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BACKGROUND AND IMPORTANCE

Clinical trials (CTs) involve different procedures in which Pharmacy Service (PS) participates.

To evaluate the difficulty of the procedures \rightarrow to Analysis of global CTs complexity \rightarrow used for Measure of resources needed in each CT by PS

AIM AND OBJECTIVES

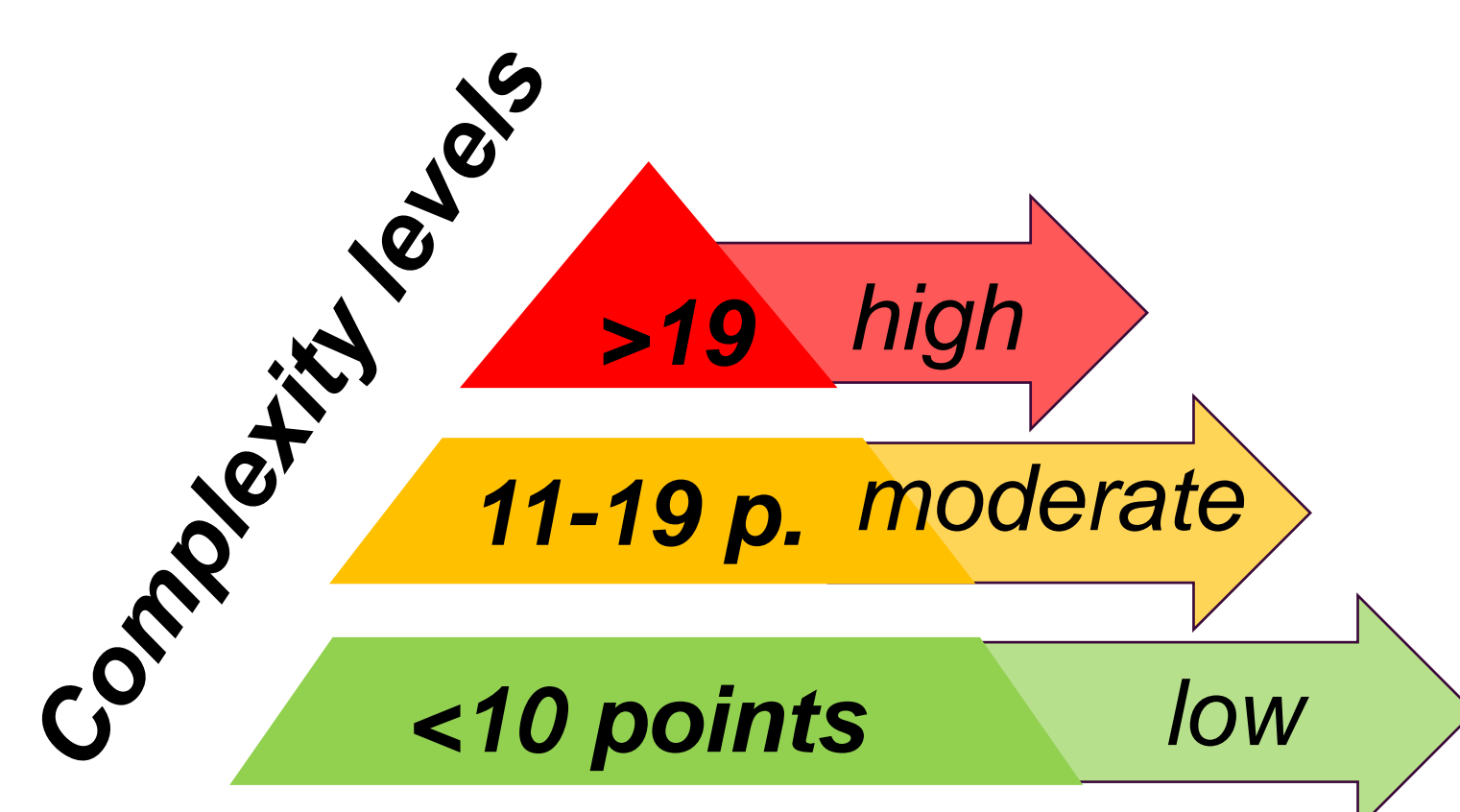
To assess the complexity of the CTs in which PS participates, depending on CTs characteristics.

MATERIALS AND METHODS

- Observational retrospective study. CTs started from 2014 to August 2023 were included.
- **Complexity scale** from Calvin-Lamas et al.,2012. was used.

Information was collected from Fundanet®.

