

EVALUATION OF DOCETAXEL IN LOW- AND HIGH-BURDEN METASTATIC HORMONE SENSITIVE PROSTATE CANCER

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L01 - Cytostatics

BACKGROUND

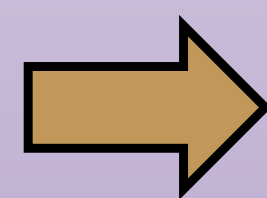
- ✓ Addition of **docetaxel** to hormonal treatment in **low- and high-burden metastatic hormone sensitive prostate cancer** (mHSPC) raised important **controversy**.
- ✓ There is literature suggesting **increased overall survival (OS)** in **high-burden disease** and **lack of benefit** for **low-volume of metastases**.

AIM

To perform a **systematic search** and **methodological evaluation** of **subgroup analyzes** about use of **docetaxel in mHSPC** according to volume of metastatic disease (VMD)

MATERIAL AND METHODS

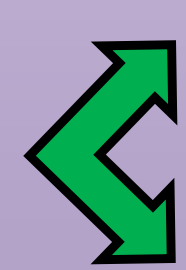
Systematic search in Pubmed® (September 25, 2020)



- ✓ Search strategy in “Clinical Queries/Narrow” tool: **(Therapy/Narrow[filter]) AND (docetaxel AND prostate cancer AND hormone sensitive)**

- ✓ Inclusion criteria: Randomized clinical trials (RCTs) with **subgroup analysis** regarding **VMD** for **OS**

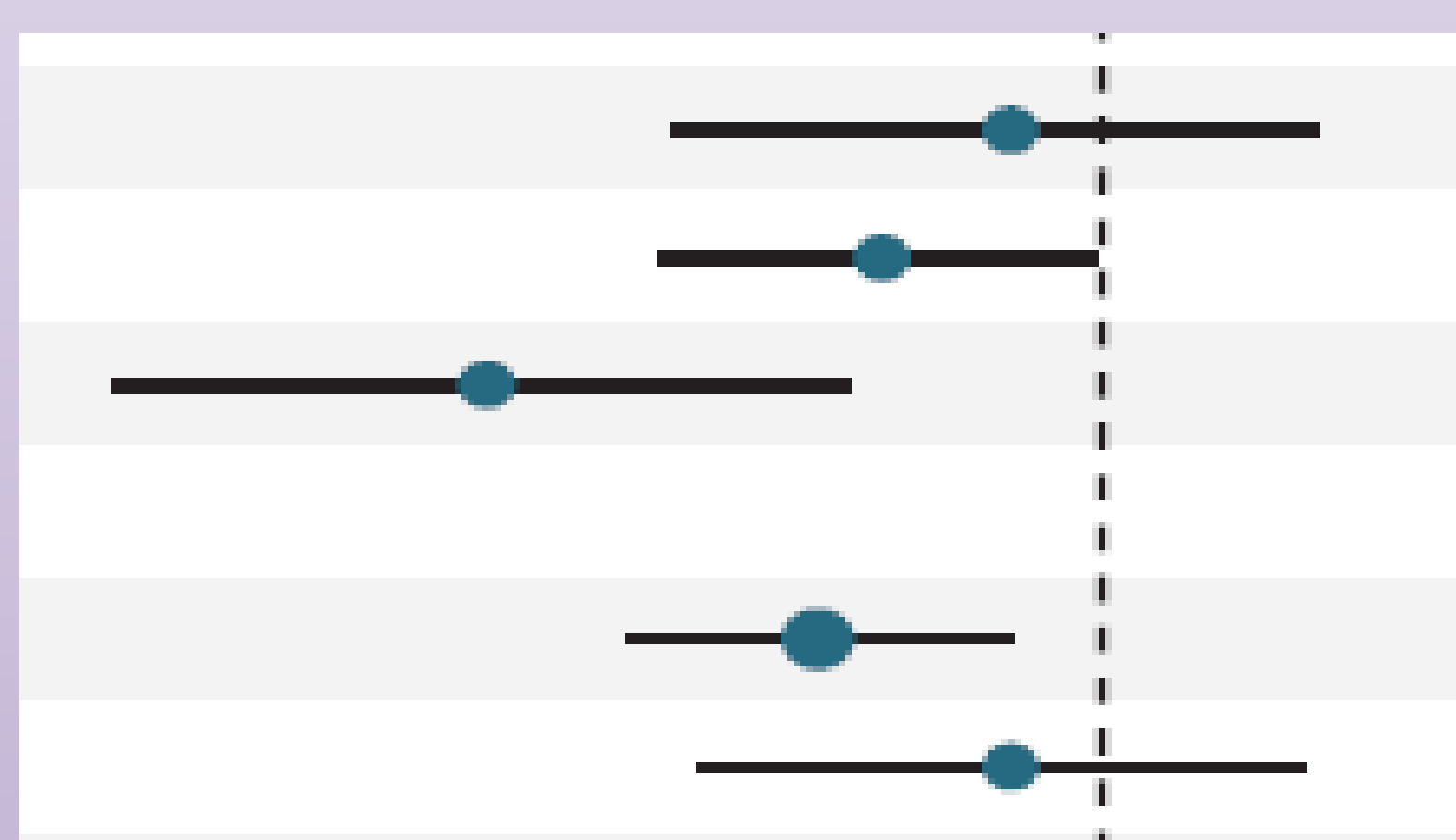
- ✓ Two **methodologies**



1° Evaluation of heterogeneity of subgroups ($p < 0.1$), prespecification, biological support and consistency

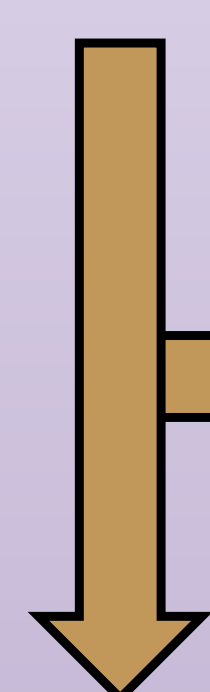
2° Validated tool with preliminary questions to discard subgroup analyzes without minimal relevance and checklist → Recommendations of applicability

RESULTS



Results of systematic review:

31 results



27 results excluded

4 RCTs included

- ✓ 9 were not RCTs
- ✓ 13 did not evaluate the effect of docetaxel
- ✓ 4 without subset analysis about VMD
- ✓ 1 did not assess OS



1° Methodology

- Heterogeneity of subgroups: heterogeneity among subgroups observed in **1 RCT**
- Pre-specification: Subset analysis was prespecified in **2 RCTs**
- Biological support: It was found in subgroup analyzes of **all RCTs**
- Consistency: No consistency among results of these subgroup analyzes



2° Methodology (validated tool)

Preliminary questions discarded applicability of subset analysis in 3 RCTs.

Recommendation in the remaining RCT: “null” recommendation was obtained for applicability of subgroup results because of **inconsistency**

CONCLUSION

About use of **docetaxel in mHSPC**, **no consistent differences** for OS were found in **subset analysis according to VMD**. Patients with low- and high-burden mHSPC benefited from docetaxel therapy. This is the first study with a systematic review and methodology of subgroup analyzes in mHSPC according to VMD.

REFERENCES AND/OR ACKNOWLEDGEMENTS

- ¹Sun X, *et al.* How to use a subgroup analysis: users' guide to the medical literature. JAMA. 2014;311(4):405-11
²Gil-Sierra MD, *et al.* Checklist for clinical applicability of subgroup analysis. J Clin Pharm Ther. 2020;45(3):530-8.