A Real-World Evidence Study Assessing the Prevalence and Prognostic Value of *FGFR* Alterations in Patients With Intermediate-Risk Non–Muscle-Invasive Bladder Cancer

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Presented by Meeks J at American Urological Association (AUA) Annual Meeting 2026; May 15-18, 2026; Washington, DC, USA

Disclosures

- Dr Meeks has received honoraria from Astellas Pharma, AstraZeneca, Imvax, Incyte, Janssen, Merck, Pfizer, Prokarium, and UroGen Pharma; research funding from Epizyme and Merck Sharp & Dohme; has patents, royalties, or other intellectual property (institutional) related to NMIBC classifier and TCGA classifier; and has a relationship (undefined) with Olympus

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Unmet Need in Intermediate- and High-Risk NMIBC and Knowledge Gaps Regarding *FGFR* alterations

- NMIBC comprises 75% of new bladder cancer diagnoses[1,2]
- Clinicopathologic features (eg, tumor grade, stage, size, multiplicity and recurrence history) are routinely used to stratify NMIBC into low risk, intermediate risk (IR) and high risk (HR) disease by risk of recurrence and progression and to guide clinical management[3,4]
- *FGFR3* alterations (*FGFRalt*) may function as oncogenic drivers in NMIBC[5]; however, their prevalence and prognostic significance across NMIBC risk categories remain incompletely characterized

Study Objective:

- To characterize the prevalence of *FGFRalt* and their association with recurrence-free survival (RFS) across EAU risk groups and tumor grades using a real-world clinical and multi-omics NMIBC dataset

EAU, European Association of Urology; FGFR, fibroblast growth factor receptor; NMIBC, non–muscle-invasive bladder cancer.

1. Grabe-Heyne, et al. *Front Oncol*. 2023;13:1170124. 2. EAU Guidelines. Edn. presented at the EAU Annual Congress Madrid 2025. ISBN 978-94-92671-29-5. 2025. 3. Babjuk M, et al. *Eur Urol*. 2022;81:75-94.
4. Ritch CR, et al. *J Urol.* 2020;203:505-511. 5. Knowles MA, et al. *Nat Rev Cancer*. 2015;15:25-41.

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Methods: Analysis of *FGFRalt* status and RFS across EAU risk stratification groups in UROMOL dataset

>2500 patients in UROMOL cohort[1,2]

- Pan-European (10 centers) dataset with clinical characteristics, molecular data, and survival outcomes

323 patients with primary or recurrent NMIBC met inclusion criteria

- No prior diagnosis of MIBC
- Data available from 2008 to 2012
- Available ***FGFRalt* status** (*FGFRalt* or *FGFR* WT) and **RFS outcomes**

21 patients excluded due to missing EAU risk stratification

302 patients with EAU risk stratification were included in the analysis[3]

FGFRalt status

- Defined as 4 *FGFR3* point mutations (R248C, *S249C*, G370C, Y373C)
- Detected by whole-exome sequencing

RFS (Primary Outcome):

- ***Outcome:*** Measured from the time of surgery for the tumor analyzed to time of the recurrence event
- ***RFS follow-up:*** Registered online from each center, censored at most recent cystoscopy and included recurrence and/or progression evaluation
- ***Recurrence events:*** As captured in UROMOL data[a]

Statistics

- ***FGFRalt prevalence:*** Descriptive statistics
- ***Propensity score weighting:*** To adjust for potential confounders in comparing *FGFRalt* vs WT groups
- ***RFS estimates:*** Kaplan-Meier method[b]
- ***Effect estimates:*** Cox proportional-hazards model[b,c] to estimate hazard ratios and 95% CIs from
- ***Statistical tests:*** Log-rank test[c] to determine P values

EAU, European Association of Urology; RFS, recurrence-free survival; WT, wildtype.

[a]10 patients with missing RFS data (LR NMIBC, n=1; IR NMIBC, n= 3; HR NMIBC, n=6) were censored on Day 1.

