

PREVALENCE OF NIVOLUMAB ADVERSE EVENTS IN ROUTINE CLINICAL PRACTICE

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BACKGROUND AND IMPORTANCE

- Nivolumab is an **anti PD-1** antibody, authorized in 2015.
- It is **indicated** in:
 - ✓ Adjuvant or metastatic melanoma (MC)
 - ✓ Metastatic non-small cell lung cancer (NSCLC)
 - ✓ Renal cell carcinoma (RCC)
 - ✓ Squamous cell carcinoma of the head and neck (HNC)
- No data reported about adverse events (AE) on long-term treatments.

AIM AND OBJECTIVES

To assess the nivolumab **tolerability** and to identify and calculate the **prevalence of AE** related to nivolumab. Compare its frequency with the one described on the data sheet.

MATERIALS AND METHODS

- Descriptive retrospective observational study
- Patients treated with nivolumab since it was commercialized (March 2016 – September 2019)

Variables collected	
Sex	Age
Diagnosis	No. nivolumab doses
Adverse Events	Deaths
Start/End date of nivolumab	Stop reason

- AE classified according the prevalence described on the summary of product characteristics:
 - ❖ Very common (>10%)
 - ❖ Common (1-10%)
 - ❖ Not common (0,1-1%)
 - ❖ Rare (0,01-0,1%)
 - ❖ Very rare (<0,01%)

