Cost analysis of ProsTAV®, a new telomere-based biomarker for the early detection of prostate cancer available in Europe

Mónica Parramón Ponz[1], Moisés Juárez[1], Paloma Hidalgo P[1], Almudena Martín A[1], Alberto Lopez-Obregón[1], Sofía de Pedro[2], María Echave[2], Itziar Oyagüez[2], Miguel Angel Casado[2]; Juan Ignacio Martínez Salamanca[3]
(1) Life Length, S.L, (2) Pharmacoeconomics & Outcomes Research Iberia (PORIB), (3) LYX-Instituto de Urología

Objectives

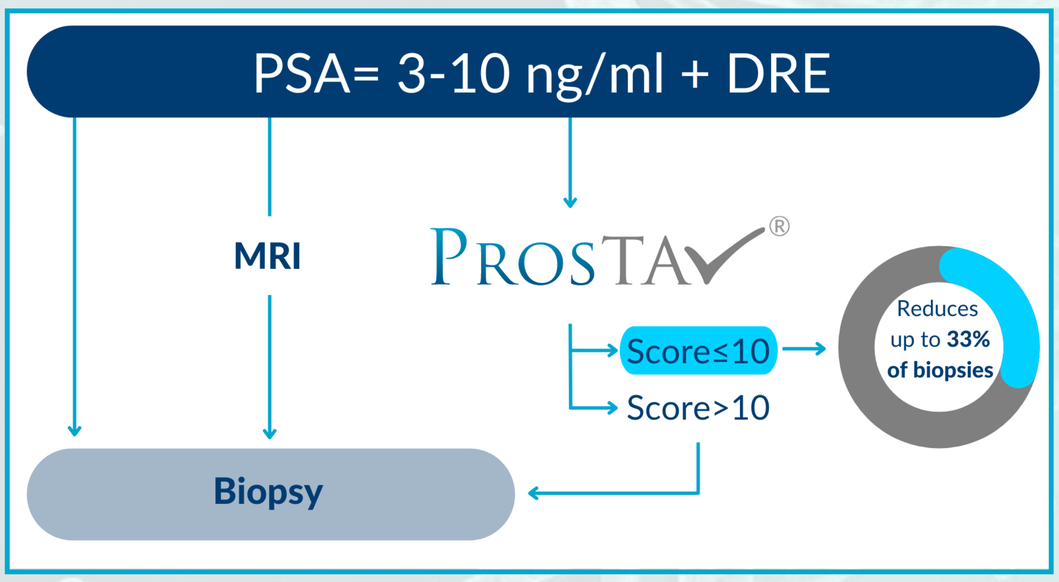
More than **1.4 million cases of prostate cancer (PCa)**, the second most common cancer in men, are diagnosed each year worldwide[1].

Patient's **risk stratification** is a crucial decision-making tool to identify clinically significant PCa, to avoid unnecessary biopsies, overdiagnosis and overtreatment.

European Guidelines indicate the need for new and improved biomarkers based in blood, urine or tissue.

ProsTAV® is a new *in vitro* blood test for the early detection of PCa authorised in Europe. It is also available in USA.

Figure 1. New proposed diagnosis scheme



PSA: prostate-specific antigen; **DRE:** digital rectal examination; **MRI:** magnetic resonance imaging

A cost analysis of ProsTAV® has been performed to determine the economic impact of its introduction in the Spanish healthcare system.

Methods

The model was built under the following considerations:

Perspective of the Spanish National Healthcare System	Population: 9.3 million (men >50 years)
One year time horizon	Number of annual biopsies in Spain: **57,568**

Direct costs (€, 2023[2]) derived from the consumption of resources required for the diagnosis of PCa:

- PSA determinations ..... *19.98€ / unit*
- Visits to urologist ..... *151.75€ / unit*
- Biopsies..... *623.78€ / unit*
- Complications arising from the performance of biopsies ..... Table 1

The model considered ProsTAV® parameters (90% sensitivity and 33% specificity)[3]