[b]Used propensity score weighting. [c]Model with *FGFRalt* status as the only explanatory variable was used. A hazard ratio greater than 1 indicates shorter RFS in the *FGFRalt* group as compared to the *FGFR* WT group.

1. Lindskrog SV, et al. *Nat Commun*. 2021;12:2301. 2. Prip F, et al. *Nat Genet*. 2025;57:115-125. 3. Babjuk M, et al. *Eur Urol*. 2022;81:75-94.

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Demographics and disease characteristics by *FGFRalt* status

- Overall, 56.0% of patients with NMIBC had *FGFRalts*

Characteristic	*FGFR* WT (n=133)	*FGFRalt* (n=169)	P-value[a]
Median age, years (range)	69 (48-94)	68 (33-92)	0.83
Sex, n (%)			
Male	107 (80.5)	131 (77.5)	0.57
Female	26 (19.5)	38 (22.5)	
Smoking status, n (%)			
Never	19 (14.3)	19 (11.2)	
Former	44 (33.1)	59 (34.9)	0.73
Current	51 (38.3)	63 (37.3)	
Missing	19 (14.3)	28 (16.6)	
Tumor grade, n (%)			
Low	63 (47.4)	117 (69.2)	1.5×10^{-4}
High	70 (52.6)	52 (30.8)	
Tumor stage, n (%)			
Ta	83 (62.4)	143 (84.6)	2.4×10^{-5}
T1	48 (36.1)	25 (14.8)	
CIS only	2 (1.5)	1 (0.6)	
Concomitant CIS, n (%)[b]			
Yes	25 (18.8)	15 (8.9)	0.016
No	108 (81.2)	154 (91.1)	

Characteristic	*FGFR* WT (n=133)	*FGFRalt* (n=169)	P-value[a]
Incident tumor, n (%)			
Yes	76 (57.1)	88 (52.1)	0.42
No	57 (42.9)	81 (47.9)	
Growth pattern, n (%)			
Papillary	123 (92.5)	160 (94.7)	
Solid	2 (1.5)	2 (1.2)	0.77
Mixed	3 (2.3)	2 (1.2)	
Not available	5 (3.8)	5 (3.0)	
Tumor size			
<3 cm	89 (66.9)	115 (68.0)	0.54
>3 cm	27 (20.3)	28 (16.6)	
Not available	17 (12.8)	26 (15.4)	
EAU risk			
Low	19 (14.3)	30 (17.8)	3.7×10^{-4}
Intermediate	28 (21.1)	67 (39.6)	
High	86 (64.7)	72 (42.6)	
EORTC risk			
Low	64 (48.1)	121 (71.6)	4.8×10^{-5}
High	69 (51.9)	48 (28.4)	

BCG, bacillus Calmette-Guérin; EORTC, European Organisation for Research and Treatment of Cancer.
[a]Nominal p-value for categorical variables were based on Fisher's test; p-value for age was based on Wilcoxon rank sum test; missing/not available values were not included in the test.
[b]CIS diagnosis at any time in the disease course. [c]BCG treatment at any time during the disease course.

