



SPECIAL ARTICLE

Preliminary results of the Spanish Association of Urology National Registry in Active Surveillance for prostate cancer[☆]



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KEYWORDS

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Abstract

Objectives: To present a National Registry of patients with prostate cancer as monitored through active surveillance, with the intention of testing the hypothesis that cancer-specific mortality in very low-risk and low-risk patients is less than 5% at 15 years.

Material and methods: A multicentre observational study (AEU-PIEM/2014/0001) sponsored by the Spanish Association of Urology was conducted using their platform for multicentre studies. The clinical–pathological inclusion criteria were as follows: cT1a–cT3a, PSA \leq 20 ng/ml, initial

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minimum biopsy of 10 cores, number of affected cores ≤ 3 , 1st Gleason score of 3 and 2nd Gleason score ≤ 4 and a known prostate volume (in cm^3). A unified follow-up was not established for all recruiting centers; however, a survey was conducted that reflects the follow-up characteristics based on a number of tangible parameters that allow for their comparison. With the same philosophy of flexibility, the use of certain biomarkers and multiparametric MRI was not considered necessary for inclusion.

Results: We describe the Registry's characteristics and possibilities, as well as the preliminary results from the 324 patients included in its first 5 months of operation in the 15 recruiting centers. We also report the clinical-pathological variables, biomarkers, radiologic techniques and quality-of-life questionnaires considered for the database, as well as the possibilities for indefinite follow-up, remaining open to any active treatment recognized in clinical guidelines.

Conclusions: The AEU-PIEM/2014/0001 represents an extremely useful tool for all Spanish urologists for multicentre clinical research. The registry will undoubtedly enable the diffusion M&M of active surveillance of our patients in a more coordinated manner, thus maintaining the advantages of optimized opportunistic screening for prostate cancer without resulting in overtreatment.

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PALABRAS CLAVE

Cáncer de próstata;
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Información

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Resumen

Objetivos: Presentar un registro nacional de pacientes con cáncer de próstata seguidos mediante vigilancia activa, con la intención de testar la hipótesis de que la mortalidad cáncer específica en pacientes de muy bajo riesgo y riesgo bajo es menor del 5% a 15 años.

Material y métodos: Estudio multicéntrico observacional (AEU-PIEM/2014/0001) promovido por la Asociación Española de Urología mediante su plataforma para estudios multicéntricos, en donde los criterios de inclusión clínico-patológicos son: cT1a-cT3a, PSA ≤ 20 ng/ml, biopsia (Bx) inicial mínima de 10 cilindros, número de cilindros afectos ≤ 3 , Gleason 1.=3 y Gleason 2. ≤ 4 , y volumen prostático conocido (en cc). No se establece un seguimiento unificado para todos los centros reclutadores, y sí una encuesta en la que se reflejen las características del seguimiento en función de unos parámetros tangibles que permitan su comparabilidad. Con la misma filosofía de flexibilidad no se considera obligada la utilización de determinados biomarcadores o de RMN mutiparamétrica para su inclusión.

Resultados: Se presentan las características y posibilidades del registro a modo descriptivo y los resultados preliminares de 324 pacientes incluidos en sus primeros 5 meses de funcionamiento por 15 centros reclutadores. De la misma forma se describen las variables clínico-patológicas, biomarcadores, técnicas de radiodiagnóstico y cuestionarios de calidad de vida contemplados por la base de datos, así como las posibilidades de seguimiento indefinido y abierto a cualquier tratamiento activo reconocido en guías clínicas.

Conclusiones: La AEU-PIEM/2014/0001 constituye una herramienta extremadamente útil a todos los urólogos españoles para la investigación clínica multicéntrica, y sin duda permitirá la difusión de la vigilancia activa entre nuestros pacientes de una forma más coordinada, permitiendo mantener las ventajas del *screening* oportunista optimizado en cáncer de próstata sin incurrir en el sobretratamiento.

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Introduction

Active surveillance (AS) is a strategy of conservative management of low-risk prostate cancer (PCa) that is recognized by European clinical guidelines with evidence level 2a, recommendation grade A.¹ It is possible that in the coming years multicenter studies such as the *Prostate Testing for Cancer and Treatment* (ProtecT)² make it possible to modify upward that level of evidence, when compared with active

treatments in a prospective, randomized manner. However, there is much retrospective evidence on the opportunity of AS to avoid overtreatment of PCa derived from the early diagnosis or opportunistic screening.^{3,4} Different groups have set guidelines of protocolization and have shown that AS is not lower in cancer-specific survival in the medium or long term,⁵ and however, clear gains have been shown in quality of life when these parameters were compared with the different existing active treatments.⁶

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