

# HOW MANY PATIENTS WITH HIGH-RESPONDING INHIBITORS DO / DID NOT UNDERGO IMMUNE TOLERANCE INDUCTION IN ITALY?

## WHY NOT ?



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### INTRODUCTION

Immune tolerance induction (ITI) is presently the only therapeutic approach able to eradicate inhibitors in haemophilia A patients and represents the first choice in children with recently onset inhibitors.

However, ITI is a highly demanding treatment and compliance and cost-utility evaluations may often influence clinical choices, particularly in adults.

A retrospective-prospective registry of ITI courses has been established by the Italian Association of Haemophilia Centres (AICE) since 2005.

### METHODS

In the frame of the Italian ITI Registry, participating Centres were asked to register all **high-responding (HR) inhibitor patients** followed between **1996 and 2009**.

For patients who did not undergo ITI, **reasons for clinical choices** were reported

### PATIENTS

**18/24 participating Centres provided data.**

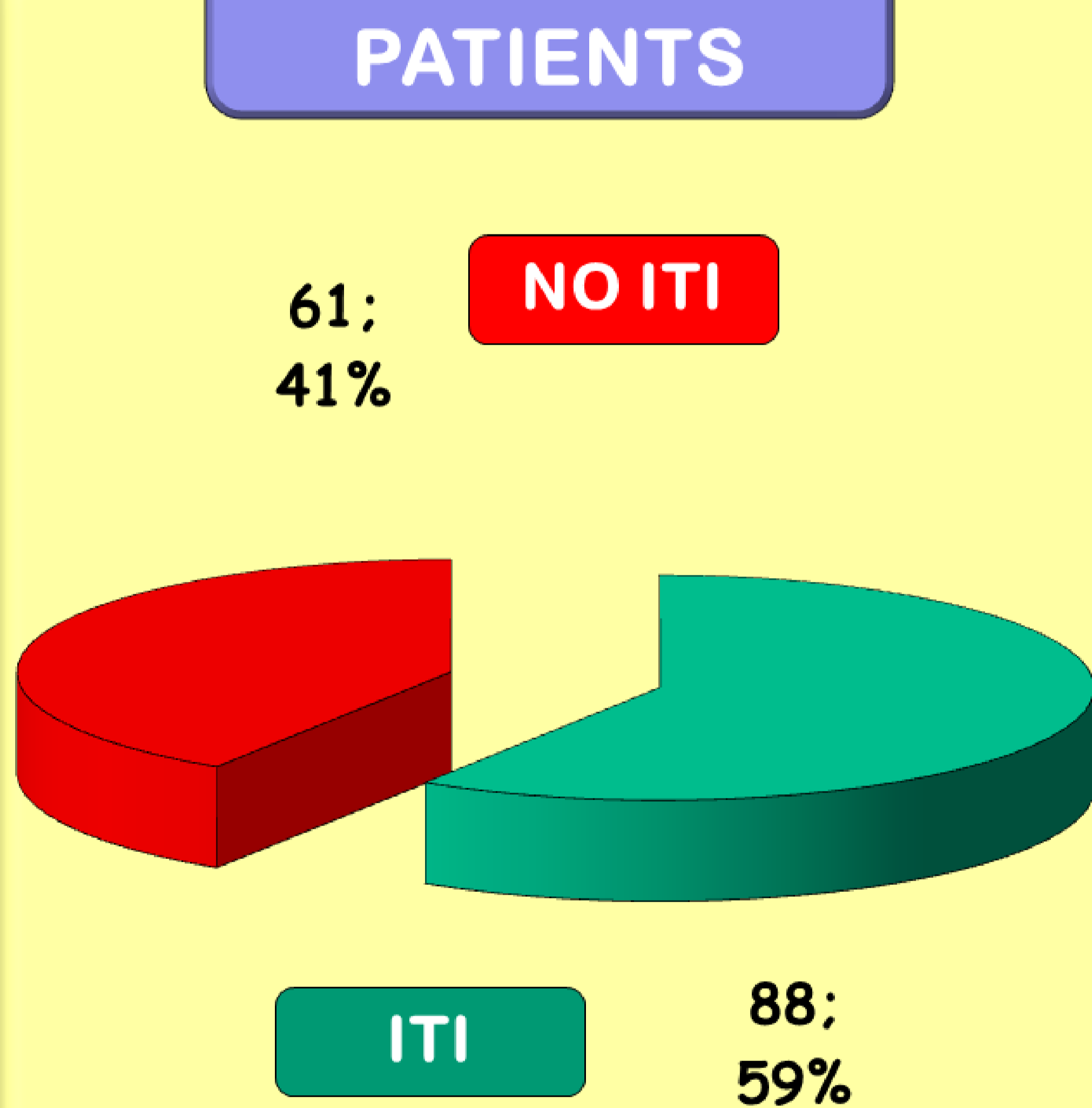
**149 HR inhibitor patients**

**140 severe haemophilia**

**Median age (range): 23 yrs (2-83)**

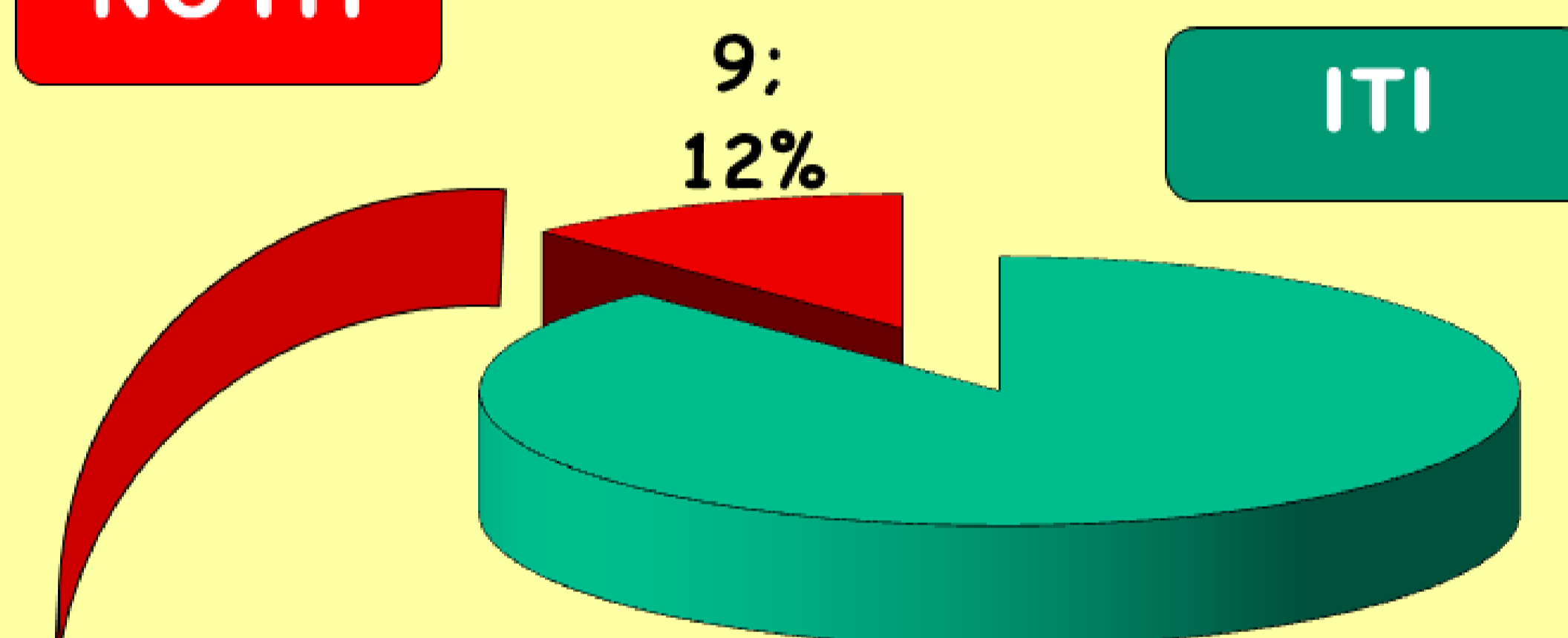
### RESULTS

#### ALL INHIBITOR PATIENTS



< 14 yrs: n=74

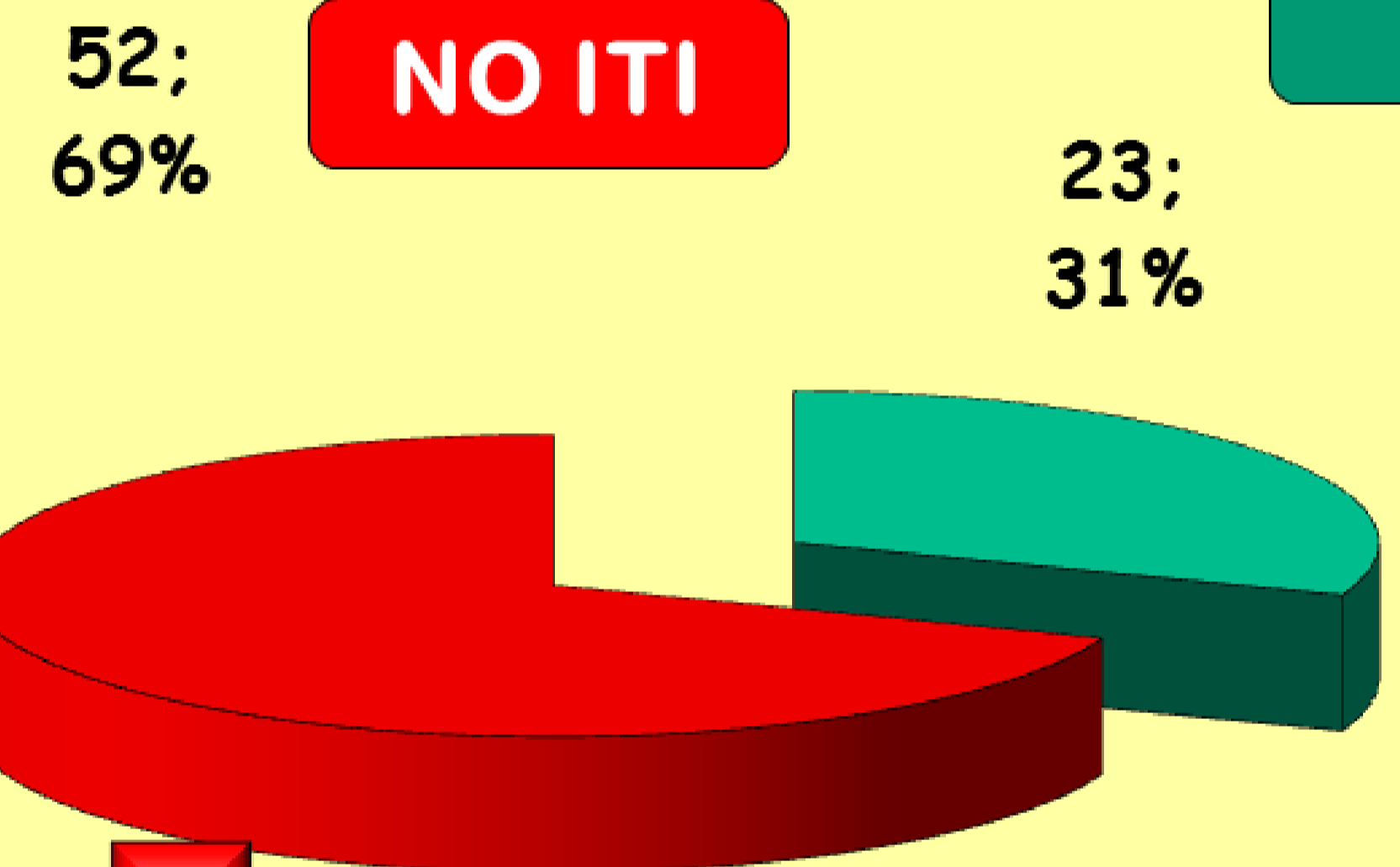
NO ITI



5 (56%) deferral because high inhibitor titre  
2 (22%) lack of consent  
2 (22%) concerns for poor adherence

> 14 yrs: n=75

NO ITI



21 (40%) perceived poor prognosis  
14 (27%) non-severe bleeding tendency  
16 (31%) lack of consent, concerns for poor adherence

6 (12%) had fatal bleeding

### CONCLUSIONS

Data from the Italian ITI registry confirm that ITI is attempted virtually in all compliant inhibitor children.

This choice currently applies to approximately 30% of patients with long-standing inhibitors.

Individual cost-utility and long-term prognostic evaluations, including the risk of severe and fatal bleeding, should be carefully considered in these patients.

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