Figure 2. Graphical representation of compared scenarios

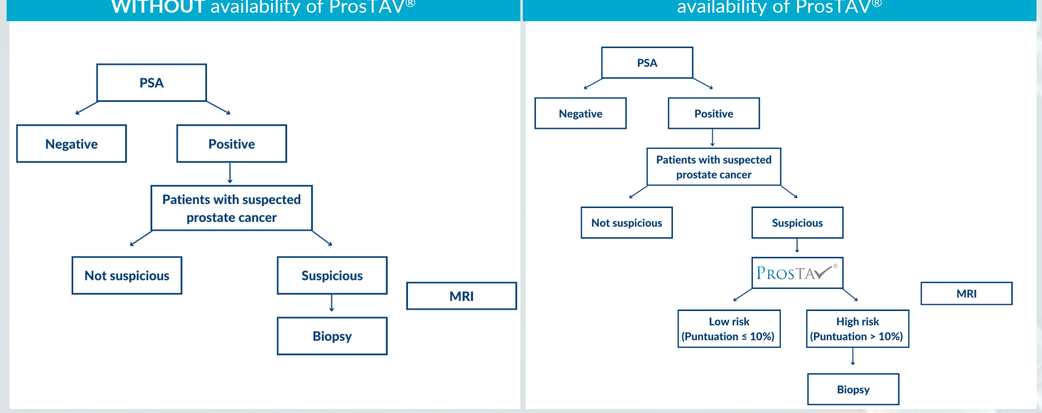


Table 1. Complications of transrectal biopsy

Benett et al. (2015)[4]	Weiner et al. (2020)[5]	Forsvall et al. (2021)[6]	Sahin et al. (2021)[7]	Bokhorst et al. (2016)[8]	*COSTS (€)[2]*
Infection: 3.50%	Infection: 6.40%	Infection: 5.37%	Infection: 5.80%	Infection: 2.30%	*4,897€*
Sepsis: 0.70%		Sepsis: 0.75%	Sepsis: 0.50%		*7,782€*
	Hematuria: 4.20%			Hematuria: 12.70%	*5,100€*
Hospitalization: 0.90%	Hospitalization: 1.90%				*1,018€ (per day)*

The use of ProsTAV® is associated with a reduction in the number of visits to urologist, avoiding 21.28% of patients with suspected PCa having to undergo a biopsy.

33% — **ProsTAV® reduce by 33% t**he number of biopsies that would end up confirming the absence of PCa.

Results

The introduction of ProsTAV® into the PCa diagnostic process in Spain has a neutral impact on the Health System, showing a range from savings (-0.18%) to a small increase (0.21%) compared to current costs (Figure 3).

Figure 3. Results of cost analysis

The introduction of ProsTAV® into the PCa diagnostic process has a neutral impact on the Spanish Health System.

Conclusion

ProsTAV® does not increase the costs associated with the diagnosis of PCa.

ProsTAV® helps to reduce the number of biopsies and the visits to the Urology Department.

ProsTAV® is associated with biopsy avoidance in patients not at risk of PCa.

ProsTAV®, therefore, promotes evident benefits for patients.

The use of the new **ProsTAV®** biomarker represents a very useful innovation in the early diagnosis of Prostate Cancer for European Health Systems

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(3) Gómez, E. G., Castiñeira, R. C., Burgos, J., Antolín, A. R., Miles, B. J., Salamanca, J. I. M., Bianco, F., Fernández, L., Calmarza, I., Pastor, J., Butler, R. G., & Pedro, N. de.(2023). ProsTAV, a novel blood-based test for biopsy decision management in significant prostate cancer. The Prostate. https://doi.org/10.1002/PROS.24594
(4) Bennett, H.Y. et al. (2015) 'The global burden of major infectious complications following prostate biopsy', Epidemiology and Infection, 144(8), pp. 1784–1791. doi:10.1017/s0950268815002885.
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(8) Bokhorst, L.P. et al. (2016) 'Complications after prostate biopsies in men on active surveillance and its effects on receiving further biopsies in the prostate cancer research international: Active surveillance (PRIAS) study', BJU International, 118(3), pp. 366–371. doi:10.1111/bju.13410.

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