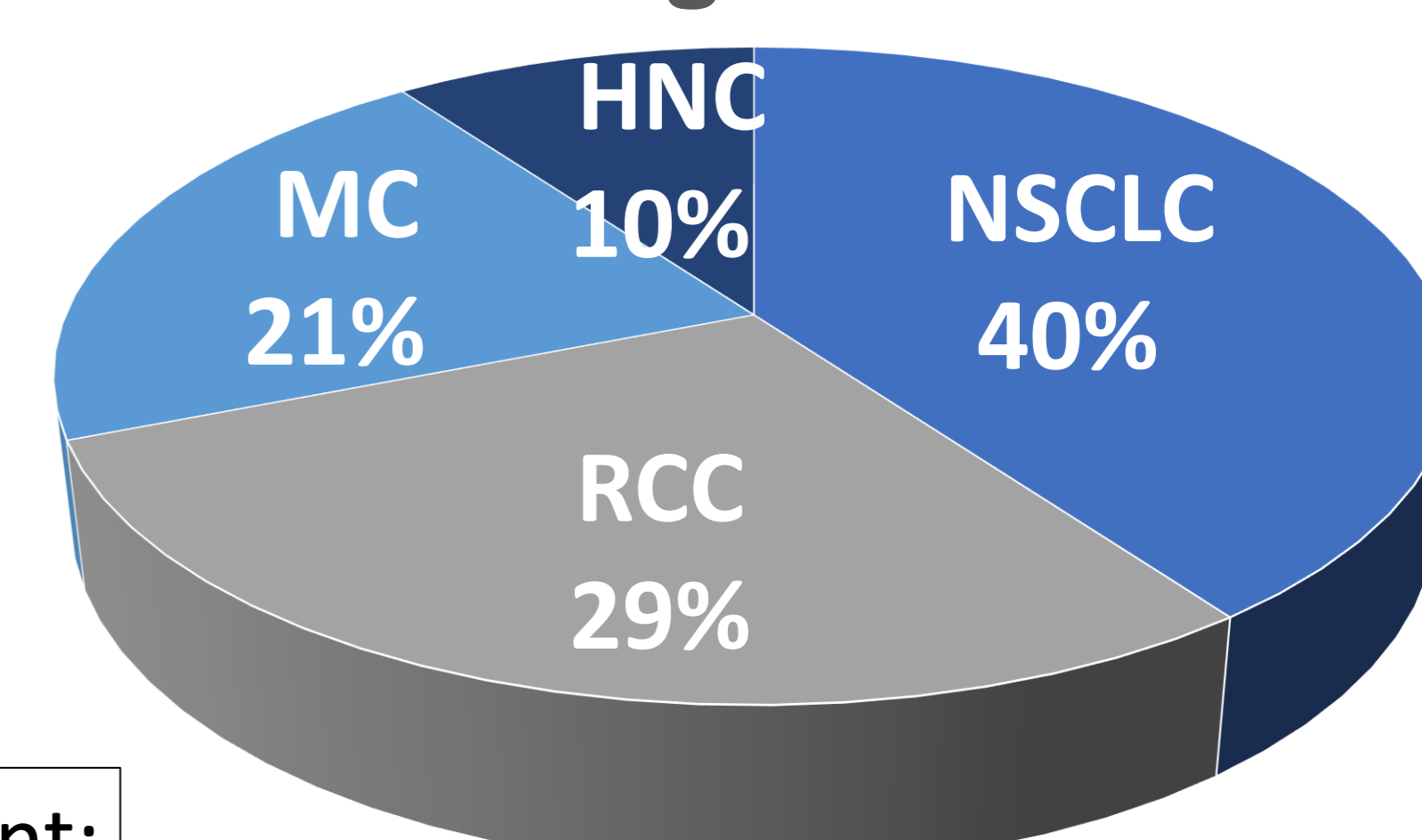
CONCLUSION

- Relevant AE occurred during the period studied.
- Higher prevalence of AE in clinical practice than expected leading to treatment interruption.
- A strict monitoring of analytical parameters is needed to detect AE as early as it could.

