

Active surveillance in young prostate cancer patients : From the PRIAS-JAPAN study

INTRODUCTION AND OBJECTIVES

Japan is participating in the Prostate cancer Research International: Active Surveillance (PRIAS) study as PRIAS-JAPAN since 2010.

We assessed the state of younger AS patients from the analysis Japanese cohort(PRIAS-JAPAN)

PATIENTS AND METHODS

The inclusion criteria for the PRIAS study

Clinical stage	T1c/T2
PSA	≤ 10 ng/ml,
PSA density	< 0.2 ng/ml
Positive biopsy cores	one or two cores
Gleason score	≤ 6

The follow-up protocol for the PRIAS study

Year	1			2			3			4			5			6			7		
Month	0	3	6	9	12	15	18	21	24	30	36	42	48	54	60	66	72	78	84		
PSA	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓		
DRE	✓		✓		✓		✓		✓		✓		✓		✓		✓		✓		
PBx	✓				✓								✓						✓		

Pathological reclassification is defined as the deviation of pathological findings on re-biopsy from the inclusion criteria.

Patients are recommended active treatment if the PSA doubling time (PSADT) is <3 years (until December 2014) or if reclassification is confirmed on re-biopsy. Since 2015, PSADT has become a trigger for extra yearly re-biopsy, and patients are not recommended active treatment because of short PSADT (<3 years).

In this analysis, we defined re-biopsy at 1-year as 1st re-biopsy and at 4-year biopsy including extra biopsy as 2nd re-biopsy. We compared the clinical outcome and pathological result of re-biopsy between the group of less than 60 years old (young group) and the groups of over 60 years old or more (aged group).

RESULTS

Until September 2017, 768 patients were enrolled from 37 institutions.

In this population, 96 were in young group at enrollment

Table 1. Baseline characteristics of the study population

	Young group (n=96)	Aged group (n=671)	p value
Age (median)	45~59 (56)	60~87 (69)	
PSA (ng/ml) (median)	0.9~9.75 (4.9)	0.75~9.93 (5.3)	0.01*
PSA density (ng/ml/ml) (median)	0.03~0.19 (0.16)	0.019~0.199 (0.14)	0.054*
Prostate volume (ml) (median)	19.8~67.7 (33.0)	13.6~80.5 (38.75)	<0.001*
T classification			
T1c	92	602	0.06**
T2	4	69	
Number of biopsy cores (median)	8~22 (12)	10~42 (12)	0.81*
Cancer positive cores			
1 core	73	494	0.7***
2 cores	23	177	
Cancer detecting rate (positive cores/total cores) (median)	0.04~0.2 (0.08)	0.02~1.0 (0.08)	0.52*
GS			
2+3	1	4	
3+2		5	
3+3	95	652	
3+4		8	
4+3		1	

*Unpaired T test **Fisher's exact test ***Chi-squared test

Table3. The details of the following therapy

	Young group (n=24)	Aged group (n=192)
prostatectomy	54%	36%
Radiation therapy		
EBRT	21%	20%
LDR	16%	17%
heavy particles irradiation		0.5%
Hormone therapy		
LH-RH	4%	10%
AA		1.5%
orchiectomy		0.5%
watchful waiting	4%	11%
unknown		3%

CONCLUSIONS

There is a not significant difference between both group in AS remaining rate.

Younger patients tend to avoid re-biopsy but to choose surgery as a definitive therapy.

