

Switching of bacillus Calmette-Guérin (BCG) strain at second course of BCG therapy may reduce BCG-related side effects in patients with BCG relapsing tumor



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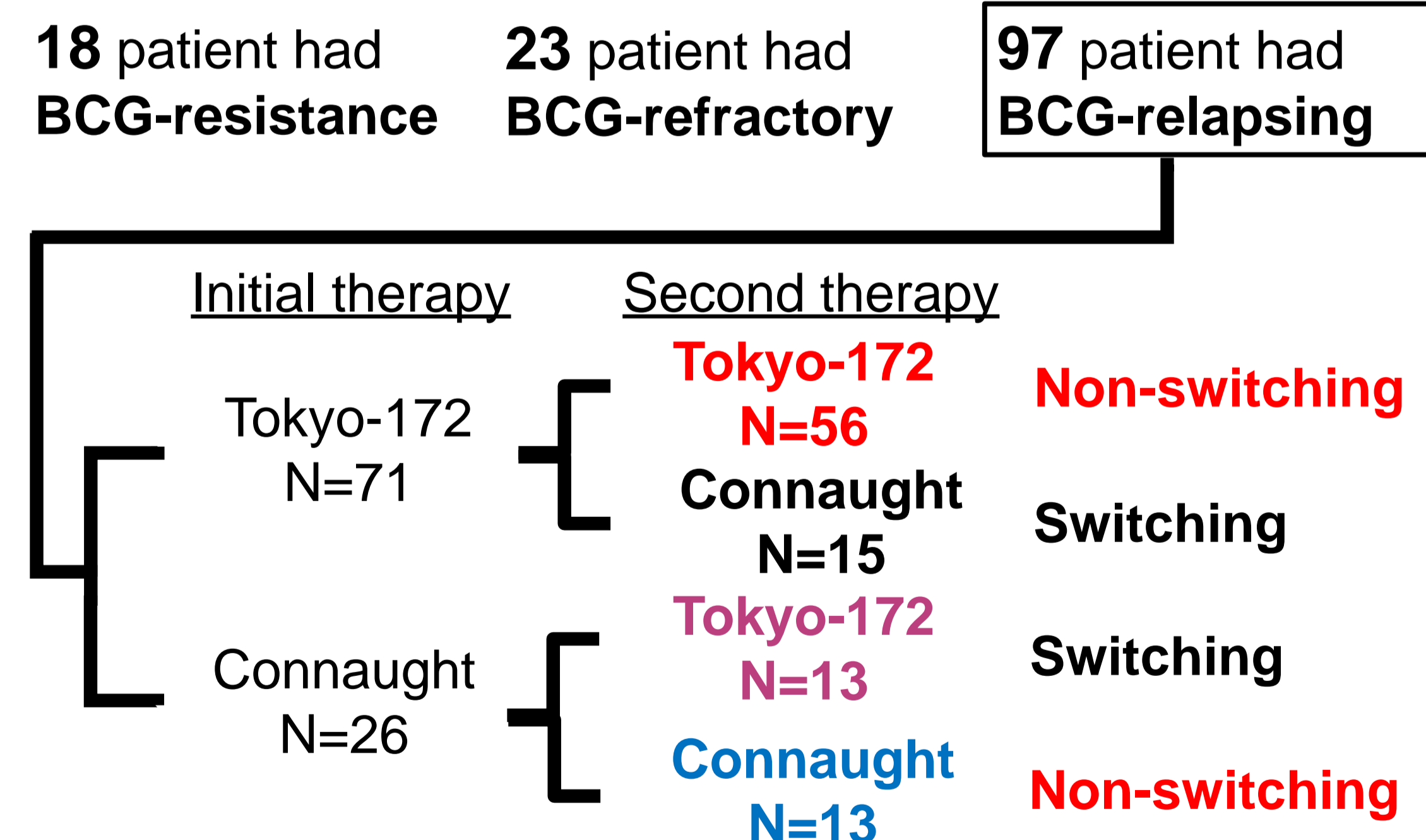
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Introduction

- To investigate the clinical efficacy and safety of switching of BCG strain at the second course of BCG therapy in patients with BCG-relapsing non-muscle-invasive bladder cancer.

