoma lesions, respectively). Second-line imaging included computed tomography (CT) relative and absolute washout or chemical shift magnetic resonance imaging (MRI). Points were totaled to five mutually exclusive outcomes and multiplied by a factor denoted as "T" if ancillary tests were recommended.

Results: A total of 48 combinations of adrenal characteristics were accounted for in our scoring system. Ancillary tests were recommended in 33% of adrenal lesions with indeterminate functionality, leaving 32 incidentalomas for concordance testing. All functional (n=14) and malignant lesions on CT or MRI (n=10) scored 80 points or more, suggesting adrenalectomy as per the guideline. Benign, low-density, non-functional, <4 cm adenomas (n=1) scored 0 points indicating no further followup. Low-density, non-functional, >4 cm lesions (n=1) scored 10 points, indicating repeat CT in 6–12 months. Repeat imaging in 3–6 months vs. adrenalectomy was recommended for all high-density, small or large, equivocal non-functional lesions (n=5). Non-functional incidentalomas with either low or high density and features suggestive of suspected metastasis (n= 5) scored between 50–70 points, indicating possible biopsy or positron emission tomography (PET)/CT.

Conclusions: Our scoring system provides guideline-based recommendations for the management of adrenal incidentalomas. Further studies are required to validate this scoring system and assess its performance in various populations.

Funding: N/A

Abstract 51

A comparative analysis of Bard AI and ChatGPT for adherence to NCCN guidelines in urologic oncology

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Introduction: ChatGPT is an artificial intelligence (AI)-based chatbot developed by OpenAI. The success of ChatGPT also spurred the development of other AI-driven language models such as Google's Bard. Understandably, patients may be using such chatbots for health concerns and possible medical advice. Here, we compare the accuracy of ChatGPT and Bard in the management of five common urologic malignancies compared to National Comprehensive Cancer Network (NCCN) guidelines.

Methods: ChatGPT 3.5 and Bard were both accessed on July 1, 2023, and the management of five urologic malignancies were queried with standardized prompts asking, "What is the management of [urologic cancer]?" The cancers included non-muscle-invasive and muscle-invasive bladder cancer, prostate cancer, penile cancer, testicular cancer, and kidney cancer. For ChatGPT, each response was regenerated once to account for the stochasticity, or randomness, of each input. For Bard, draft 1 and draft 2 were used for each input to account for the differences in content between drafts. A board-certified urologic oncologist scored the therapies as a correct percentage based on the initial management or primary treatment categories of the 2023 NCCN guidelines.

Results: Bard was found to be more accurate than ChatGPT for four cancers: nonmetastatic muscle-invasive and non-muscle-invasive bladder cancer, prostate cancer, penile cancer, and kidney cancer. ChatGPT was slightly more accurate than Bard for the management of testicular cancer, with an average percent correct of 52.8% compared to Bard's 42.59%. In general, Bard had a higher percentage correct in 25 of the 34 cancer stages. The average percent correct for penile cancer with Bard was 96.9% and 55.1% with ChatGPT. However, the Fisher's exact test did not reveal statistical significance and had p-values ranging from 0.33 to 1.0.

Conclusions: In its current form, ChatGPT and Bard cannot accurately depict current cancer treatment guidelines. Bard was able to provide more accurate answers than ChatGPT, but this was not found to be statistically significant. This indicates that neither AI is superior to the other in their current form. Patients should use caution when using AI to search for management options for various urological cancers. Further research should be done to see if the chatbots improve in their answers over time. One limitation of our study is that ChatGPT's database only includes information up to September 2021, whereas current NCCN guidelines are from 2023. Regardless, patients may still be relying on the language models for medical information.

Funding: N/A

Abstract 52

Pelvic exenteration urologic complications: A 90-day audit of the practice at a single tertiary-level medical center

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Introduction: The management of locally advanced and/or recurrent pelvic malignancies has evolved significantly over the years, with improvements in neoadjuvant treatments and perioperative care. Yet, pelvic exenteration remains a highly morbid procedure. In this series, we sought to summarize recent outcomes with a urologic focus and to investigate which factors were associated with morbidity and survival.

Methods: We conducted a retrospective review of patients who underwent pelvic exenteration at a tertiary-level medical center from 2009 to 2022 and had a urinary diversion for an underlying malignancy. Patient demographics, comorbidities, neoadjuvant therapy, urinary diversion type (ileal/colonic), and surgical data were recorded. The primary end points included 90-day postoperative complication rates, hospital length of stay (LOS), intensive care unit (ICU) course, and survival rates.

Results: Thirty-nine patients met our inclusion criteria. Of the primary malignancies recorded, 38% (n=15) were urologic, 10% (n=4) gynecologic, 33% (n=13) colorectal, and 5% (n=2) soft tissue origin. The median patient age was 73 years. Twenty-three per cent (n=9) of patients had a history of diabetes and 77% (n=30) underwent neoadjuvant treatment. Seven (18%) had colonic/sigmoid urinary diversion, while 82% (n=31) had ileal urinary diversion. Twenty-eight per cent (n=11) of patients required a ventral rectus abdominus flap (VRAM) or gracilis flap; three were men. Thirty-eight per cent (n=15) experienced a major complication (Clavien-Dindo>=3). There were six patients who had a major cardiopulmonary/cerebrovascular event. Overall, 51% of patients died, with 26% dying within one year of surgery. Three patients required a laparotomy within 30 days, and two patients had *C. difficile* from long use of prophylactic antibiotics. Twenty-eight per cent (n=11) had urine leaks requiring either a nephrostomy tube placement or drain insertion. Ten per cent of patients (n=4) had urinary tract infections (UTIs) in the immediate postoperative period. While multivariate regression analysis did not demonstrate definitive risks, a history of diabetes correlated to higher Clavien-Dindo complication scores ($p<0.05$), and hospital LOS statistically correlated with body mass index (BMI) ($p<0.05$). History of neoadjuvant chemotherapy trended toward higher Clavien-Dindo scores, but was not statistically significant (5.75, $p=0.063$).

Conclusions: Pelvic exenteration remains a morbid procedure with the potential of cerebrovascular events and myocardial infarctions. Urologic complications predominate, often resulting in subsequent procedures. Consideration should be given to prolonged use of nephrostomy tubes.