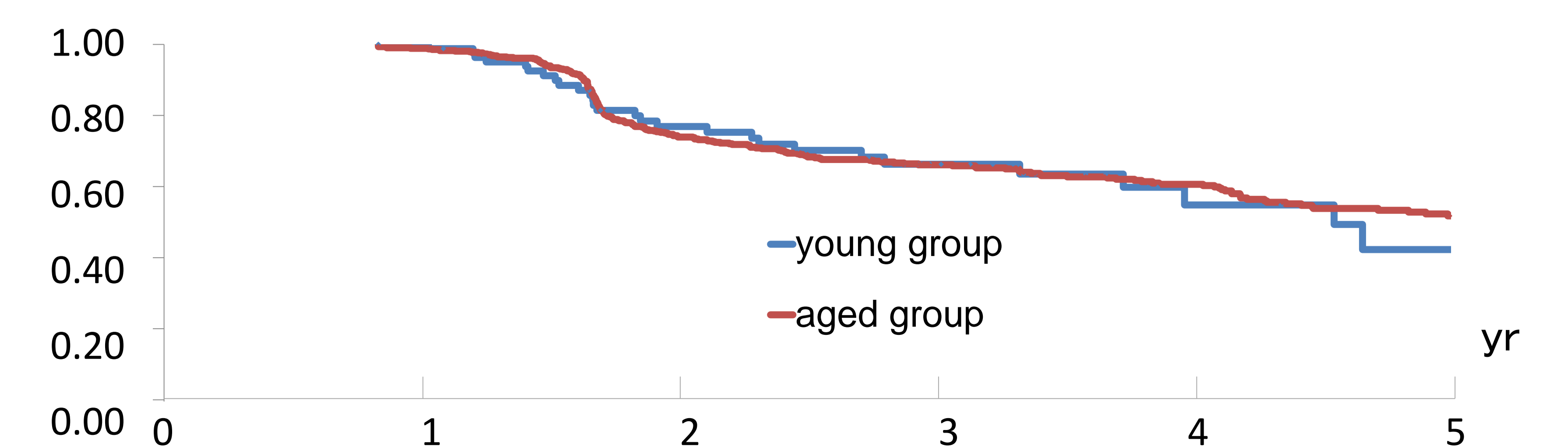
COI: nothing to disclose

Table2. Results of 1st and 2nd repeat biopsy

	1st repeat biopsy			2nd repeat biopsy		
	Young group (n=49)	Aged group (n=447)	P value	Young group (n=10)	Aged group (n=93)	P value
PSA (ng/ml) (median)	1.2~17 (5.3)	0.4~25.3 (5.7)	0.74*	1.7~16.8 (5.8)	1.8~25.8 (7.1)	0.54*
T classification						
T1c	48	416	0.3**	9	87	0.52**
T2	1	31		1	6	
unknown		2				
Number of biopsy core (median)	7~22 (12)	8~25 (12)	0.71*	10~22 (12)	8~25 (12)	0.23*
Number of cancer positive cores (median)	0~7 (1)	0~8 (1)	0.24***	0~4 (1)	0~7 (1)	0.84***
Cancer detecting rate (positive cores/total cores) (median)	0~0.57 (0.05)	0~0.66 (0.08)	0.21*	0~0.3 (0.083)	0~0.41 (0.083)	0.75*
Reclassification	8 (16.3%)	124 (27.7%)		2 (20%)	21 (22.5%)	
Non-reclassification	18 (36.7%)	157 (35%)		5 (50%)	32 (34.4%)	
Non-reclassification (GS3+4 for the patient more than 70years)		17 (3.8%)			8 (8.6%)	
No cancer	23 (46.9%)	149 (33.3%)		3 (30%)	32 (34.4%)	

*Unpaired T test **Fisher's exact test ***Chi-squared test

Figure1. Active surveillance remaining rate



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PSA density	< 0.2 ng/ml
positive biopsy cores	one or two cores
Gleason score	≤ 6

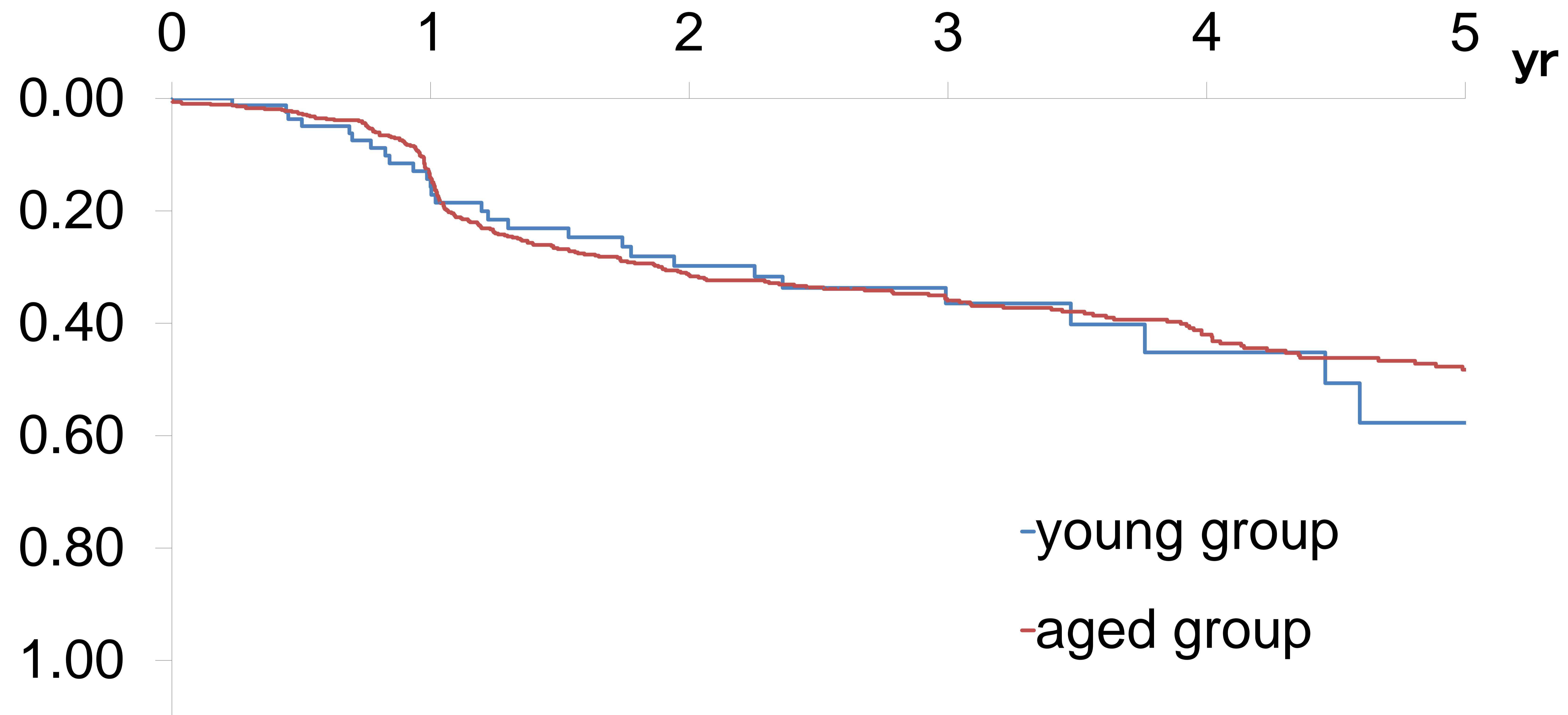
Year	1				2				3	4		5		6		7			
Month	0	3	6	9	12	15	18	21	24	30	36	42	48	54	60	66	72	78	84
PSA	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
DRE	✓		✓		✓		✓		✓		✓		✓		✓		✓		✓
PBx	✓				✓								✓						✓