Patients and methods

138 NMIBC patients were treated with a second induction course of BCG therapy for tumor recurrence after initial BCG therapy

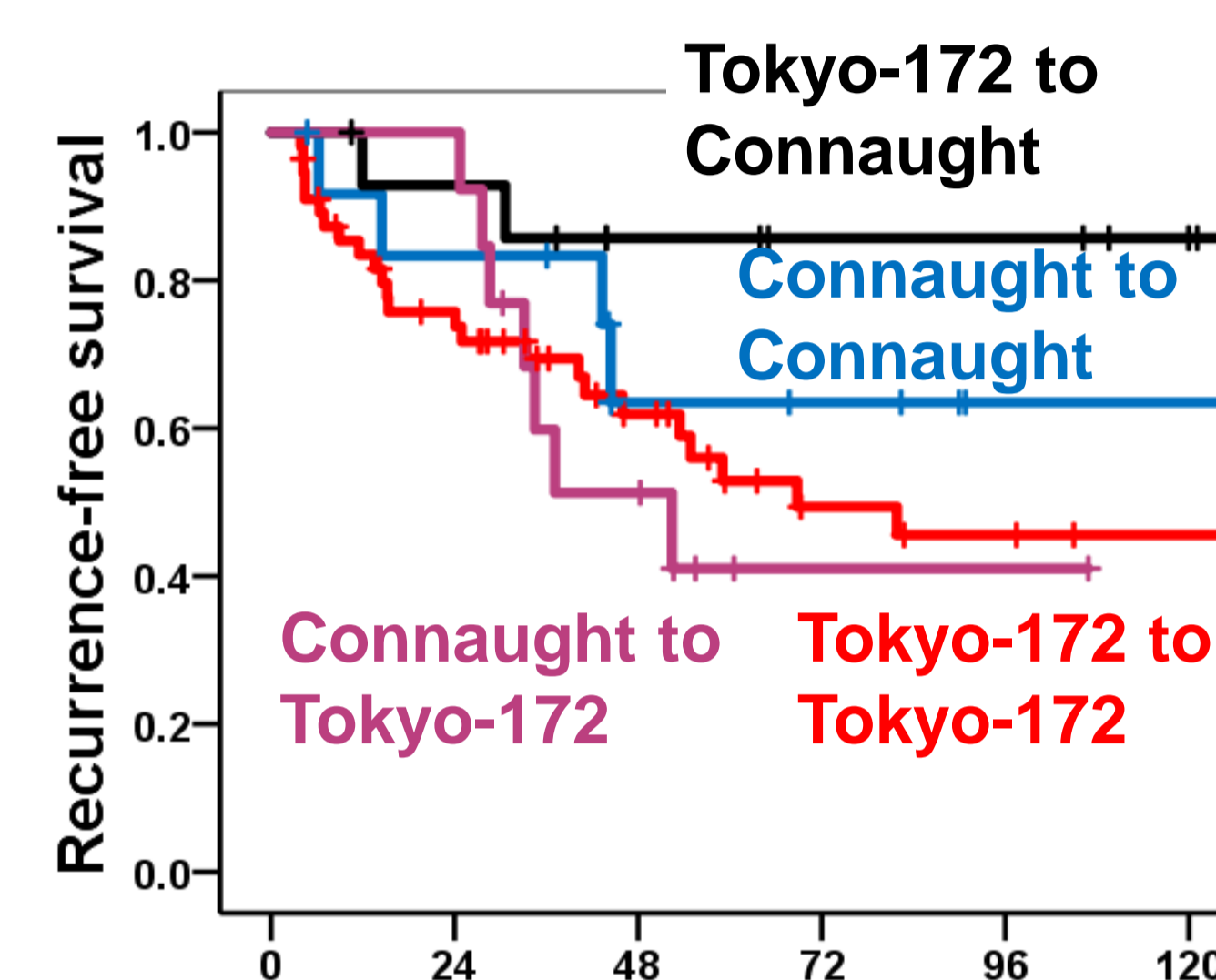


Patients characteristics

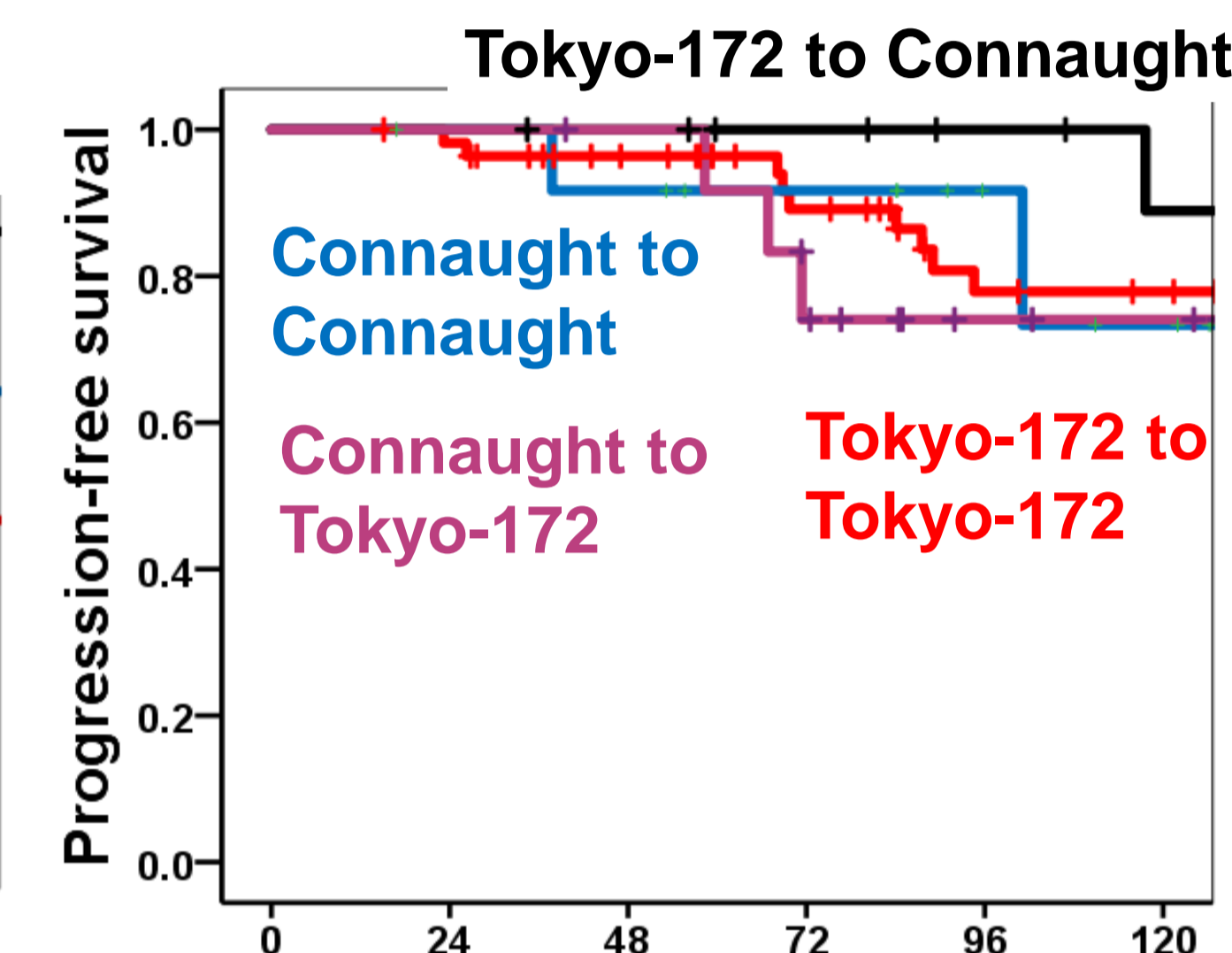
		Non-switching	Switching	p value
No. of patients.		69 (100)	28 (100)	
Age, n(%)	<65 yrs	34 (49)	18 (64)	0.18
	≥65 yrs	35 (51)	10 (36)	
Sex, n(%)	Male	58 (84)	23 (82)	0.82
	Female	11 (16)	23 (18)	
Clinicopathological findings at initial BCG therapy				
Tumor grade	G1,2	32 (46)	13 (46)	0.99
	G3	37 (54)	15 (54)	
T stage	Ta/is	45 (65)	21 (75)	0.35
	T1	24 (35)	7 (25)	
Multiplicity	Single	22 (32)	2 (7)	0.01
	Multiple	47 (68)	26 (93)	
Concurrent CIS	Negative	55 (80)	23 (82)	0.78
	Positive	14 (20)	5 (18)	
BCG relapse	≤24 mo	24 (49)	12 (43)	0.57
	>24 mo	35 (51)	16 (57)	
Clinicopathological findings of BCG-relapsing tumors				
Tumor grade	G1, 2	33 (48)	13 (46)	0.90
	G3	36 (52)	15 (54)	
T stage	Ta/is	49 (71)	20 (71)	0.97
	T1	20 (29)	8 (29)	
Multiplicity	Single	34 (49)	7 (25)	0.03
	Multiple	35 (51)	21 (75)	
Concurrent CIS	Negative	58 (84)	23 (82)	0.82
	Positive	11 (16)	5 (18)	