Funding: N/A

Abstract 53

Utilization of alternate intravesical therapies in the management of non-muscle invasive bladder cancer during Bacillus Calmette-Guérin shortages: An interrupted time-series analysis

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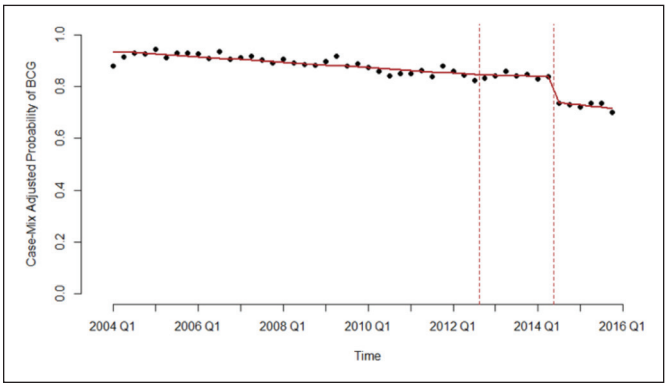
Introduction: Intravesical Bacillus Calmette-Guérin (BCG) is the mainstay of therapy for intermediate and high-risk non-muscle-invasive bladder cancer (NMIBC). Unfortunately, several factors have resulted in repeated shortages of this instrumental therapy over the last decade, resulting in the rise of alternative intravesical agents. We aim to evaluate the trends in the use of BCG versus non-BCG agents in the management of NMIBC during times of BCG shortage.

Methods: Using Medicare data from the Surveillance, Epidemiology and End Results (SEER) program, we conducted a retrospective study that includes patients diagnosed with NMIBC between 2005 and 2014 with followup claims through 2015. We grouped encounters into a BCG or non-BCG therapy group comprising of mitomycin, gemcitabine, docetaxel, valrubicin, thiotepa and agents not otherwise specified. We used Bayesian logistic regression with random effects to predict quarterly, case-mix adjusted probabilities of BCG treatment. We adjusted for age, sex, race, marital status, education, population, urban residence, income, region, comorbidities, and tumor grade. We used an interrupted time series for these case-mix adjusted probabilities to examine trends before and during shortages.

Results: We identified 23 869 patients, 18 002 of whom received any BCG treatment during the study period. Compared to patients who never received BCG, those who did were more likely to reside in the Northeastern and Western USA, and had fewer comorbidities and more aggressive pathology (Table 1, $p<0.05$). Following the first known BCG shortage in 2012, the case-mix adjusted probability of BCG treatment was unchanged. Immediately following the second known BCG shortage in 2014, the case-mix adjusted probability of BCG decreased by 0.097 ($p<0.05$), with a sustained trend that remained constant (Figure 1).

Conclusions: The use of intravesical BCG compared to non-BCG agents in the management of NMIBC remained consistent after the first known BCG shortage in 2012 and decreased slightly after the second known BCG shortage in 2014. Further investigation is warranted to assess the impact of this on oncologic outcomes and disease progression.

Funding: Tippins Foundation Scholar Award, Urology Care Foundation 2019 Research Scholar Award



Abstract 53. Figure 1. Interrupted time series for case-mix adjusted probability of BCG. BCG: Bacillus Calmette-Guérin.

Abstract 53. Table 1. Patient demographics

	Ever BCG N=18 002 (%)	Never BCG N=5867 (%)	p
Age at diagnosis, years			<0.0001
66–69	2687 (14.9)	787 (13.4)	
70–74	4470 (24.8)	1205 (20.5)	
75–79	4535 (25.2)	1343 (22.9)	
80+	6310 (35.1)	2532 (43.2)	
Sex			0.0897
Male	14 001 (77.8)	4625 (78.8)	
Female	4001 (22.2)	1242 (21.2)	
Race			0.0292
White	16 585 (92.1)	5388 (91.9)	
Black	615 (3.4)	242 (4.1)	
Hispanic	174 (1.0)	59 (1.0)	
Other	628 (3.5)	178 (3.0)	
Region			<0.0001
Northeast	4920 (27.3)	1354 (23.1)	
South	4167 (23.2)	1241 (21.2)	
Central	2247 (12.5)	894 (15.2)	
West	6668 (37.0)	2378 (40.5)	
Charlson Comorbidity Index			<0.0001
0	8473 (47.1)	2456 (41.8)	
1	4806 (26.7)	1518 (25.9)	
2	2403 (13.3)	839 (14.3)	
3 or more	2320 (12.9)	1054 (18.0)	
Tumor grade			<0.0001
Well differentiated	1590 (8.8)	1037 (17.7)	
Moderately differentiated	3737 (20.8)	1930 (32.9)	
Poorly differentiated/undifferentiated	9337 (51.9)	1795 (30.6)	
Unknown	3338 (18.5)	1105 (18.8)	

BCG: Bacillus Calmette-Guérin.

Abstract 54

MoonRISe-1: Phase 3 study of TAR-210, an erdafitinib intravesical delivery system, vs. intravesical chemotherapy in intermediate-risk non-muscle-invasive bladder cancer patients with susceptible FGFR alterations

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Introduction: Despite available treatment options for patients with intermediate-risk non-muscle-invasive bladder cancer (IR NMIBC), recurrence rates remain high, underscoring the need for new therapies. TAR-210 is a novel intravesical targeted releasing system designed to provide sustained local delivery of erdafitinib (selective pan-FGFR tyrosine kinase inhibitor) within the bladder while limiting systemic toxicities. MoonRISe-1 (NCT06319820) is an open-label, multicenter, randomized phase 3 study evaluating the efficacy and safety of TAR-210 vs. investigator's choice of intravesical chemotherapy (mitomycin C [MMC] or gemcitabine [gem]) in patients with IR NMIBC with susceptible FGFR alterations (FGFRalt).

Methods: Eligible patients are aged ≥18 years with histologically confirmed Ta low-grade (LG)/G1 (recurrent or primary with either multifocal or tumor ≥3 cm) or Ta LG/G2 (primary/recurrent) IR NMIBC diagnosed ≤90 days of randomization with ≥1 of the following risk factors: multiple Ta LG tumors, tumor >3 cm, early (≤1 year) recurrence, frequent (>1/year) recurrences, or recurrence after intravesical chemotherapy received >6 months prior. Patients have tumors with susceptible FGFR2/3alt (mutation/fusion) identified by tissue testing from transurethral resection of bladder tumor (TURBT) or urine cell-free DNA testing. All visible papillary tumor must be fully resected prior to randomization and treatment start. Intravesical Bacillus Calmette-Guérin (BCG) >2 years before enrollment is allowed. Patients will be stratified based on intravesical chemotherapy (MMC vs. gem), disease status (newly diagnosed vs. recurrent), and cystoscopic assessment method (white light vs. enhanced assessment). Patients (N=540) were randomized 1:1 to receive TAR-210 Q12W for 1 year or intravesical chemotherapy (MMC or gem) weekly for 4–6 induction doses followed by maintenance therapy for 6 months to 1 year. Assessments of recurrence/progression include urine cytology, cystoscopy, biopsy/TURBT of bladder lesions, ultrasound, and urography. The primary end point is disease-free survival (DFS), defined as time from randomization to first documented recurrence of any-grade NMIBC, disease progression, or death from any cause, whichever occurs first. Key secondary end points are time to next-line treatment, high grade recurrence-free survival, progression-free survival, rate of diagnostic and therapeutic urological interventions, and safety and tolerability. The study will assess whether TAR-210 will result in longer DFS vs. IVES chemotherapy in this population. Enrollment is expected to open by April 30, 2024.