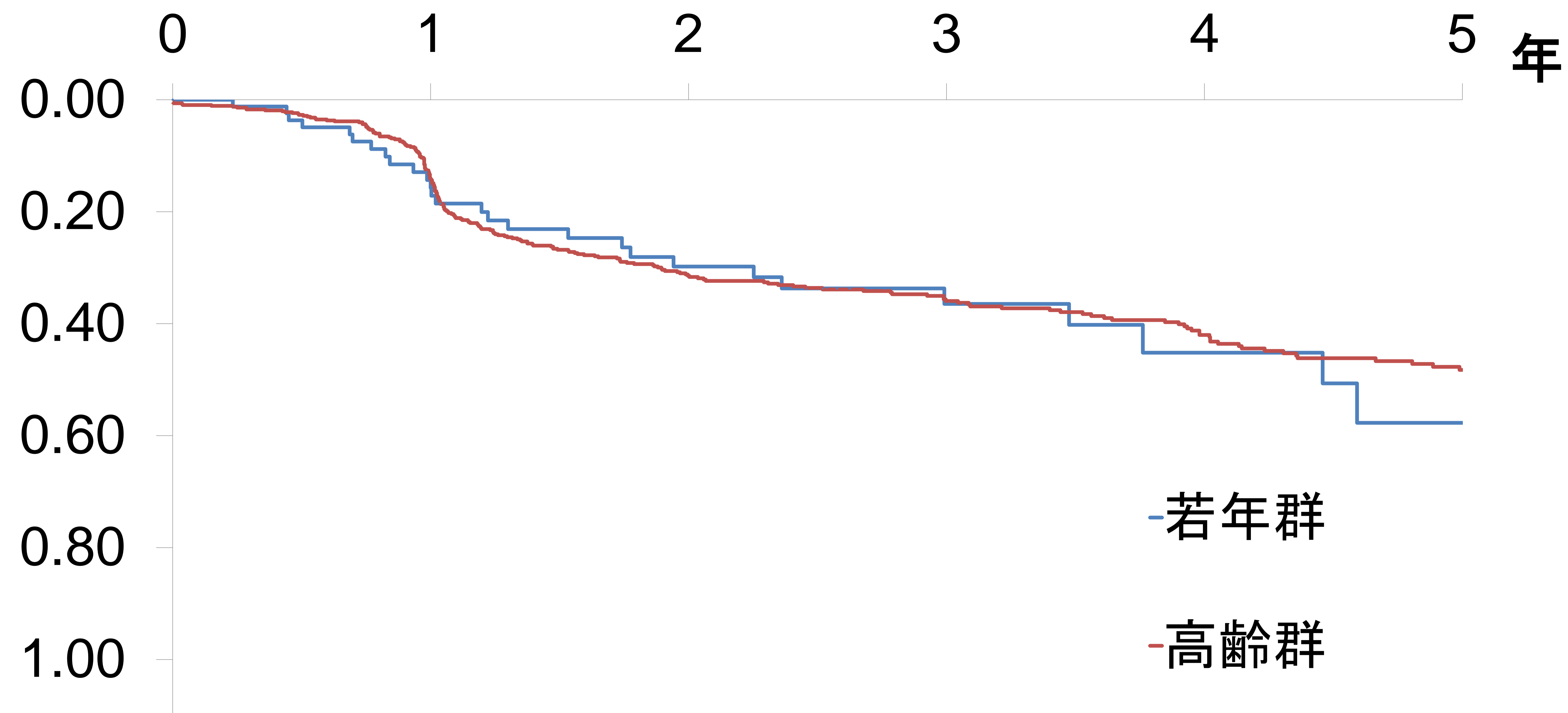
		60歳未満(n=96)	60歳以上(n=671)	p 値
年齢 (中央値)		45~59歳 (56歳)	60~87歳 (69歳)	
PSA (ng/ml) (中央値)		0.9~9.75 (4.9)	0.75~9.93 (5.3)	0.01*
PSA density (ng/ml/cm ³) (中央値)		0.03~0.19 (0.16)	0.019~0.199 (0.14)	0.054*
前立腺体積 (cm ³) (中央値)		19.8~67.7 (33.0)	13.6~80.5 (38.75)	<0.001*
T分類	T1c	92	602	0.06**
	T2	4	69	
生検コア数(本) (中央値)		8~22 (12)	10~42 (12)	0.81*
がん陽性コア数(本)	1本	73	494	0.7***
	2本	23	177	
がん陽性率 (positive cores/total cores) (中央値)		0.04~0.2 (0.08)	0.02~1.0 (0.08)	0.52*
GS	2+3	1	4	
	3+2		5	
	3+3	95	652	
	3+4		8	
	4+3		1	