- During the follow-up period, 38 (42%) and 16 (15%) patients developed tumor recurrence and stage progression, respectively.
- Detailed descriptions of side effects were available for 76 patients

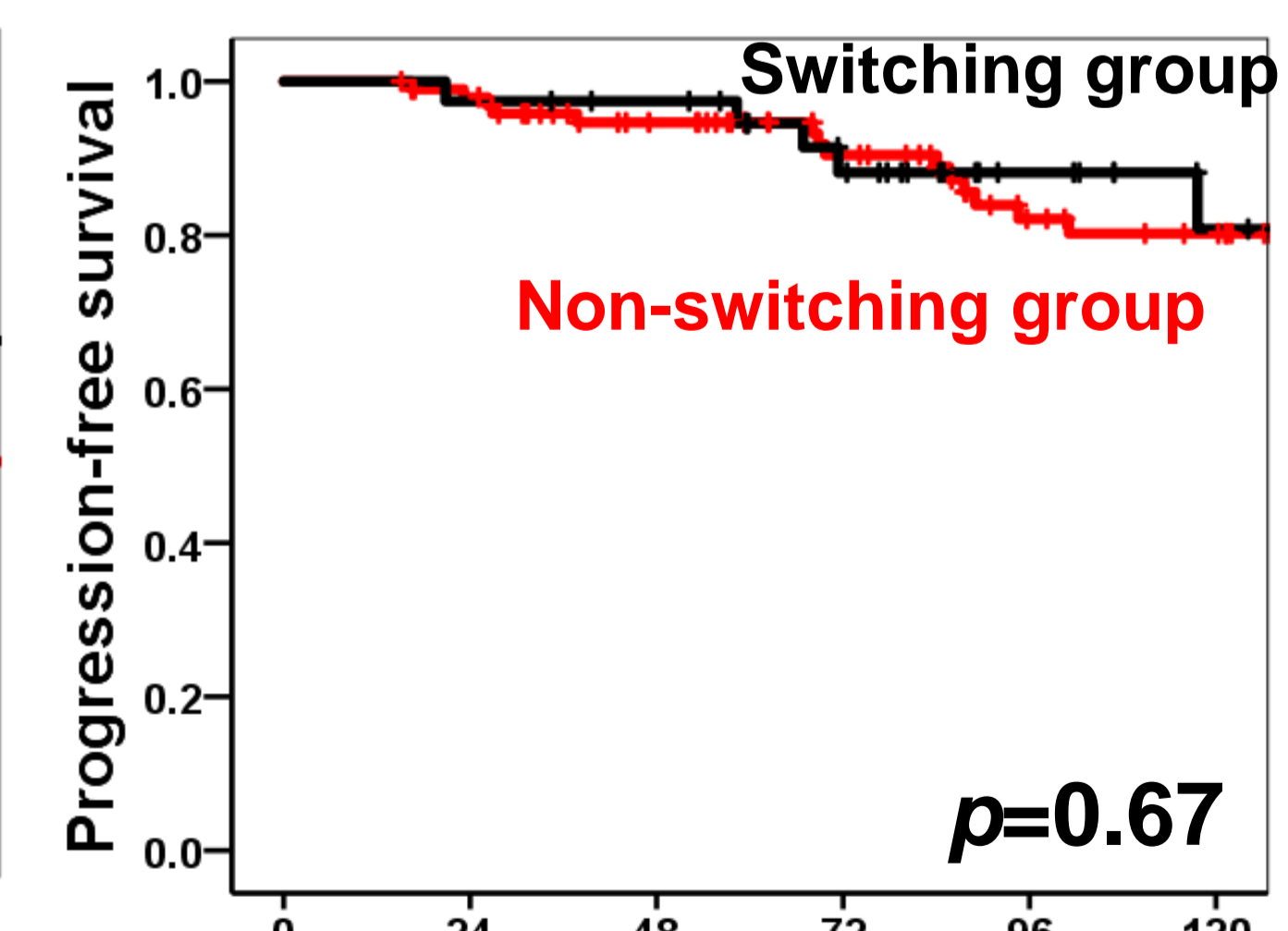
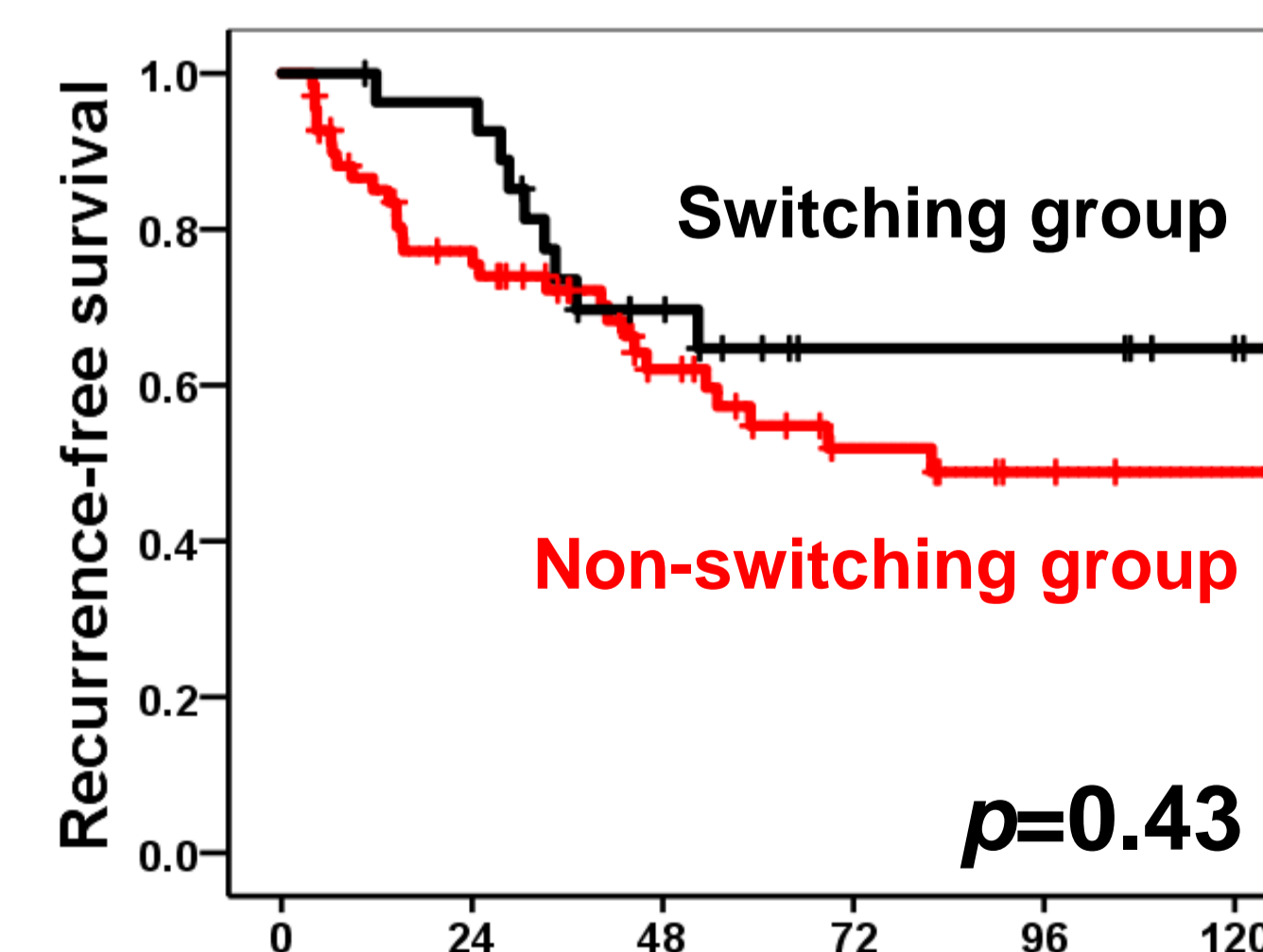
Oncological outcomes