Funding: Janssen Research Development

Abstract 55

TAR-200 in patients with Bacillus Calmette-Guérin-unresponsive high-risk non-muscle-invasive bladder cancer: Results from SunRISe-1 study

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Introduction: Patients with Bacillus Calmette-Guérin (BCG)-unresponsive high-risk non-muscle-invasive bladder cancer (HR NMIBC) are at high risk of disease progression and have limited bladder-sparing treatment options. TAR-200, an intravesical targeted releasing system, is designed to provide sustained delivery of gemcitabine in the bladder over three weeks. SunRISe-1 (NCT04640623) is an ongoing, randomized, phase 2b study assessing efficacy and safety of TAR-200 + cetrelimab (anti-PD1) (Cohort 1 [C1]), TAR-200 alone (C2), or cetrelimab alone (C3) in patients with BCG-unresponsive HR NMIBC with carcinoma in situ (CIS), with or without papillary disease, who are ineligible for or refusing radical cystectomy. As of Amendment 4, TAR-200 alone is also being assessed in patients with papillary disease only (C4). We report results from C2.

Methods: Eligible patients aged ≥18 years had histologically confirmed CIS ± papillary disease (high-grade Ta, any T1) after adequate BCG, with last dose of BCG ≤12 months prior to CIS diagnosis, and ECOG performance status 0–2. TAR-200 was dosed every three weeks through week 24, then every 12 weeks until week 96. Response was assessed by cystoscopy and centrally assessed urine cytology, CT/MRI, and bladder biopsy (at weeks 24, 48, and as clinically indicated). The primary end point was overall complete response (CR) rate. Secondary end points included duration of response (DOR), overall survival, safety, and tolerability.

Results: At data cutoff (January 2, 2024), 85 patients (median age: 71 years; range: 40–88; 33% with concurrent papillary disease) received TAR-200 monotherapy. Fifty-eight patients were efficacy evaluable. Centrally confirmed CR rate was 83% (95% CI, 71–91) by urine cytology and/or biopsy. The estimated one-year DOR rate is 75% (95% CI 50–88), with median followup in responders of 30 weeks (range: 14–140); 41 of 48 responders (85%) remain in CR at data cutoff. Forty-seven of 48 (98%) CRs were achieved at first disease assessment (week 12). CR rate by investigator assessment (86%; 95% CI, 75–94) correlated strongly with central results. Sixty-one patients (72%) had treatment-related adverse events (TRAEs); the most common (≥10%) were pollakiuria (35%), dysuria (29%), micturition urgency (15%), and urinary tract infection (15%). Seven patients (8%) had grade ≥3 TRAEs, four (5%) had serious TRAEs, and four (5%) had TRAEs leading to discontinuation. No treatment-related deaths were reported.

Conclusions: In SunRISe-1, TAR-200 monotherapy is associated with a clinically meaningful, high, centrally confirmed CR rate, durable responses, and a favorable benefit-risk profile in patients with BCG-unresponsive CIS.

Funding: Janssen Research Development

Abstract 56

First safety and efficacy results of the TAR-210 erdafitinib intravesical delivery system in patients with non-muscle-invasive bladder cancer with select *FGFR* alterations

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Introduction: Treatment options are limited in non-muscle-invasive bladder cancer (NMIBC) that recurs after intravesical chemotherapy or Bacillus Calmette-Guérin (BCG). TAR-210 is a novel intravesical targeted releasing system designed to provide local, sustained delivery of erdafitinib (selective pan-FGFR tyrosine kinase inhibitor) within the bladder while limiting systemic toxicities. This open-label, multicenter phase 1 study (NCT05316155) evaluated the safety, pharmacokinetics (PK), and efficacy of TAR-210 in patients with NMIBC whose tumors harbor select FGFRalt.

Methods: FGFRalt were identified in tumor tissue or urine cell-free DNA. Cohort 1 (C1) patients had recurrent, BCG-experienced high-risk NMIBC (high-grade Ta/T1; papillary only) and refused or were ineligible for radical cystectomy. Cohort 3 (C3) patients had recurrent, intermediate-risk NMIBC (Ta/T1) with history of only low-grade papillary disease. Before treatment, C1 patients must have all visible disease resected; C3 requires the presence of visible tumors. TAR-210 systems with two different erdafitinib release rates were evaluated. Response is assessed every three months with continued treatment for up to one year if recurrence-free (RF) (C1) or in complete response (CR) (C3).

Results: As of August 29, 2023, 16 patients in C1 and 27 patients in C3 have been treated; 11 and 15 patients, respectively, had ≥1 response assessment. Eighty-two per cent in C1 were RF; 87% in C3 achieved CR (Table 1). Most common treatment-related adverse events (TRAE) were grade 1/2 lower urinary tract TRAEs. There were no dose-limiting toxicities. No deaths were reported. Two patients discontinued due to TRAEs of low-grade urinary symptoms, and one patient had serious TRAEs of pyelonephritis and sepsis. Pharmacokinetic (PK) data showed sustained erdafitinib concentrations in urine with very low plasma exposures. Initial results are reported; updated data (≈47 response evaluable patients) will be included in the presentation.

Conclusions: TAR-210 appears safe and well tolerated with predominantly low-grade urinary system TRAEs and high CR rate and RF survival in patients with NMIBC with FGFRalt. Results justify further study of targeted treatment of erdafitinib using a novel intravesical delivery system in early-stage bladder cancer.

Funding: Janssen Research Development

Abstract 56. Table 1. Efficacy outcomes and treatment exposure

Cohort 1 (n=11 with response assessment)	
RF, n (%)	9 (81.8)
Median RFS (95% CI), mo	NE (2.96-NE)
Cohort 3 (n=15 with response assessment)	
CR, n (%)	13 (86.7)
Median duration of CR (95% CI), mo*	NE (NE-NE)
Both Cohorts (n=43 all-treated)	
Median duration of treatment exposure (range), mo	3.7 (0-12)
Total duration of treatment, n (%)	
≥0-<3 mo	18 (41.9)
≥3-<6 mo	13 (30.2)
≥6-<9 mo	6 (14.0)
≥9-<12 mo	5 (11.6)
≥12 mo	1 (2.3)

CI: confidence interval; CR: complete response; NE: non-estimable; RF: recurrence-free; RFS: recurrence-free survival.

Abstract 57

KCRNC consensus statement impact on renal mass biopsy in a community hospital system in Ontario

Maximiliano Ringa[1], Maria Azab[2], Parker McNabb[2], Ceilidh Matthews[2], Jethro CC Kwong[3,4], Amna Ali[1], Andrew Feifer[1,3,5]

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Introduction: Renal mass biopsy (RMB) is an important diagnostic tool to guide the management of small renal masses (SRM). We aim to analyze the impact of the Kidney Cancer Research Network of Canada (KCRNC) consensus statement on RMB (1) in a community hospital setting.