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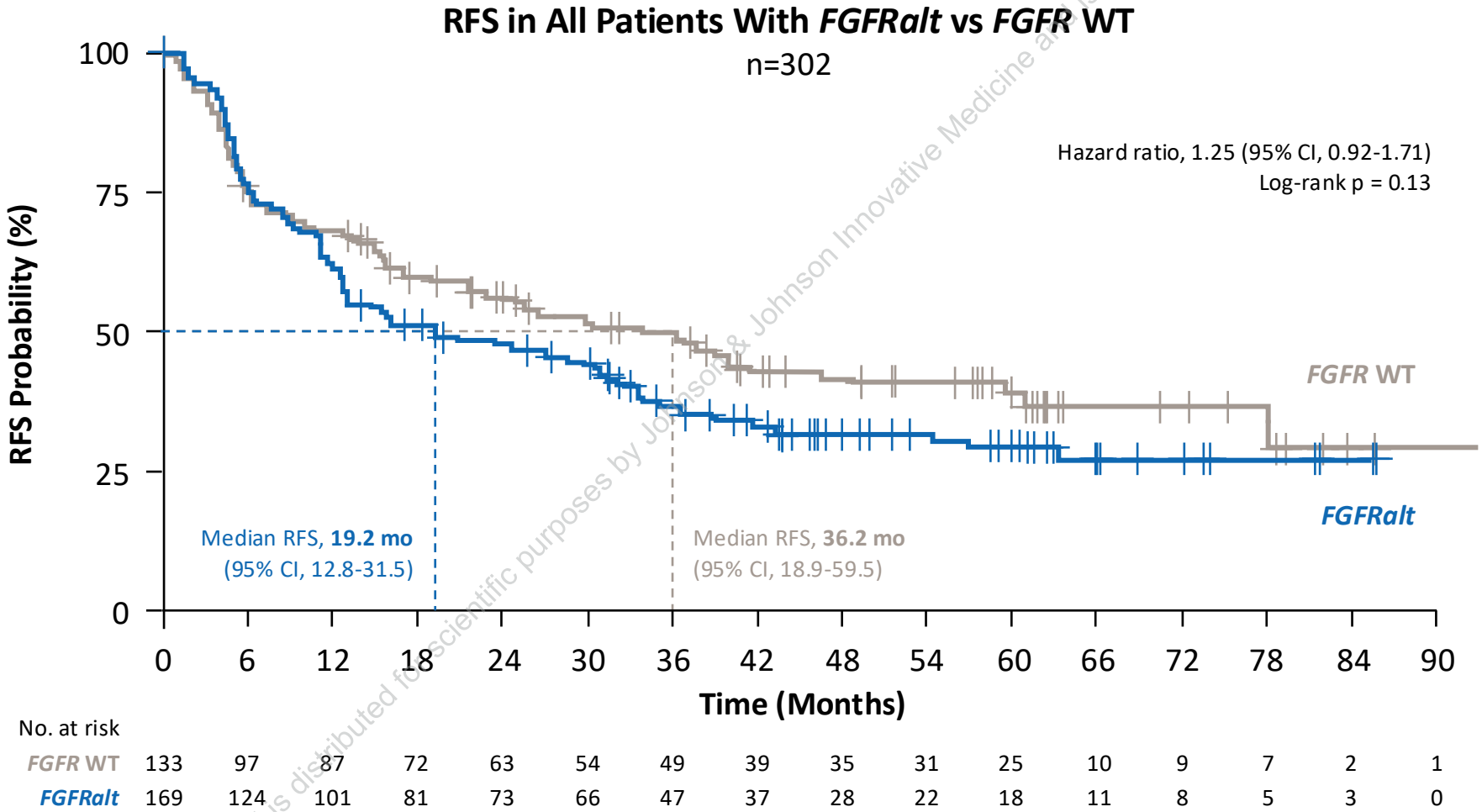
No significant difference in RFS was seen between patients with NMIBC with *FGFRalt* vs *FGFR* WT



Propensity score weighting adjusted for incident tumor (yes/no), tumor stage, tumor grade, sex, and age.

