

Real-World Incidence and Management of Hypothyroidism Secondary to Apalutamide in Patients with Prostate Cancer

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BACKGROUND AND IMPORTANCE

Apalutamide is an androgen receptor signaling inhibitor widely used in **prostate cancer** (PC). **Hypothyroidism** is a recognized adverse event, though its incidence and clinical management in real-world practice remain underreported.

AIM AND OBJECTIVES

To evaluate the **incidence, management, and outcomes** of **hypothyroidism** in PC patients treated with **apalutamide**.

MATERIALS AND METHODS



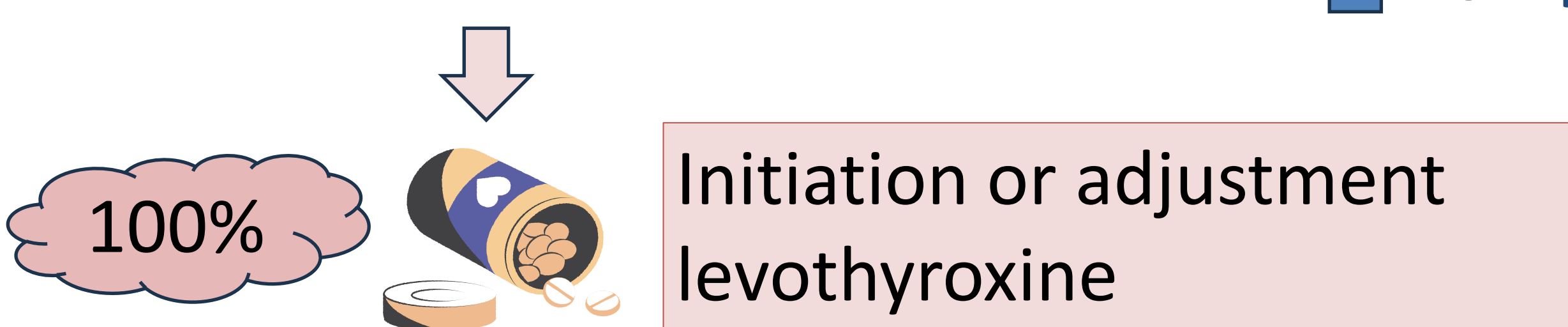
- ✓ **Retrospective observational study**
- ✓ **PC patients treated with apalutamide** between August 1, 2020, and September 30, 2025.

Collected variables: age, oncologic diagnosis, TSH, T4, time to thyroid alteration, prior hypothyroidism, endocrine diagnoses, and thyroid treatment during follow-up.

RESULTS

- ✓ 85 ♂
- ✓ Median age 73 years (IQR 52–91)
- ✓ 97.6% mHSPC, 2,4% nmCRPC

6 patients with pre-existing hypothyroidism

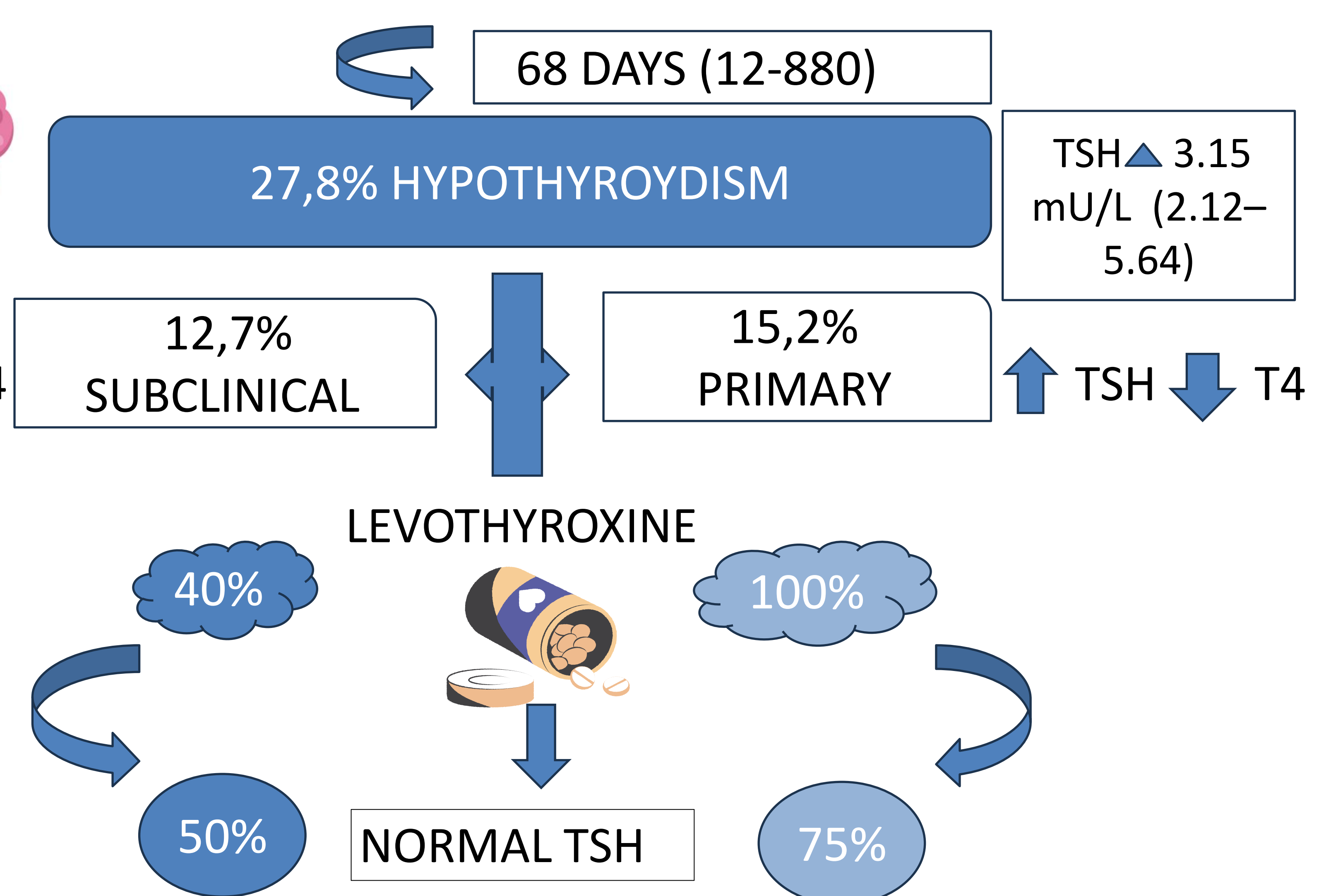


7 patients Apalutamide.

85,7% Maintained the same levothyroxine dose



79 patients without prior hypothyroidism



CONCLUSION AND RELEVANCE

- The **incidence** of hypothyroidism with apalutamide was **higher than reported** in the product label (8%), particularly in patients without prior thyroid disease.
- Most cases occurred **in the first months**, though late onset was also observed, supporting the need for **long-term monitoring**.
- Patients with **pre-existing hypothyroidism** required **closer monitoring**, as all needed levothyroxine initiation or adjustment.
- **Levothyroxine** effectively managed **primary hypothyroidism**, whereas subclinical cases showed heterogeneous approaches in clinical practice.
- **Thyroid function reassessment after apalutamide discontinuation** is recommended to avoid unnecessary lifelong therapy.
- **Standardized protocols** and multidisciplinary collaboration (Urology, Oncology, Endocrinology, Primary Care) could optimize patient care.