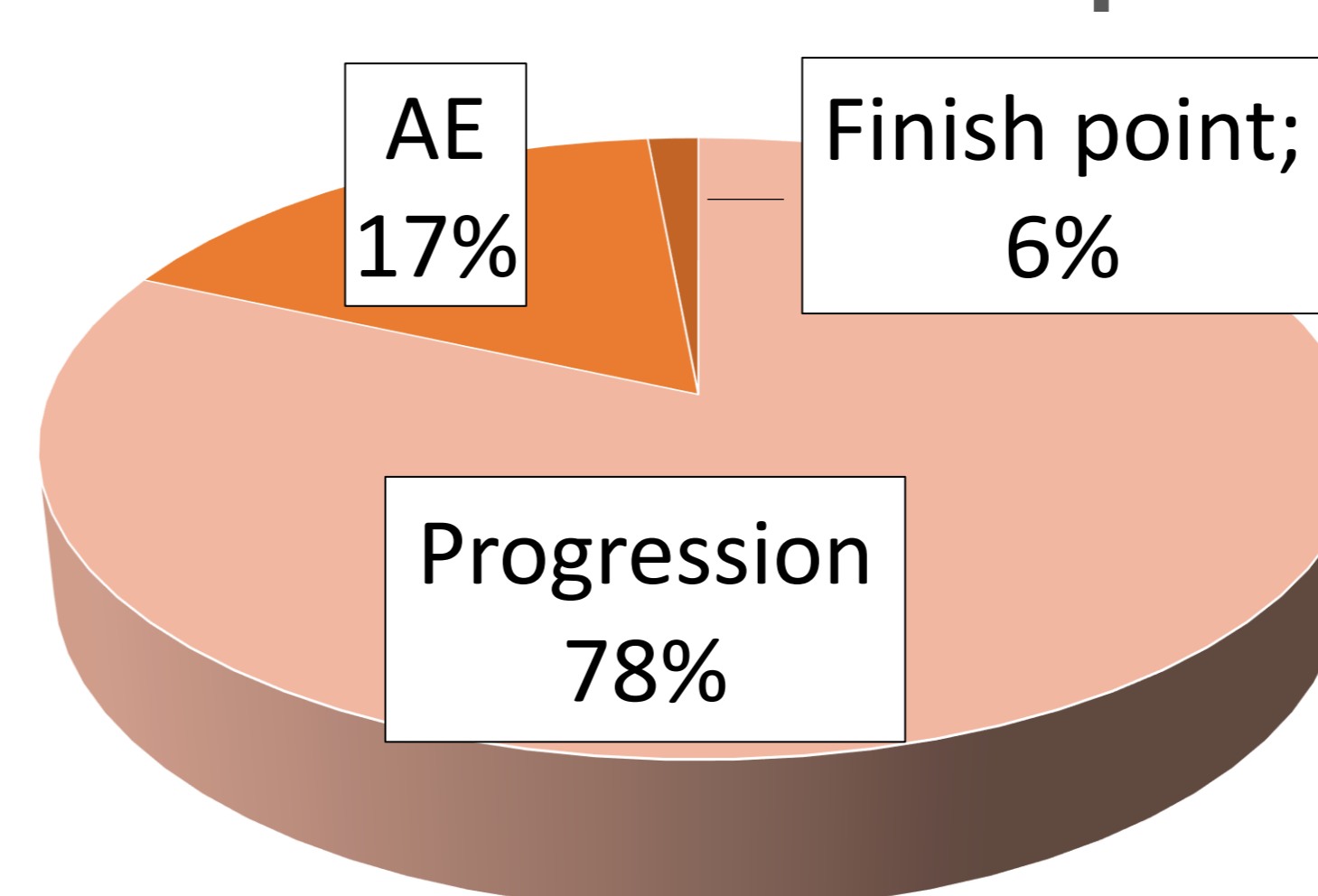
RESULTS

- 48 patients
- 77% male
- Median of 63 years old
- 77% interrupted nivolumab

Prevalence main diagnosis



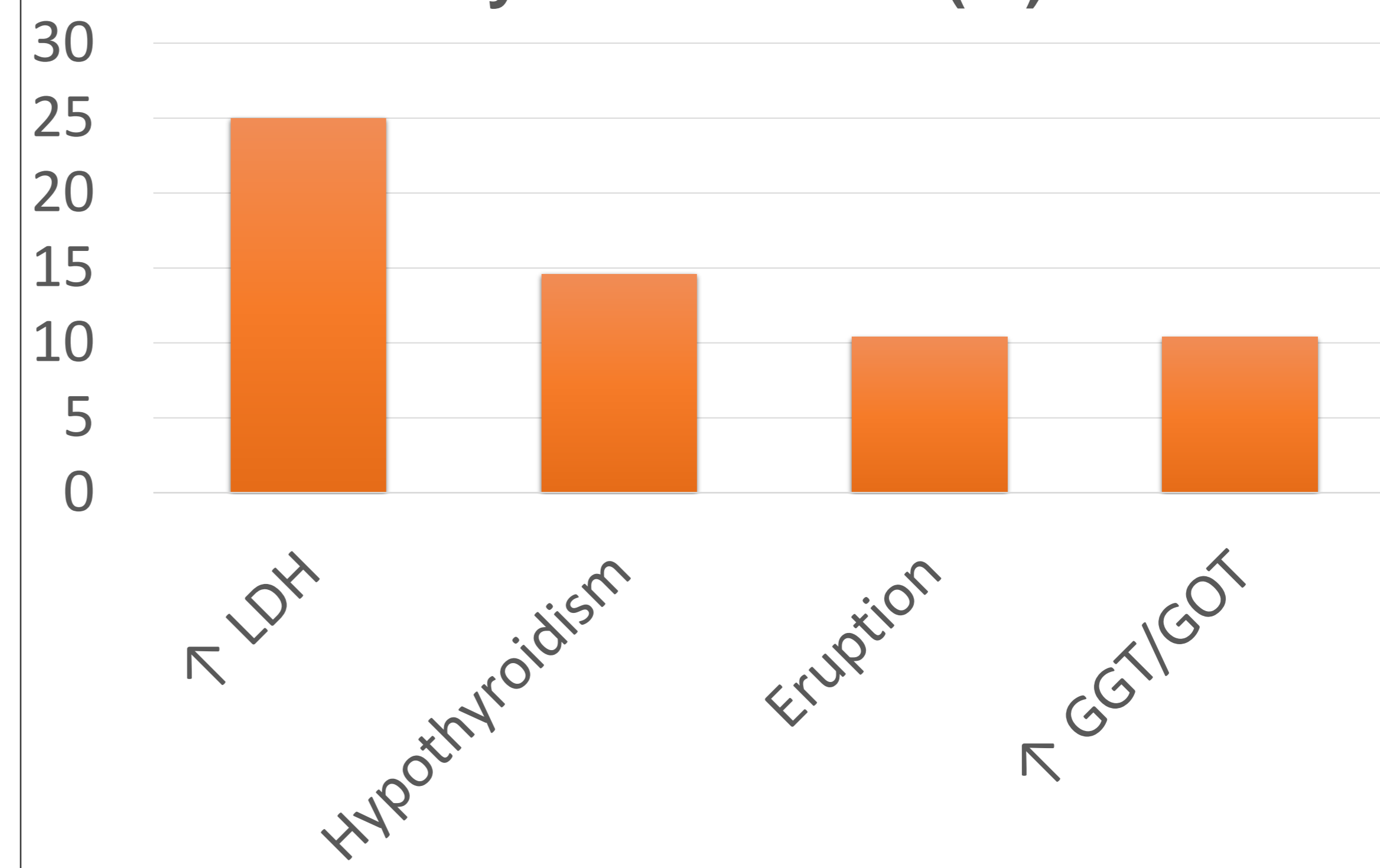
Reason to interrupt



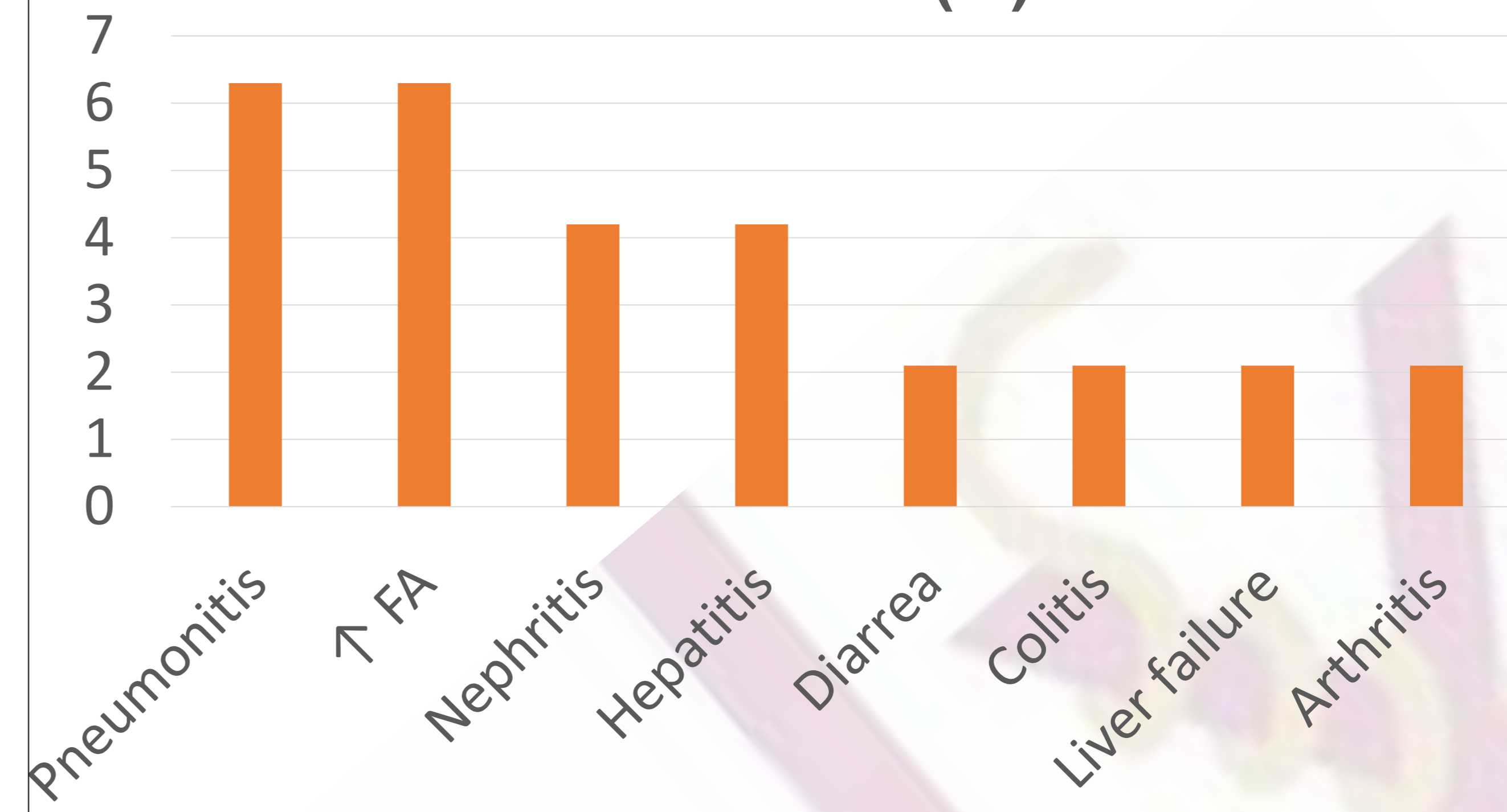
Deaths:

- 84,2% NSCLC
- 60% HNC
- 50% RCC
- 20% MC

Very common AE (%)



Common AE (%)



Prevalence of *hypothyroidism, colitis, hepatitis, nephritis* and *arthritis* is higher than the one reported in clinical trials.

