

## Favourable and reliable PSA doubling time can improve confidence in reducing the number of repeat biopsy during active surveillance

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Badenchini F.<sup>1</sup>, Marenghi C.<sup>1</sup>, Avuzzi B.<sup>2</sup>, Bellardita L.<sup>1</sup>, Casale A.<sup>3</sup>, Catanzaro M.<sup>4</sup>, Claps M.<sup>5</sup>, Colecchia M.<sup>6</sup>, De Luca L.<sup>1</sup>, Di Florio T.<sup>1</sup>, Donegani S.<sup>1</sup>, Dordoni P.<sup>1</sup>, Macchi A.<sup>4</sup>, Messina A.<sup>3</sup>, Morlino S.<sup>2</sup>, Noris Chiorda B.<sup>2</sup>, Stagni S.<sup>4</sup>, Tesone A.<sup>4</sup>, Torelli T.<sup>4</sup>, Villa S.<sup>2</sup>, Zollo F.<sup>1</sup>, Magnani T.<sup>1</sup>, Rancati T.<sup>1</sup>, Valdagni R.<sup>2</sup>, Nicolai N.<sup>4</sup>

<sup>1</sup>Fondazione IRCCS Istituto Nazionale dei Tumori, Prostate Programme, Milan, Italy, <sup>2</sup>Fondazione IRCCS Istituto Nazionale dei Tumori, Dept. of Radiation Oncology, Milan, Italy, <sup>3</sup>Fondazione IRCCS Istituto Nazionale dei Tumori, Dept. of Radiology, Milan, Italy, <sup>4</sup>Fondazione IRCCS Istituto Nazionale dei Tumori, Dept. of Urology, Milan, Italy, <sup>5</sup>Fondazione IRCCS Istituto Nazionale dei Tumori, Dept. of Oncology, Milan, Italy, <sup>6</sup>Fondazione IRCCS Istituto Nazionale dei Tumori, Dept. of Pathology, Milan, Italy

**Introduction & Objectives:** Active Surveillance (AS) implies monitoring patients with repeat biopsies and PSA, to promptly detect tumor reclassification (mainly upgrading from Gleason score 3 to 4 or higher) and switch pts to radical treatment. We evaluated if selected PSA doubling time (PSA-DT) is a reliable tool to identify pts with no upgrading at subsequent rebiopsies.

**Materials & Methods:** Since 2005, 1120 patients were enrolled in AS. Eligibility criteria: clinical stage  $\leq$ T2a, initial PSA  $\leq$ 10 ng/mL and Gleason Pattern Score GPS  $\leq$ 3+3; number of positive cores  $\leq$ 25% of total cores and a maximum core length containing cancer  $\leq$ 50% in the mono-institutional SAINT protocol,  $\leq$ 2 positive cores and PSA density  $<$ 0.2 ng/mL/cm<sup>3</sup> in the international PRIAS study. Starting from 2016, multiparametric MRI (mpMRI) target biopsies of mpMRI PIRADS  $>$ 2 lesions allowed the inclusion of patients with GPS 3+3, regardless of the number of positive cores. Four PSA determinations are provided per year. Repeat biopsies are scheduled at year 1, 4, 7 in PRIAS protocol and at yr 1, 2 and every 2 yrs up to 8<sup>th</sup> yr in SAINT; then every 5 yrs. Extra-biopsies might be ruled by PSA-DT  $<$ 10 yrs. Switching to active treatment were advised if upgrading (GPS  $\geq$ 3+4) occurred.

**Results:** Since March 2005 to May 2019, 13979 PSA were collected from 1120 patients and 1848 repeated biopsies (excluding the diagnostic ones) were recorded. Of these 286 (15%) scored an upG.

Association between PSA-DT and upG at repeated biopsies resulted to be significant for  $R^2$  values  $\geq$ .5 ( $P <$ 0.0001 vs  $P =$ 0.12). A trend upG was also detected in PSA-DT categories ( $P <$ 0.0001), with an increasing of upG in unfavorable and very unfavorable categories. Considering cases with favorable PSA-DT, 868/968 (90%) had not experimented upG. After the first yr of AS, only 1 patient out of 62 (1.6%) with a favorable PSA DT and good fit of the model ( $R^2 \geq$ 0.5) experimented upG at repeated biopsy.

**Conclusions:** PSA-DT with a  $R^2 \geq$ 0.5 may represent a stable and reliable kinetics in predicting tumor reclassification. Favorable PSA-DT with good fit value ( $R^2 \geq$ 0.5) was found to associate to low risk of upG at the repeat biopsy during AS, especially after the first rebiopsy. This finding could support a risk-based scheduling of repeat biopsy, to reduce the overload of re-biopsies and their potential side effects.