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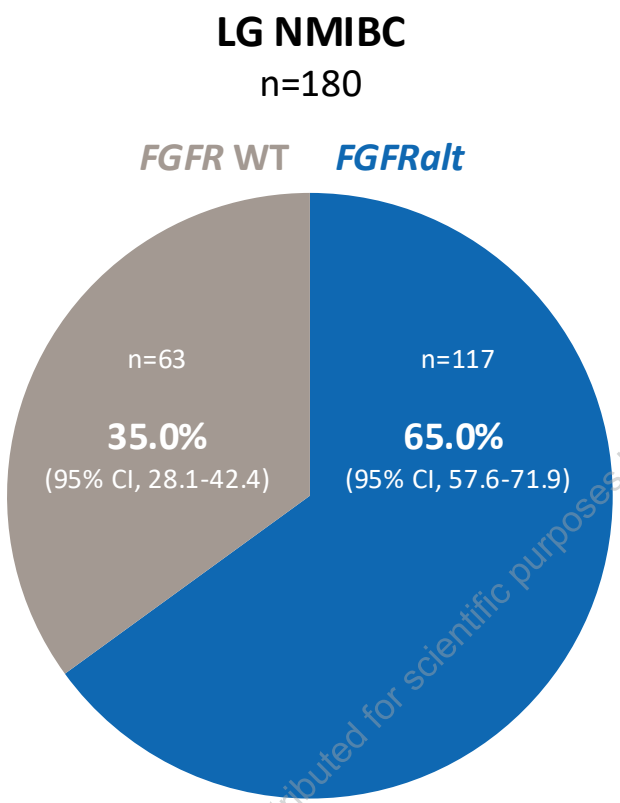
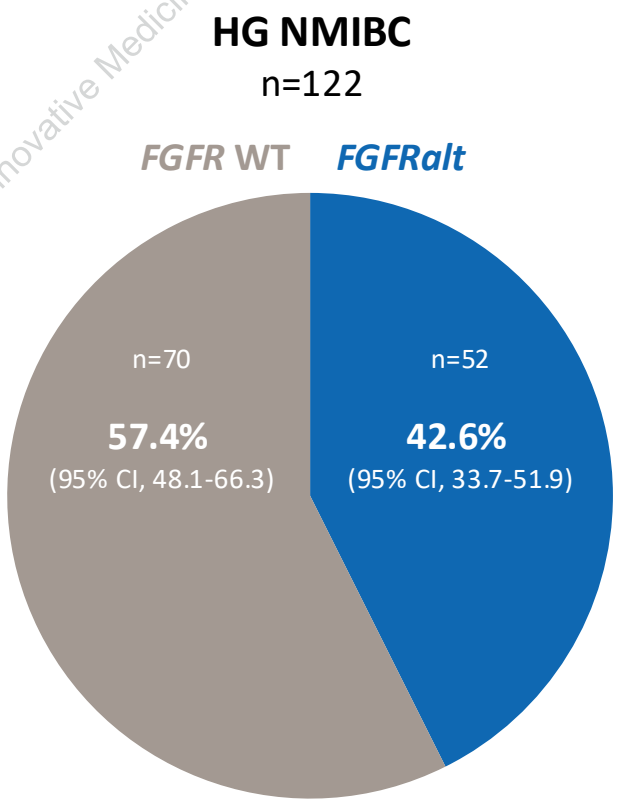
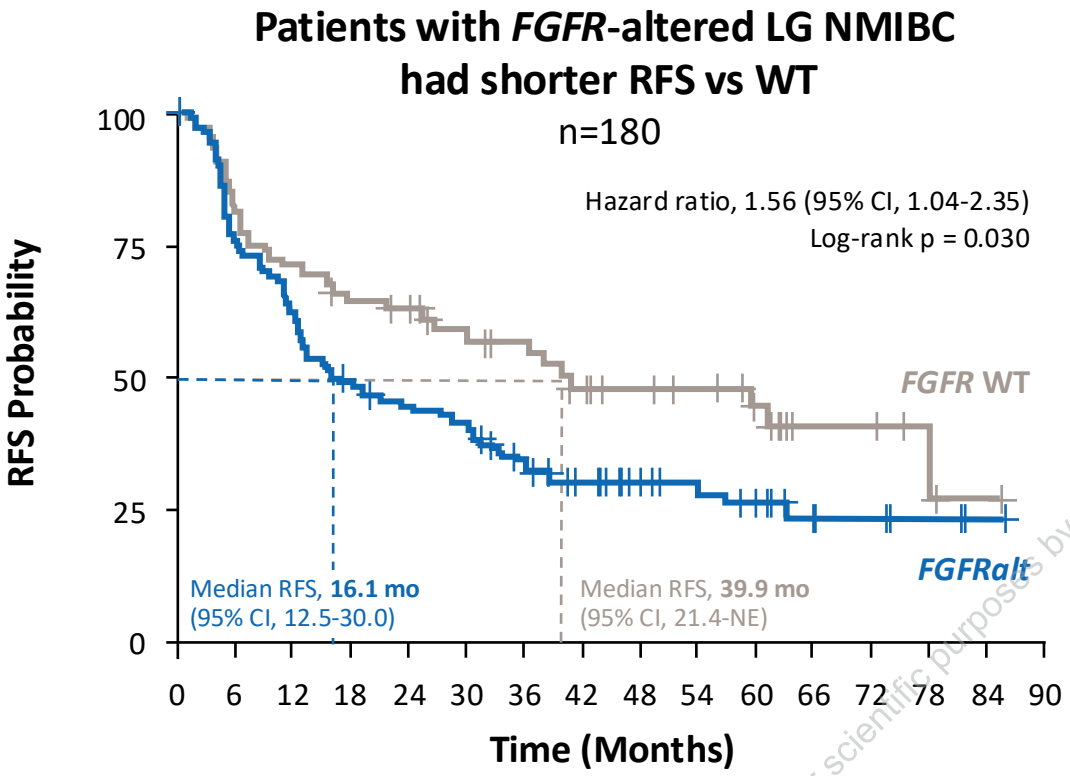
Prevalence of *FGFR* alterations by tumor grade