Methods: A retrospective chart review and analysis was conducted at Trillium Health Partners of patients referred for SRM suspicious for renal cell carcinoma (RCC) between May 2016 and April 2023. Demographic data, clinical and disease characteristics, biopsy (yes/no), and extirpative pathology were collected. Continuous variables were reported as medians (interquartile range [IQR]) and categorical variables were described with proportions. The patient characteristics with a RMB diagnosis before and after KCRNC statement were compared and contrasted using the Wilcoxon rank-sum test for continuous variables and the chi-square test for proportions.

Results: The cohort includes 502 patients with localized RCC with a median followup of 2.4 years. Of these, 152 (30%) patients had a RMB. Biopsy was diagnostic and non-diagnostic in 131 cases (86%) and 21 cases (14%) respectively. Among diagnostic biopsies, 126 (95%) were malignant. Histologic subtyping and grading of RCC was possible in 83% and 48% of cases, respectively. After biopsy, 133 (88%) patients had surgery, of which 88 (66%) had partial and 45 (34%) radical nephrectomy. The final pathology concordance was 99% (107/108) for biopsies with malignant pathology and 100% for benign biopsy results (4/4 oncocytoma and 1/1 angiomyolipoma) undergoing surgery. All non-diagnostic biopsies having surgery had a final malignant pathology (20/20). When comparing biopsy and treatment patterns before and after KCRNC consensus statement, we found a significant increase in overall (25% vs. 36%, p=0.011) and SRM (30% vs. 44%, p=0.021) biopsy rates. There was no significant reduction in surgical management rates for SRM with improved RMB rates (98% vs. 93%, p=0.302) (Table 1).

Conclusions: We found a significant increase in the utilization of RMB for the diagnosis and management of SRM in our patient population. The results may be partially attributed to the KCRNC consensus statement implementation. These results are encouraging and support further implementation of guideline-based practices.

Funding: N/A

Abstract 57. Table 1. Patient characteristics and treatment patterns

	Total	KCRNC Consensus Statement		
		Before	After	
	n= 502	n= 258 (51%)	n= 244 (49%)	
Age, y (IQR)				p=0.261
	61 (53–69)	60 (53–69)	63 (53–70)	
Followup, y (IQR)				p<0.001
	2.4 (1.2–4.1)	4 (2.8–5.1)	1.4 (0.7–2)	
Gender, n (%)				p=0.729
Female	167 (33)	84 (33)	83 (34)	
Male	335 (67)	174 (67)	161 (66)	
Clinical stage, n (%)				p=0.426
T1a	257 (51)	133 (52)	124 (51)	
T1b	130 (26)	71 (28)	59 (24)	
T2a	40 (8)	21 (8)	19 (8)	
T2b	28 (6)	15 (6)	13 (5)	
T3	47 (9)	18 (7)	29 (12)	
Kidney biopsy, n (%)	152 (30)	65 (25)	87 (36)	p=0.011
T1a	95 (37)	40 (30)	55 (44)	
T1b	41 (32)	18 (25)	23 (39)	
T2a	8 (20)	5 (23)	3 (15)	
T2b	3 (11)	1 (7)	2 (15)	
T3	5 (3)	1 (6)	4 (14)	
Kidney biopsy pathology, n (%)				p=0.337
Benign	6 (4)	4 (6)	2 (2)	
Malignant	125 (82)	54 (83)	71 (82)	
Non-diagnostic	21 (14)	7 (11)	14 (16)	
Nephrectomy after biopsy, n (%)	133 (88)	59 (91)	74 (85)	p=0.292
T1a	90 (94)	39 (98)	51 (93)	
T1b	35 (85)	16 (89)	19 (83)	
T2a	4 (50)	2 (40)	2 (67)	
T2b	1 (33)	1 (100)	-	
T3	5 (100)	1 (100)	2 (50)	

IQR: interquartile range; KCRNC: Kidney Cancer Research Network of Canada.

Abstract 58

Survival analysis of metastatic renal cell carcinoma patients treated with combination therapy: Results from a community hospital in Ontario

Maximiliano Ringa[1], Parker McNabb[2], Ceilidh Matthews[2], Maria Azab[2], Jethro CC Kwong[3,4], Amna Ali[1], Andrew Feifer[1,3,5]

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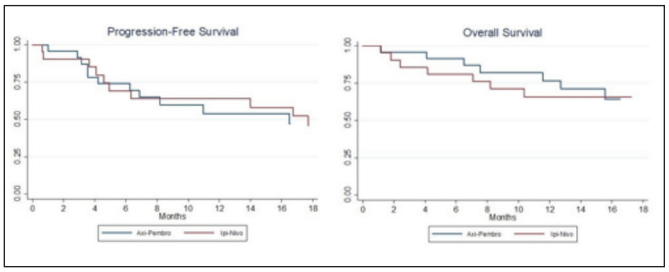
Introduction: Combination therapies such as axitinib-pembrolizumab (Axi-Pembro) and ipilumab-nivolumab (Ipi-Nivo) have emerged as the standard of care (SOC) for patients with metastatic renal cell carcinoma (mRCC). In Canada, there is limited published data showing patient outcomes with these systemic treatments, and the existing literature solely focuses on outcomes in academic centers. We aim to analyze treatment outcomes of patients with mRCC being treated with Axi-Pembro or Ipi-Nivo at Trillium Health Partners (THP), a large tertiary care community-based hospital in Ontario.

Methods: A retrospective chart review of 51 patients with mRCC being treated with Axi-Pembro or Ipi-Nivo as first-line therapy between 2018–2023 was conducted. Data was abstracted into the Canadian Kidney Cancer Information System (CKCis) database. Epidemiologic data, International Metastatic RCC Database Consortium (IMDC) prognostic risk, and treatment information were collected. Time-to-event to assess for overall survival (OS) and progression-free survival (PFS) was performed using Kaplan-Meier analysis. The findings were compared to the published randomized controlled trials of each therapy regimen.

Results: Demographic and clinical data can be found in Table 1. Median followup was 19.6 months. Median PFS was 16.5 months for Axi-Pembro and 17.7 months for Ipi-Nivo. Median OS was not reached in any of the groups. The 12-month OS rate was 73%, 79%, and 67% for all cohorts, Axi-Pembro, and Ipi-Nivo, respectively. Figure 1 demonstrates the Kaplan-Meier PFS and OS curves. Grade 3 or higher adverse events occurred in 31% of patients, with 69% of these in the Axi-Pembro group.

Conclusions: PFS was consistent with published data. The OS rate was slightly lower than reported results in the literature. This can be explained by a proportionally greater number of IMDC poor prognostic patients in our population. Our real-world outcomes validate reported data and demonstrated the generalizability, reproducibility, and effectiveness of these treatment options within the community setting.

Funding: N/A



Abstract 58. Figure 1. Progression-free survival and overall survival.