*:unpaired T test **Fischer exacty rate ***X2検定

		Young group (n=96)	Aged group (n=671)	p value
age (median)		45~59 (56)	60~87 (69)	
PSA (ng/ml) (median)		0.9~9.75 (4.9)	0.75~9.93 (5.3)	0.01*
PSA density (ng/ml ^{cm}) (median)		0.03~0.19 (0.16)	0.019~0.199 (0.14)	0.054*
Prostate volume (cm ³) (median)		19.8~67.7 (33.0)	13.6~80.5 (38.75)	<0.001*
T classification	T1c	92	602	0.06**
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	Young group (n=24)	Aged group (n=192)
prostatectomy (RP+LRP+RALP)	13 (54.1%)	69 (35.9%)
EBRT	5 (20.8%)	38 (19.7%)
LDR	4 (16.6%)	32 (16.6%)
重粒子線		1 (0.5%)
HT x LH-RH	1 (4.1%)	20 (10.4%)
AA		3 (1.5%)
orchiectomy		1 (0.5%)
watchful waiting	1 (4.1%)	22 (11.4%)
unknown		6 (3.1%)

		60歲未満 (n=24)	60歲以上 (n=192)
前立腺全摘 (RP+LRP+RALP)		13 (54.1%)	69 (35.9%)
EBRT		5 (20.8%)	38 (19.7%)
LDR		4 (16.6%)	32 (16.6%)
重粒子線			1 (0.5%)
HT x	LH-RH	1 (4.1%)	20 (10.4%)
	AA		3 (1.5%)
	除辜術		1 (0.5%)
watchful waiting		1 (4.1%)	22 (11.4%)
不明			6 (3.1%)

再生検の結果

		1回目の生検の結果			2回目の生検の結果				
		60歳未満 (n=49)	60歳以上 (n=447)	p値	60歳未満 (n=10)		60歳以上 (n=93)	p値	
PSA (ng/ml) (中央値)		1.2~17 (5.3)	0.4~25.3 (5.7)	0.74	1.7~16.8 (5.8)		1.8~25.8 (7.1)	0.54	
T分類	T1c	48	416	0.3	9		87	0.52	
	T2	1	31		1		6		
	不明		2						
生検コア数(本) (中央値)		7~22 (12)	8~25 (12)	0.71	10~22 (12)		8~25 (12)	0.23	
がん陽性コア数(本) (中央値)		0~7 (1)	0~8 (1)	0.24	0~4 (1)		0~7 (1)	0.84	
がん陽性率 (positive cores/total cores) (中央値)		0~0.57 (0.05)	0~0.66 (0.08)	0.21	0~0.3 (0.083)		0~0.41 (0.083)	0.75	
reclassification		8 (16.3%)	124 (27.7%)		2 (20%)		21 (22.5%)		
non-reclassification		18 (36.7%)	157 (35%)		5 (50%)		32 (34.4%)		
non-reclassification (70歳以上のGS3+4)			17 (3.8%)				8 (8.6%)		
no cancer		23 (46.9%)	149 (33.3%)		3 (30%)		32 (34.4%)		

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