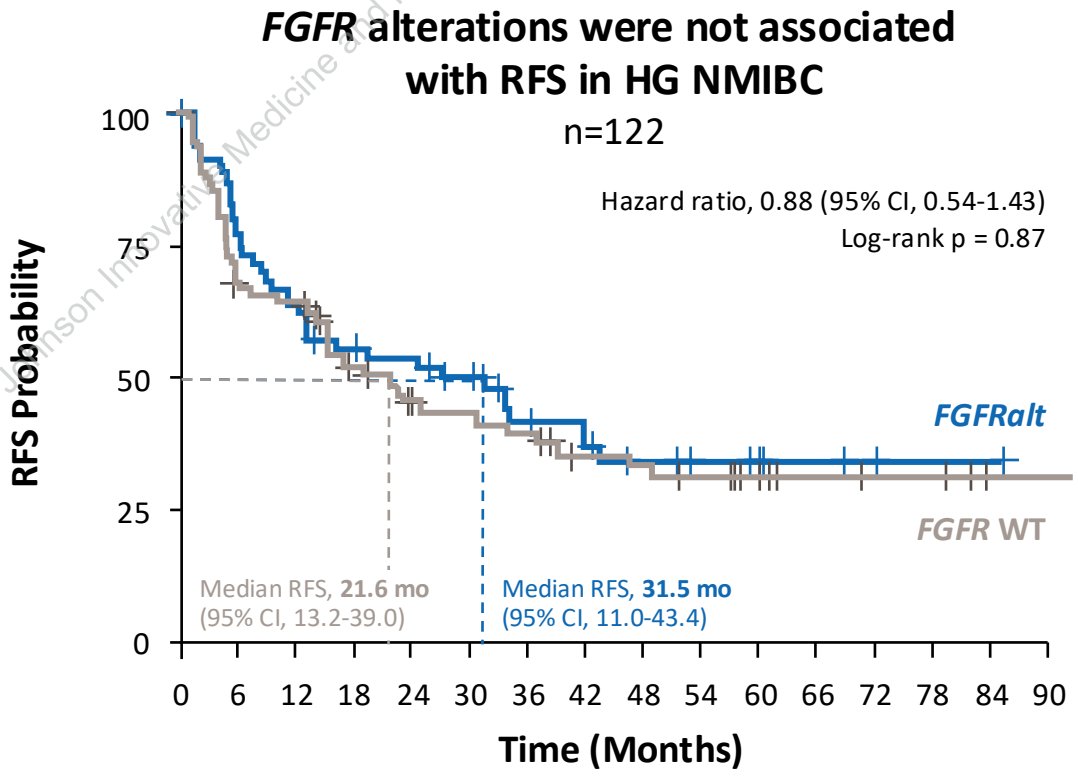
HG, high-grade; LG, low-grade.