Abstract 58. Table 1. Baseline demographic and clinical characteristics

	Total n=51	Axitinib + pembrolizumab n=28	Ipilimumab + nivolumab n=23
Age			
Median (range)	68 (46–83)	67 (49–83)	68 (46–75)
<65 y – n (%)	22 (43)	12 (43)	10 (43)
Male sex – n (%)	40 (78)	21 (75)	19 (83)
IMDC prognostic risk – n (%)			
Favorable	10 (20)	7 (25)	3 (13)
Intermediate	20 (39)	10 (36)	10 (43.5)
Poor	21 (41)	11 (39)	10 (43.5)
Sarcomatoid features – n/ total known status (%)	3/21 (14)	1/11 (9)	2/10 (20)
No. of organs with metastases – n (%)			
1	17 (33)	11 (39)	6 (26)
≥2	34 (67)	17 (61)	17 (74)
Most common sites of metastasis – n (%)			
Lung	33 (65)	18 (64)	15 (65)
Lymph node	14 (27)	8 (29)	6 (26)
Bone	12 (24)	6 (21)	6 (26)
Adrenal gland	6 (12)	4 (14)	2 (9)
Liver	3 (6)	1 (4)	2 (8)
Previous treatment			
Radiotherapy – n (%)	16 (31)	10 (36)	6 (26)
Nephrectomy – n (%)	18 (38)	9 (35)	9 (41)

IMDC: International Metastatic RCC Database Consortium.

Abstract 59

Comparison of percutaneous cryoablation vs. microwave ablation of small renal masses in a large community hospital setting

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Introduction: Percutaneous needle ablation of small renal masses has become widely accepted in the treatment of confirmed or presumed renal cell carcinoma. Few studies have compared the efficacy of microwave needle ablation (MA) to more widely accepted cryoablation (CA) with regard to long-term oncologic outcomes. The primary aim of our study was to compare MA and CA with regard to technique-specific odds of residual tumor after primary treatment, delayed in field recurrence after treatment, and risk of developing post-treatment metastases. The secondary aim of our study was to compare outcome variables such as complications and the impact of tumor size, polar location, and endophytic/exophytic status on the primary outcome measures noted above.

Methods: We conducted a retrospective cohort study comparing the above-mentioned outcome measures for CA vs. MA. All treatments were performed in a community hospital setting jointly with an interventional radiologist and a urologist on the treatment team. Patient demographics and tumor characteristics for both treatment groups were analyzed for significant differences utilizing T-tests, χ^2 analyses and proportion testing. Logistic regression modeling of procedure type against outcomes of interest was performed to calculate odds-ratios for each outcome. Followup time was a known bias prior to analysis; thus, a time-to-event analysis was conducted using a Kaplan-Meier curve as well as a log-rank test.
Results: The two treatment groups were similar with respect to patient demographics, tumor size, laterality, location, and endophytic/exophytic status. Median followup time for CA was 54.3 months. A total of 119 patients underwent CA; of which 13 had residual tumor(s), 18 developed recurrent tumor(s), and nine developed distant metastases. Median followup time for MA was 28.2 months. Seventy-one patients underwent MA; of which two had residual tumor(s), seven developed recurrent tumor(s), and three developed distant metastases. Using logistic models, we found no difference in odds of disease recurrence [95% CI (-2.17, 0.15), p=0.27], odds of residual tumor [CI (-3.67, 0.05), p=-0.22), or odds of developing metastatic disease [CI (-1.54, 0.73), p=2.11], with respect to both treatment modalities. Followup time did not impact the odds of disease recurrence, as a time-to-event analysis resulted in no significant findings (p=0.3).
Conclusions: CA and MA offer similar cancer-specific outcomes in terms of risk of residual, recurrent, and metastatic disease in the management of small renal masses.
Funding: N/A

Abstract 60 – WITHDRAWN

Abstract 61

Applying single cell RNA sequencing of sarcomatoid renal cell carcinoma for the development of a novel transcriptomic biomarker to predict immunotherapy response

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Introduction: Renal cell carcinoma with sarcomatoid features (sRCC) is a unique kidney cancer subtype associated with aggressive biology and poor clinical outcomes. Intriguingly, sRCC has recently exhibited preferential responsiveness to immune checkpoint blockade (ICB) therapies. Therefore, we applied transcriptomic techniques to identify features encapsulating this paradoxical hyper-aggression and ICB-responsiveness to identify patients most likely to benefit from ICB in RCC.
Methods: Nephrectomy specimens from patients with RCC underwent single-cell RNA sequencing (scRNAseq). Clustering was performed and annotated tumor cells were computationally isolated. Tumor cell counts were aggregated and differential expression between sRCC and non-sRCC cases was performed. Genes significantly upregulated in sRCC were next filtered against differential gene expression data of sRCC vs. non-sRCC from three clinical RCC datasets to identify genes enriched in sRCC across scRNAseq and bulk RNA sequencing. The prognostic and predictive features of this gene signature were then assessed in cohorts of patients with RCC receiving ICB.
Results: In total, 73 123 unique cells from 18 RCC patients (10 sRCC, 8 clear cell RCC) were analyzed by scRNAseq, including 5386 tumor cells. Differential gene expression of tumor clones revealed 20 genes significantly enriched for in sRCC relative to ccRCC. Filtering against public differential gene expression resulted in 10 genes included within the final sarcomatoid signature (SS). SS expression scores for clinical specimens were calculated by single-sample gene set enrichment analysis. SS scores were significantly enriched in sRCC patient tumors across TCGA KIRC, IMmotion151, and CheckMate datasets (p<0.001 for all cohorts). Within TCGA KIRC, SS scores were significantly increased in patients with nuclear grade 4 (p<0.001) and metastatic (p<0.001) disease, while stratification by median SS score revealed worsened overall (HR=2.19, p<0.001) and disease-free (HR=2.08, p<0.001) survival among SS-high patients. In the IMmotion151 trial, SS-high patients experienced reduced progression-free survival (PFS) duration (HR=1.39, p<0.001), irrespective of treatment arm. However, SS-high patients experienced improved response rates with the ICB-containing atezolizumab/bevacizumab regimen compared to sunitinib (p<0.001) and rela-

tive to SS-low patients receiving atezolizumab/bevacizumab (p=0.028). Within the SS-high population, patients experienced prolonged PFS with atezolizumab/bevacizumab (HR=0.70, p=0.003) relative to sunitinib, whereas no PFS difference between arms was seen in the SS-low population (HR=1.01, p>0.99).
Conclusions: This novel SS derived from scRNAseq demonstrates negative prognostic yet positive predictive value for ICB response. In a domain currently void of efficacious biomarkers, the SS, upon prospective validation, may assist in optimal therapy selection for patients with RCC.
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Abstract 62

Artificial intelligence modeling for prediction of renal cancer recurrence: A systematic review