*IP: Investigational Product



CTs characteristics	PS procedures evaluated	
Medical service	IP receipt	IP conditioning
Pathology	IP conservation	IP dispensation
Uni/Multicentric	IP assignment	Randomization
Phase	IP preparation	Blinding

RESULTS

➤ 101 CTs

- 99,0% multicentric
- 52,5% unblinded

CT phase

- 1,0% I
- 25,7% II
- 67,3% III
- 5,9% IV

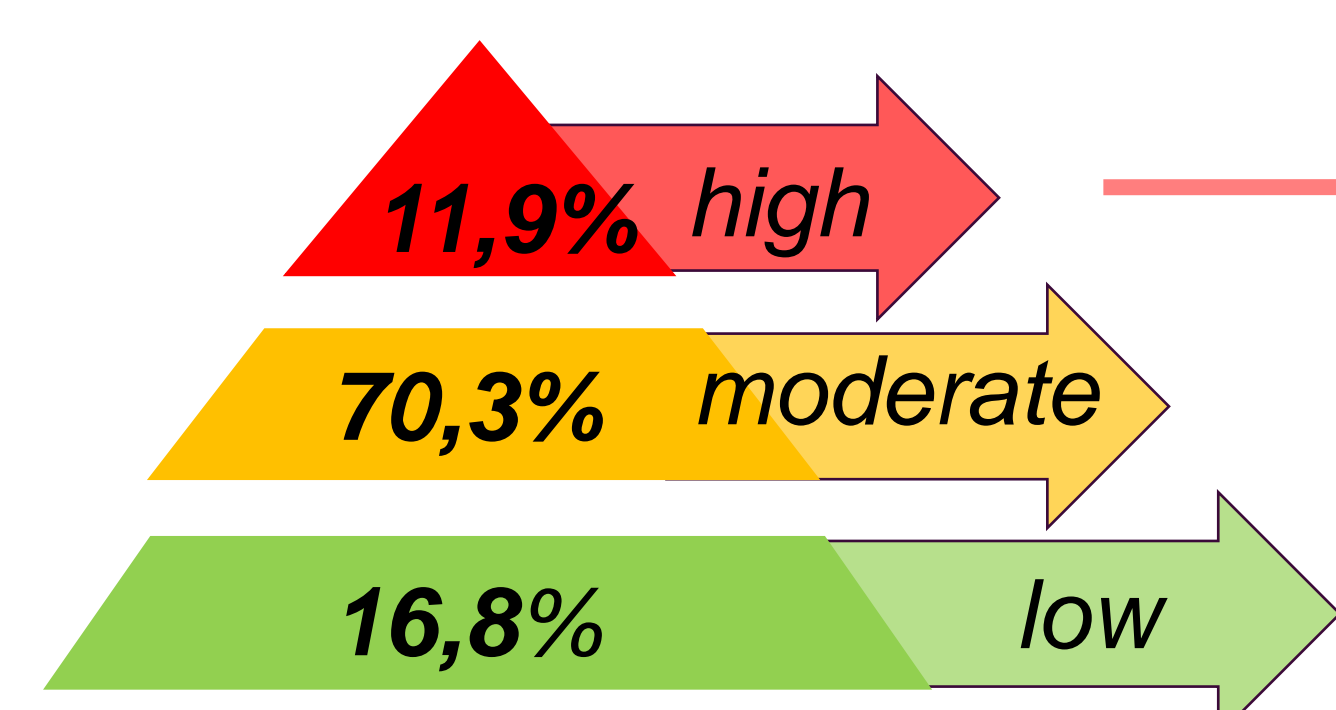
Medical services (MS):

- 48,5% oncology
- 21,8% infectious diseases
- 20,8% neurology
- 5,9% rheumatology
- 2,0% surgery
- 1,0% psychiatry

Pathologies:

- 16,8% HIV
- 12,9% breast cancer
- 12,9% parkinson disease
- 7,9% colorectal cancer
- 6,9% Alzheimer disease
- 5,0% lung cancer
- 5,0% gastric cancer
- 5,0% rheumatoid arthritis

CTs complexity analysis



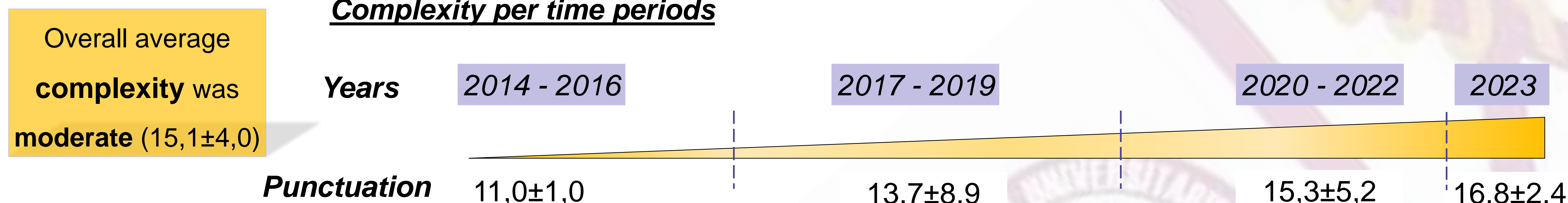
Higher complexity:

- MS: Neurology
- Pathologies:
 - Gastric cancer
 - Alzheimer disease
 - Lung cancer

CTs which required:

- 47,5% aseptic preparation
- 74,3% dispensation to the research team
- 37,6% two pharmacists

Complexity per time periods



CONCLUSION

- CTs complexity has increased over the years.
- Most complex CTs correspond to oncological and neurological pathologies.
- These types of evaluations are important to optimize resources.

References: Calvin-Lamas M,Pita-Fernandez S,Pertega-Diaz S,Rabunal-Alvarez MT,Martin-Herranz I.A complexity scale for clinical trials from the perspective of a pharmacy service.Eur J Hosp Pharm.2018 Sep;25(5):251-256.