RFS outcomes vary by *FGFR* status in patients with LG NMIBC vs HG NMIBC



No. at risk

FGFR WT	63	50	44	39	36	29	27	22	19	17	14	5	5	3	1	0
FGFRalt	117	84	69	29	48	45	33	25	19	16	13	8	5	3	1	0



No. at risk

FGFR WT	70	44	42	30	24	22	20	15	14	13	10	4	4	4	1	1
FGFRalt	52	39	32	27	25	21	14	12	9	6	5	3	2	2	2	0

Propensity score weighting adjusted for incident tumor (yes/no), tumor stage, sex, and age.

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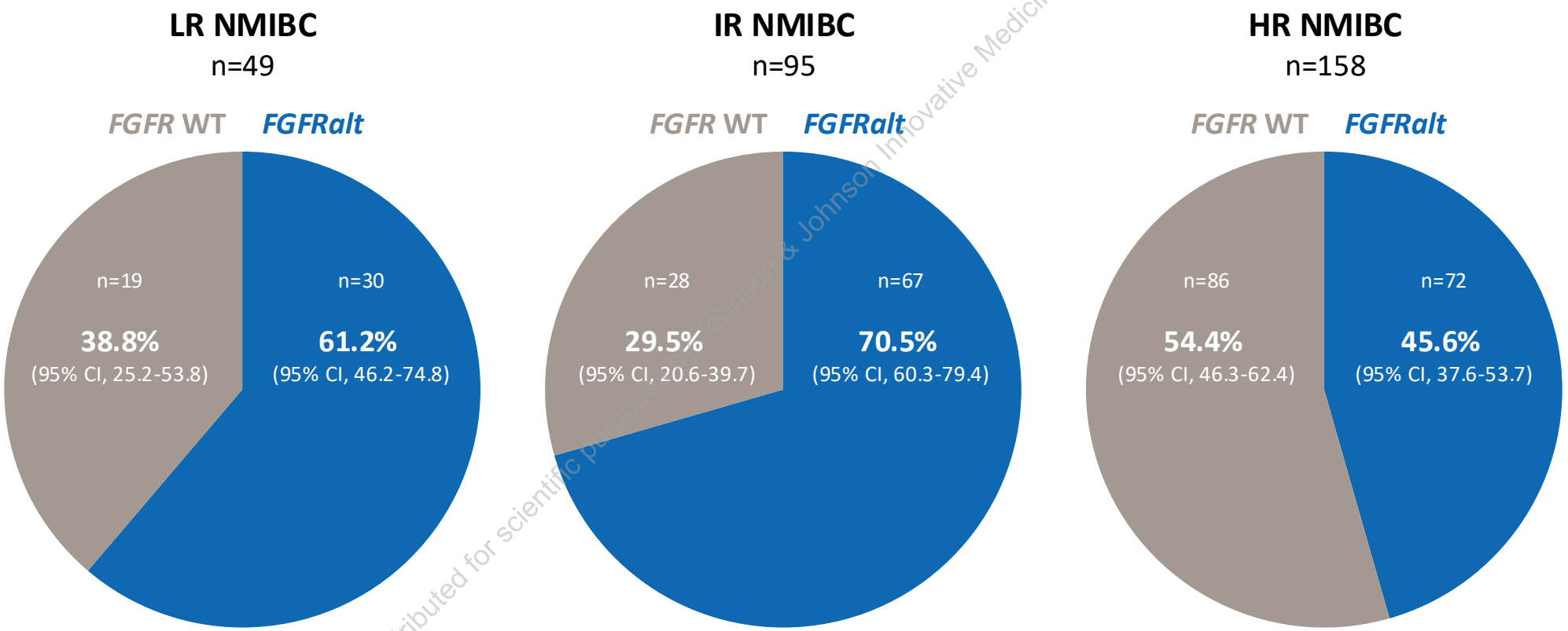
Prevalence of *FGFR* alterations by EAU risk category