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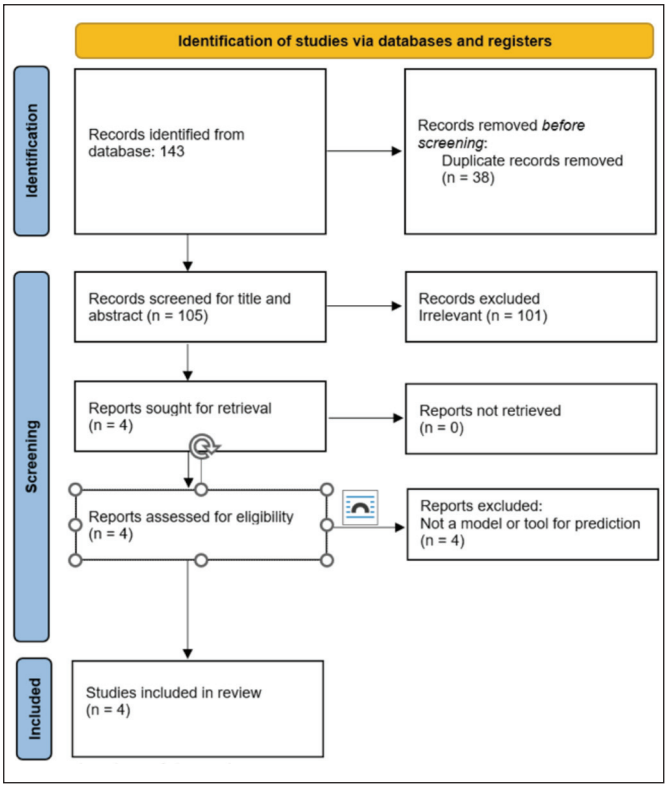
Introduction: This systematic review aims to provide an overview of artificial intelligence (AI) techniques for predicting renal cancer recurrence.
Methods: This review included searching for published studies from inception until January 2023 from Cochrane Central Register, PubMed, EMBASE, ProQuest, Scopus, and Google Scholar. Search terms included "renal cancer" OR "renal cell carcinoma" OR "kidney cancer" AND "artificial intelligence" OR "machine learning". We considered all studies that used machine learning-based analysis to predict renal cancer recurrence. Non-English articles and those unrelated to the topic were excluded. The PROBAST tool was used to evaluate the risk of bias and the applicability of each included study.
Results: The search strategy yielded 143 citations; 105 full-text articles were evaluated for eligibility after the screening. Four studies were included in this review. Based on the risk of bias assessment, three studies had a low risk of bias and one had low to moderate risk. Ten distinct models were chosen as machine learning algorithms (range 2–8 per study). From the four studies, 13 unique variables, including age, gender, smoking, body mass index (BMI), pathological tumor stage, histologic type, necrosis, lymphovascular invasion, capsular invasion, Fuhrman grade, operation type (radical or partial nephrectomy), operation method (laparoscopic or open), and tumor size were chosen as candidate predictors to train the model. Naïve Bayes, Decision Tree, AdaBoost, and Random Forest were among the best models to predict renal cancer recurrence. All four studies used the area under the curve (AUC) to report the accuracy. The AUC of machine learning models varied from 0.740–0.877 in four studies.
Conclusions: The results of AI models for predicting renal cancer recurrence are promising. AI has the potential to aid in a wide range of clinical domains in the urology setting, and researchers should continue to investigate its vast potential.
Funding: N/A



Abstract 62. Figure 1. Flowchart of the study.

Abstract 63

Efficacy of intravesical nadofaragene firadenovec-vncg for patients with Bacillus Calmette-Guérin-unresponsive non-muscle-invasive bladder cancer: 36-month followup from a phase 3 trial

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Introduction: Local bladder-preserving treatment options are needed for patients with Bacillus Calmette-Guérin (BCG)-unresponsive non-muscle-invasive bladder cancer (NMIBC). Nadofaragene firadenovec-vncg, a non-replicating adenovirus vector-based gene therapy, is approved by the US Food and Drug Administration for patients with BCG-unresponsive NMIBC with carcinoma in situ (CIS) with/without papillary tumors (±Ta/T1). The primary end point of the open-label, multicenter, phase 3 study (NCT02773849) of nadofaragene firadenovec was met, as 53.4% (95% confidence interval [CI]: 43.3, 63.3) of patients with CIS ±Ta/T1 achieved complete response (CR) at three months. Thirty-six-month followup results of this study are reported here.
Methods: Patients with BCG-unresponsive NMIBC (N=157) were enrolled; 107 and 50 patients were in the CIS ±Ta/T1 (CIS) and Ta/T1 without CIS (papillary disease [PD]) cohorts, respectively. Efficacy analysis included 103 and 48 patients in the CIS and PD cohorts, respectively, who met the protocol definition of BCG-unresponsive NMIBC. Patients received nadofaragene firadenovec once every three months with cystoscopy and cytology assessments. Biopsies were taken at 12 months and patients who remained high-grade recurrence-free (HGRF) were offered continued treatment at the investigator's discretion.
Results: All patients completed the 36-month visit or discontinued by September 9, 2021. The mean (standard deviation) duration of followup was 42.6 (12.2) months; 13/107 (12.1%) and 10/50 (20.0%) patients in the CIS and PD cohorts received nadofaragene firadenovec at month 36, respectively. Among patients with CIS who achieved CR at three months, 14/55 (25.5%) remained HGRF at 36 months. Eleven patients with PD (22.9%) were HGRF at 36 months. Four patients with CIS (3.9%) and one patient with PD (2.1%) experienced progression to muscle-invasive disease documented by transurethral resection of bladder tumor

Abstract 62. Table 1. Summary of findings of included studies

Author	Country	Data source	Prediction time	Type of ML	Findings		
					Best ML performance	Accuracy	Features used to train the model
Kim et al	Republic of Korea	Dataset of 6849 patients with renal cancer	5–10 Years after surgery	SVM LR DT KNN NB EGBM AdaBoost GB	NB	AUC: 0.84 for models of recurrence within 5 years AUC: 0.79 for models of recurrence within 10 years	Age BMI Gender Smoking Pathological tumor stage Histologic type Necrosis Lymphovascular invasion Capsular invasion Fuhrman grade
Guo et al	Canada	Dataset of 697 patients with renal cancer	Not mentioned	DT Neural network	DT	AUC: 0.87	Age Gender Tumor laterality Radical or partial nephrectomy Pathological tumor stage Margin status Fuhrman grade
Kim et al	Republic of Korea	Dataset of 2956 patients with renal cancer	5 years after surgery	SVM LR DT KNN NB EGBM AdaBoost GB	AdaBoost	AUC: 0.740 Sensitivity: 0.673 Specificity: 0.807 Accuracy: 0.799	Operation type Operative method Pathological tumor stage Pathological node stage Histologic type Lymphovascular invasion Tumor size
Khene et al	France	Dataset of 4067 patients with renal cancer	57 months	SVM RF EGBM	RF	AUC: 0.794	Pathological tumor stage Pathological node stage Fuhrman grade

AUC: area under curve; BT: boosted tree; DT: decision tree; DL: deep learning; EGBM: extreme gradient boosting model; GB: gradient boost; KNN: K nearest neighbor; LR: logistic regression; ML: machine learning; NB: naïve Bayes; SP: support vector; SVM: kernel support vector machine; RF: Random Forest.

at the time of high-grade recurrence as collected in the electronic case report form; 54 patients (35.8%) in total underwent cystectomy. The Kaplan-Meier-estimated cystectomy-free survival rate at month 36 was 53.8% (95% CI: [43.3, 63.1]) and 63.6% (95% CI: [48.0, 75.6]) in the CIS and PD cohorts, respectively. Two patients with CIS (1.9%) and one patient with PD (2%) discontinued treatment due to an adverse event.

