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Objectives

This abstract reports the 9-year experience of the SIURo Prostate cancer Research International: Active Surveillance (PRIAS) ITA working group, composed of 13 Italian centers participating in the PRIAS protocol. Possible predictors of reclassification during AS were also evaluated.

Patients and Methods

In December 2009 SIURo-PRIAS-ITA working group started including patients in the PRIAS protocol.

Eligibility criteria:

- prostate-specific antigen at diagnosis (iPSA) ≤ 10 ng/ml
- Gleason Score (GPS) ≤ 6
- clinical stage $\leq T2a$
- PSA density ≤ 0.2 ng/ml/cc
- maximum of 2 positive cores at diagnostic biopsy.

In case of saturation biopsy, up to 15% of the total number of cores can be positive. No limit of positive cores is required if mpMRI results negative or GPS 3+3 is confirmed at fusion biopsy.

Results

Between December 2009 and October 2018, 1335 prostate cancer patients were included in PRIAS.

Patients data:

- Median age at inclusion: 66 years (range=42-81)
- Median iPSA: 5.9 ng/ml (range=0.2-10)
- 450 patients (34%) had at least two positive cores at diagnostic biopsy
- 1261 (95%) were classified as T1c at Digital Rectal Exploration (DRE)
- Median time on AS was 31 months (range=1-138).

Drop Out from Active Surveillance:

- Of the 543 patients (41%) that dropped out from AS:
- 329 were due to upgrading and/or upsizing at re-biopsy (190/329 at first re-biopsy, one year after inclusion)
 - 44 patients were lost to follow-up
 - 70 chose to end active surveillance and switched to active treatment or Watchful Waiting
 - 11 dropped out due to non PCa related death
 - 24 patients switched to Watchful Waiting due to age
 - 65 patients discontinued AS due to other reasons (i.e. clinical worsening, radiological progression, anxiety, PSA doubling time).

Cox model (3 variable, overall $p < 0.0001$):

- age (continuous variable, risk factor, HR=1.0187)
- prostate volume (continuous variable, protective factor, HR=0.9824)
- number of positive core at diagnosis (continuous variable, risk factor, HR=1.2561).

Conclusions

- Most of drop out events occurred after the re-biopsy at 12 month, which should probably be considered as a confirmatory biopsy
- PSA density, prostate volume, number of positive cores and total cores at diagnostic biopsy were correlated with biopsy-related ATFS
- Cox multivariable model suggested age at diagnostic biopsy, number of positive cores and prostatic volume as predictive variables of ATFS
- The protective result of prostate volume could be explained with an incorrect sampling in high-volume prostate

Follow up schedule:

- PSA examinations are performed every 3 months and visits every 6 months in the first 2 years
- PSA is performed every 6 months and visits yearly thereafter.
- Repeated biopsy is scheduled at years 1, 4, 7 and 10, and subsequently every 5 years.

Drop out reasons:

- upgrading (GPS>6)
- upsizing (>2 positive cores, before the introduction of MRI criteria in 2013)

Kaplan-Meier analysis

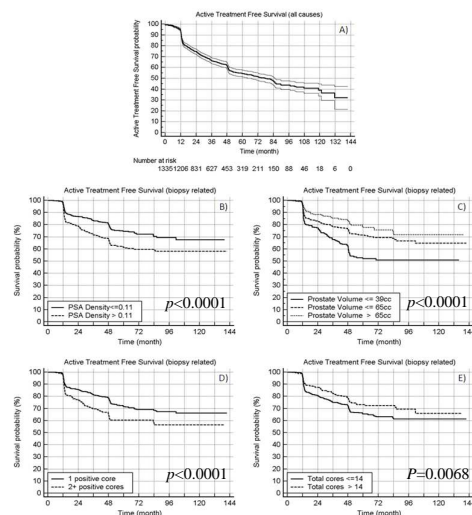


Figure 1: Kaplan-Meier curves for Active Treatment Free Survival: (A) Overall Survival, (B) as a function of PSA density; (C) as a function of Prostate Volume; (D) as a function of number of positive cores at diagnostic biopsy, (E) as a function of number of total cores at diagnostic biopsy.