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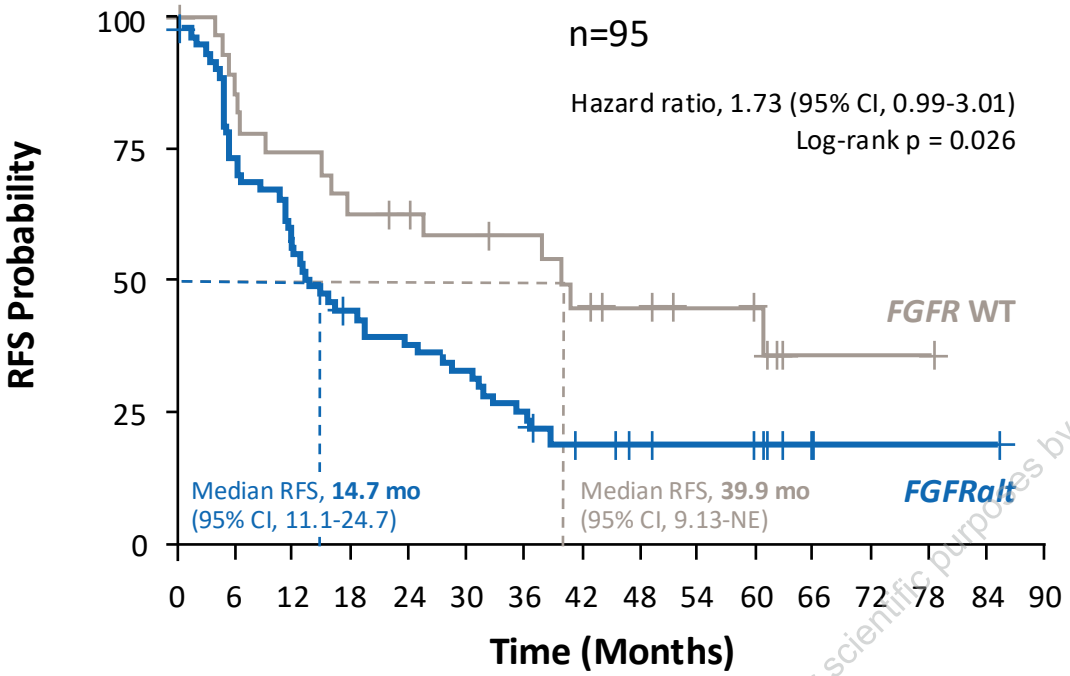
RFS outcomes vary by *FGFR* status in patients with IR NMIBC vs HR NMIBC