Conclusions: Intravesical nadofaragene firadenovec, administered once every three months, demonstrated a durable response in patients with BCG-unresponsive CIS ±Ta/T1 and high-grade BCG-unresponsive papillary NMIBC. Nadofaragene firadenovec is a novel and safe intravesical treatment option for BCG-unresponsive NMIBC.

Funding: Ferring Pharmaceuticals

Abstract 64

Real-world treatments following Bacillus Calmette-Guérin induction in patients with non-muscle-invasive bladder cancer: A contemporary US claims analysis

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Introduction: There has been a recent surge in clinical trials focused on patients who have recurrent disease of their non-muscle-invasive bladder cancer (NMIBC) after Bacillus Calmette-Guérin (BCG). Due to ongoing BCG shortages and access to alternative agents, the true number of patients who are receiving BCG induction is unclear. Herein, we evaluated this question and elucidated alternative treatment agents that patients received among a contemporary US insurance claims database.

Methods: From the Komodo Health claims database (January 2018–March 2023) with Medicare Advantage, Medicaid, Managed Medicaid, and commercially insured patients, we identified patients with NMIBC using the following algorithm: a) presence of carcinoma in situ (CIS), or b) presence of bladder cancer ((BCa) and transurethral resection of bladder tumor, followed by intravesical chemotherapy or immunotherapy or 12 months with no treatment and no evidence of muscle-invasive BCa. Patients were further queried to identify those who received adequate BCG induction (i.e., ≥5 weekly instillations). We summarized the distribution of this group and the treatments following BCG induction with ≥12 months of evaluable data for the overall population and the CIS subgroup.

Results: Of 7058 patients with NMIBC receiving BCG, more than half (4478, 63.4%) had adequate BCG induction; of these patients, 3206 had ≥12-month data (including 28.8% patients with CIS). Following adequate BCG induction, 49.3% had further BCG and 24.9% had ≥2 doses of maintenance BCG; 38.4% had no further treatment, and 12.3% (394 patients) were treated with other therapies, including gemcitabine (26.6%), radical cystectomy or exenteration (21.6%), mitomycin C (19.0%), BCG + interferon-α (10.9%), radiotherapy (7.4%), and pembrolizumab (4.8%). A similar distribution was observed in the CIS subgroup, though BCG + interferon-α was the third most common treatment (Table 1).

Conclusions: In this analysis, we found that more than half of patients with NMIBC treated with BCG received adequate BCG induction, but only one-

quarter received maintenance BCG. Among patients who received other therapies after induction, gemcitabine, radical cystectomy or exenteration, and mitomycin C were the most commonly used. These patterns have implications not only for patient care, but especially for clinical trial design and enrollment.

Funding: Ferring Pharmaceuticals Inc.

Abstract 64. Table 1. Real-world treatments after adequate BCG induction

	Overall N=3206	CIS subgroup N=922
Additional BCG treatment	1580 (49.3)	478 (51.8)
No further treatment with additional BCG or alternative therapies[a]	1232 (38.4)	298 (32.3)
Treatment with another therapy (percentages are based on the total number of patients treated with another therapy)	394 (12.3)	146 (15.8)
Gemcitabine	105 (26.6)	38 (26.0)
Radical cystectomy or exenteration	85 (21.6)	31 (21.2)
Mitomycin C	75 (19.0)	17 (11.6)
Combo BCG therapies: BCG + interferon-α	43 (10.9)	23 (15.8)
Radiotherapy	29 (7.4)	9 (6.2)
Pembrolizumab	19 (4.8)	10 (6.8)
Sequential gemcitabine/docetaxel	16 (4.1)	7 (4.8)
Combo BCG therapies: BCG + other therapies (excluding interferon-α)	10 (2.5)	4 (2.7)
Valrubicin	6 (1.5)	4 (2.7)
Other combination treatments	3 (0.8)	2 (1.4)
Sequential gemcitabine/mitomycin	2 (0.5)	1 (0.7)
Interferon-α	1 (0.3)	0 (0.0)

aNo further treatment refers to the absence of any of the other treatments listed here. Among patients without further treatment, 472 patients (38.3%) underwent TURBT after BCG induction. BCG, Bacillus Calmette-Guérin; CIS, carcinoma in situ; TURBT, transurethral resection of bladder tumor.

Abstract 65

Oncological outcomes for T1 and T2 kidney tumors upstaged to T3a on pathology: A 20-year retrospective review from a single institution

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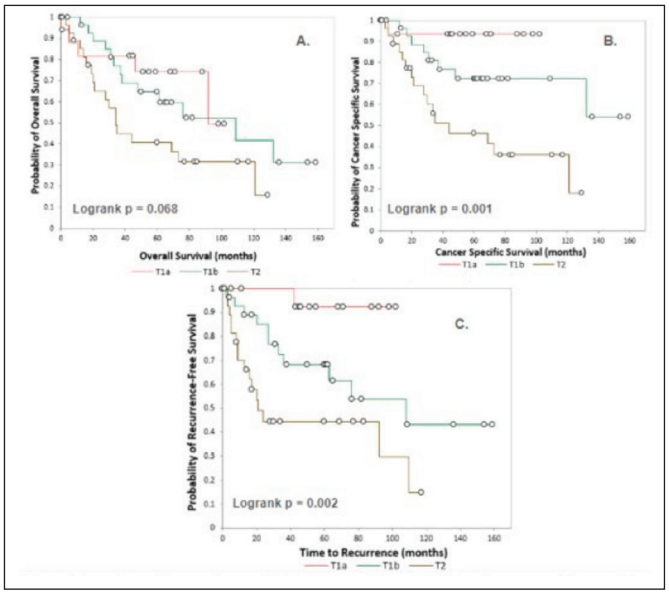
Introduction: There is a paucity of data on oncological outcomes for T1 and T2 renal cell carcinoma (RCC) tumors upstaged to T3a on final pathology. We will describe oncological outcomes of clinical T1 and T2 RCC, re-classified to T3a upon pathological examination from 20 years of retrospective followup at our institution.