	T to T	T to C	C to T
T to T	-	-	-
T to C	p=0.08	-	-
C to T	p=0.69	p=0.45	-
C to C	p=0.40	p=0.27	P=0.34



	T to T	T to C	C to T
T to T	-	-	-
T to C	p=0.23	-	-
C to T	p=0.50	p=0.13	-
C to C	p=0.94	p=0.24	P=0.66



BCG-related side effects

	Non-switching	Switching	p value
No. of patients.	51 (100)	25 (100)	
Initial BCG therapy			
Hematuria, n(%)	3 (6)	3 (12)	0.35
LUTS, n(%)	1 (2)	4 (16)	0.02
Fever, n(%)	1 (2)	4 (16)	0.02
All, n(%)	7 (14)	11 (44)	<0.01
Second BCG therapy			
Hematuria, (%)	5 (10)	0 (0)	0.11
LUTS, n(%)	20 (39)	6 (24)	0.19
Fever, n(%)	16 (31)	6 (24)	0.51
All, n(%)	32 (63)	8 (32)	0.011

BCG-related major side effects were defined according to our previous study (Takeda et al. Urology 2009)

- Macroscopic hematuria and lower urinary tract symptoms (LUTS) that persisting more than 48 hours
- A fever persisting beyond 2 days or a fever ≥38°C
- Other side effects such as epididymitis, prostatitis, and systemic infection were classified as major side effects.

Conclusions

- In patients with a BCG-relapsing tumor after the initial BCG therapy, the same BCG strain as that administered at the initial BCG therapy could be utilized effectively for the second BCG therapy.
- Patients treated with BCG Tokyo-172 for an initial tumor had a higher incidence of side effects during the second BCG therapy using the same strain.