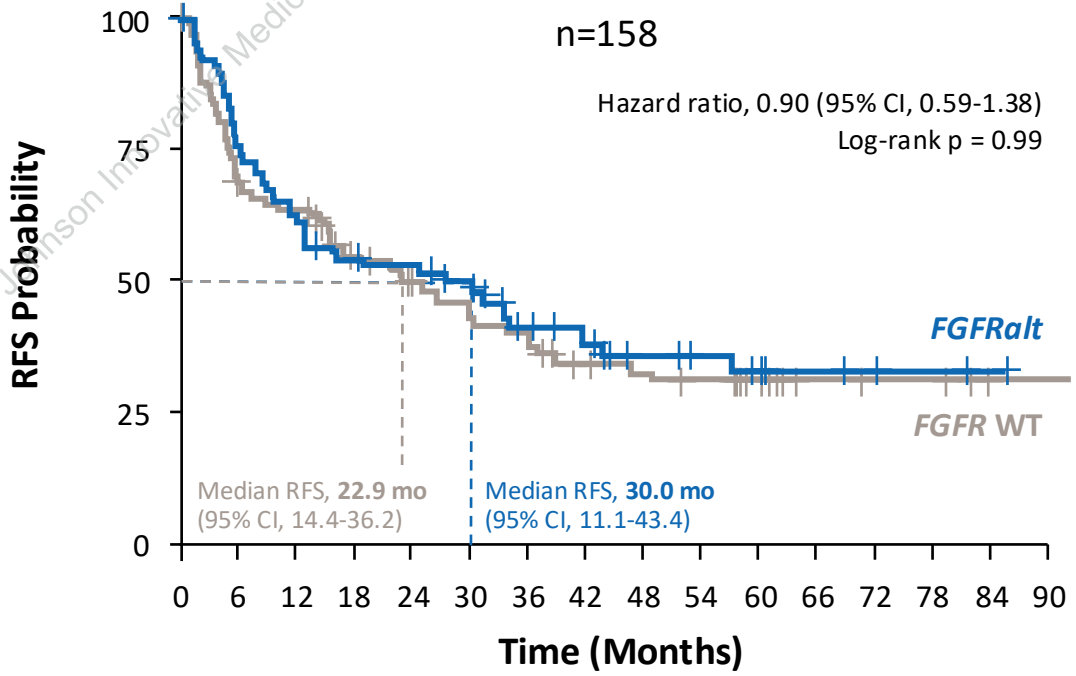
Patients with *FGFR*-altered IR NMIBC had shorter RFS vs WT



No. at risk

FGFR WT	28	23	20	17	16	14	13	10	8	6	1	1	1	0	0	
FGFRalt	67	47	37	29	25	22	17	11	9	8	8	4	1	1	1	0

FGFR alterations were not associated with RFS in HR NMIBC



No. at risk

FGFR WT	87	56	52	39	33	28	26	19	17	16	11	4	4	4	1	1
FGFRalt	71	52	43	36	34	30	19	16	11	8	6	4	4	3	2	0

Propensity score weighting adjusted for incident tumor (yes/no), sex, and age for IR NMIBC and adjusted for incident tumor (yes/no), tumor stage, tumor grade, sex, and age for HR NMIBC.

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Limitations

- This was a retrospective analysis; prospective studies are needed to validate the findings
- *FGFR* fusions were not included in the *FGFR* status definition
- Treatment effects, including BCG, cannot be assessed, as the timing of treatments was not captured
- PFS data were insufficient in the database to be included in this analysis

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Conclusions

- The analyzed ***FGFR* alterations were prevalent** in patients with NMIBC
- *FGFR* alterations were associated with ***shorter median RFS*** compared with *FGFR* WT in patients with **IR NMIBC** (EAU definition) and in patients with **LG disease**, suggesting ***negative prognostic value*** for recurrence
- In patients with **HR** or **HG NMIBC**, *FGFR* alterations were associated with ***similar RFS*** compared with *FGFR* WT
- In the first-in-human study (NCT05316155), erda-iDRS showed preliminary efficacy in patients with recurrent IR NMIBC (CR rate, 89%) or with BCG-treated HR NMIBC (12-month RFS rate, 83%) with select *FGFR* alterations[1]
  - Erda-iDRS is under investigation in the ongoing MoonRISe-1 (NCT06319820), MoonRISe-2 (NCT05316155, Part 4), and MoonRISe-3 studies (NCT06919965)

Erda-iDRS, erdafitinib intravesical drug-releasing system (previously TAR-210).

1. Vilaseca A, et al. 41st Annual European Association of Urology Congress (EAU26), abstract #LB008, presented Friday, March 13, 2026.

https://www.congresshub.com/Oncology/AUA2026/Erda-iDRS/Meeks

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- This study was sponsored by Janssen Research & Development LLC, a Johnson & Johnson company
- Erdafitinib was discovered in collaboration with Astex Pharmaceuticals
- Writing support was provided by Benjamin Ricca of Johnson & Johnson