Methods: A retrospective review was conducted of patients who underwent partial (PN) or radical nephrectomies (RN) between January 1998 and December 2018 whose RCC was upstaged to T3a on final pathology. Patients' clinical and pathological demographics were correlated. Local recurrence and survival analyses were performed using Kaplan-Meier and Cox regression analyses stratified by T staging.

Results: We identified 81 clinical T1 and T2 tumors whose RCC was upstaged to T3a on final pathology. Twenty-two (26.8%), 46 (54.8 %), 1 (1.21%) and 12 (14.6%), underwent robotic PN, robotic RN, open PN, and open RN, respectively. Median followup was 43 months. Table 1 contains demographic and clinical information for our cohort. Upon multivariate analysis, recurrence was found to be significant for overall mortality (HR 1.8, 95% CI 1.8–19.7, p=0.003). Additionally, tumor size (HR 1.17, 95% CI 1.03–1.33, p=0.01) and T stage (HR 1.81, 95% CI 1.14–2.86, p=0.01) were significant for recurrence on univariate analysis. Figure 1 demonstrates Kaplan-Meier curves for recurrence, overall, and cancer-specific mortality (CSM). Kaplan-Meier analysis indicates that T staging has strong significance for CSM (p=0.001). Pathology subtype, marginal status, sarcomatoid features, age at recurrence, and type of surgery were not significant for recurrence or mortality. Patients with recurrence had a mean time to death of 38 months after surgery. Similarly, mean time to death after surgery was 55 months for those without recurrence.

Conclusions: T1 and T2 RCC tumors upstaged to T3a on pathology is significant for recurrence (p=0.002) and CSM (p=0.001), yet not significant for overall mortality. Due to earlier recurrence for clinical T1b and T2 tumors and the impact of T staging on CSM, it may be beneficial to treat unique cases of upgraded T stages as T3a tumors, independent of tumor size. More data is needed to hold this hypothesis.

Funding: N/A



Abstract 65. Figure 1. Log-rank tests for A) overall survival, B) cancer-specific survival, and C) recurrence across T stagings after surgery.

Abstract 65. Table 1. Age at surgery, mass size, marginal status, sarcomatoid features, recurrence, time to recurrence, age at recurrence, and mortality categorized by T stage

	Age at surgery (years)	Mean tumor size (cm)	Positive margins	Sarcomatoid features	Recurrence	Time to recurrence (months)	Age at recurrence (years)	Overall mortality (% cohort died)	Cancer-specific mortality (% of overall mortality)	Time to death from surgery ± SD (months)
T1a	62.9±13.7	3.51±0.95	1/17 (0.06)	0 (0)	1/17 (0.06)	42	64	5/17 (0.29)	1/17 (0.06)	38.5±59.5
T1b	66.6±8.5	5.7±1.2	5/31 (0.16)	3/31 (0.10)	11/31 (0.35)	37.5±32.2	72.1±7.0	13/31 (0.42)	8/31 (0.26)	56.2±37.6
T2a	60.5±7.4	8.8±1.8	2/14 (0.14)	1/14 (0.07)	7/14 (0.5)	28.7±36.3	62.3±8.6	8/14 (0.57)	7/14 (0.5)	47.7±27.4
T2b	64.5±11.8	10.0±3.5	3/19 (0.16)	1/19 (0.05)	9/19 (0.47)	17.4±28.7	63.4±12.4	10/19 (0.53)	9/19 (0.47)	33.3±40.2
All	64.2±10.5	6.7±3.1	11/81 (0.14)	5/81 (0.06)	28/81 (0.35)	29.0±31.6	66.6±10.1	36/81 (0.44)	25/81 (0.31)	44.7±38.9

SD: standard deviation.

Abstract 66 – WITHDRAWN

Abstract 67 – WITHDRAWN

Abstract 68

Factors that define the poor outcomes for Black Americans with bladder cancer: Does treatment type contribute?

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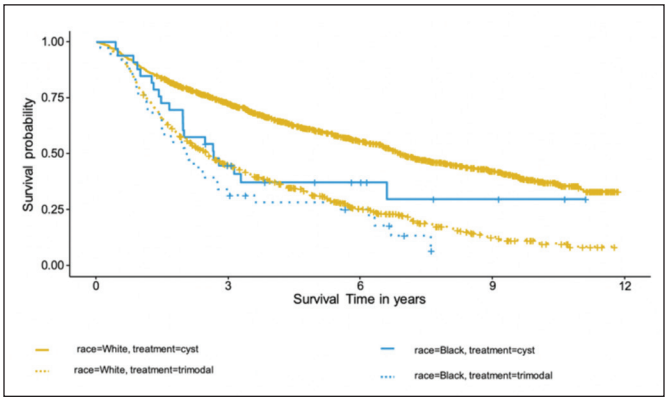
Introduction: Black patients diagnosed with bladder cancer have been found to have worse outcomes than their White counterparts, despite having a lower incidence of disease. Prior studies have elucidated factors contributing to the disparity in outcomes: stage at presentation, access to care, and treatment decision-making. Treatment type (i.e., radical cystectomy or trimodal therapy) is another factor that may contribute to worse outcomes in Black patients. The primary objective of our analysis was to further explore potential racial disparities between these two groups by investigating patients' survival based on treatment types.

Methods: We studied 2120 bladder cancer patients diagnosed between 2008 and 2017 from the SEER-Medicare database, focusing exclusively on White and Black patients who were treated with either cystectomy or trimodal therapy. Survival disparities among patients across different racial groups were assessed using Kaplan-Meier survival curves. Additionally, Cox proportional hazards regression analyses were employed to determine hazard ratios (HRs) and corresponding 95% confidence intervals (CIs) for the relationship between race and mortality, while adjusting for key risk factors including treatment modality, tumor stage, age, comorbidity score, and marital status.

Results: Based on the Kaplan-Meier curves, the survival probability consistently favored the White group over the Black group in both the overall cohort and when stratified by treatment type. Notably, even within treatment categories, cystectomy consistently exhibited superior survival outcomes compared to trimodal therapy. After adjusting for pertinent risk factors including treatment modality, tumor stage, age, comorbidity score, and marital status, Black patients exhibited a 1.3 increased risk of death (95% CI: 1.1–1.7) compared to White patients. Moreover, tumor stage emerged as a significant predictor of mortality, with patients classified as T3/T4 exhibiting 1.6 times hazard of death (95% CI: 1.4–1.8) compared to those with T2 tumors.

Conclusions: Black patients were found to have worse overall survival from bladder cancer regardless of treatment type. Black patients treated with a radical cystectomy survived slightly longer than their White counterparts who received trimodal therapy. Our study re-demonstrated Black patients' worse outcomes for bladder cancer treatment. There continues to be a difference in treatment outcomes and future studies should tease out the contributing factors with aims of developing interventions.

Funding: N/A



Abstract 68. Figure 1. Survival curve by race and treatment.