

# Presentazione del Rapporto sui farmaci in Toscana 2019

CONVEGNO  
11 DICEMBRE 2019  
8.30 - 17.00

SALONE DELLE ROBBIANE  
VILLA LA QUIETE  
VIA DI BOLDRONE 2 - FIRENZE

Organizzato da ARS Toscana



Regione Toscana



In Toscana si osserva un  
ritardo nella diagnosi e  
l'inizio della terapia di  
prima linea delle  
malattie infiammatorie  
dell'intestino?

*Irma Convertino*, Pharm D, PhD student,

in Clinical and Translational Sciences

Division of Pharmacology and Pharmacovigilance,

Department of Clinical and Experimental Medicine,

University of Pisa



## ***BACKGROUND***

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- ✓ The IBD are a group of immuno-mediated inflammatory disease involving the gastrointestinal tract (ulcerative colitis and Crohn's disease)
- ✓ Gastrointestinal symptoms may occur before and after diagnosis
- ✓ Evidence suggests that the diagnostic delay is a common reality and it is caused by the difficulty in recognizing unspecific abdominal symptoms
- ✓ Timely diagnosis is therefore crucial for optimal management of patients with IBD

## **RESEARCH QUESTION**

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*Can we observe the phenomenon of diagnostic delay  
among IBD patients in Tuscany*



## ***OBJECTIVES***

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- ✓ **To explore the diagnostic delay in IBD Tuscan patients**
- ✓ **To describe the clinical impact of the diagnostic delay**



## ***METHODS: Study design***

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Data source

Study cohort

Study period

**Regional administrative healthcare  
databases**

**Index drug: the first prescription of oral budesonide OR mesalazine**  
**Index date: from January 1<sup>st</sup>, 2012 to December 31<sup>st</sup>, 2015**

**Look back: 5 years**

**Follow up: 3 years**

# ***METHODS: Study design***

**Regional administrative healthcare databases**

**Index drug: the first prescription of oral budesonide OR mesalazine**

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**Look back: 5 years**

**Follow up: 3 years**

**Anal surgeries**  
**Endoscopic evaluations**  
**Accesses to ED and hospitalizations for gastroenterological events**  
**Accesses to ED for gastroenterological events**

Data source

Study cohort

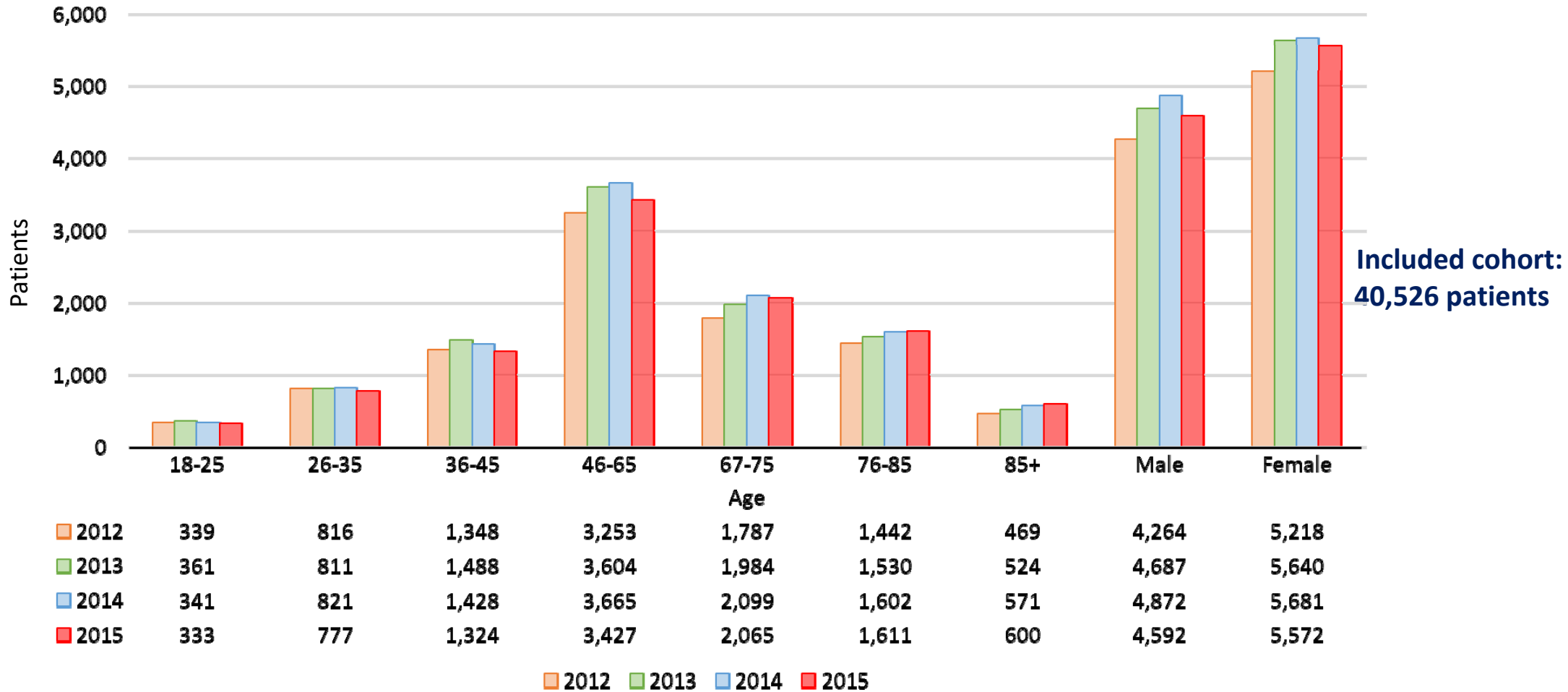
Study period

Covariates

# ***METHODS: Study design***



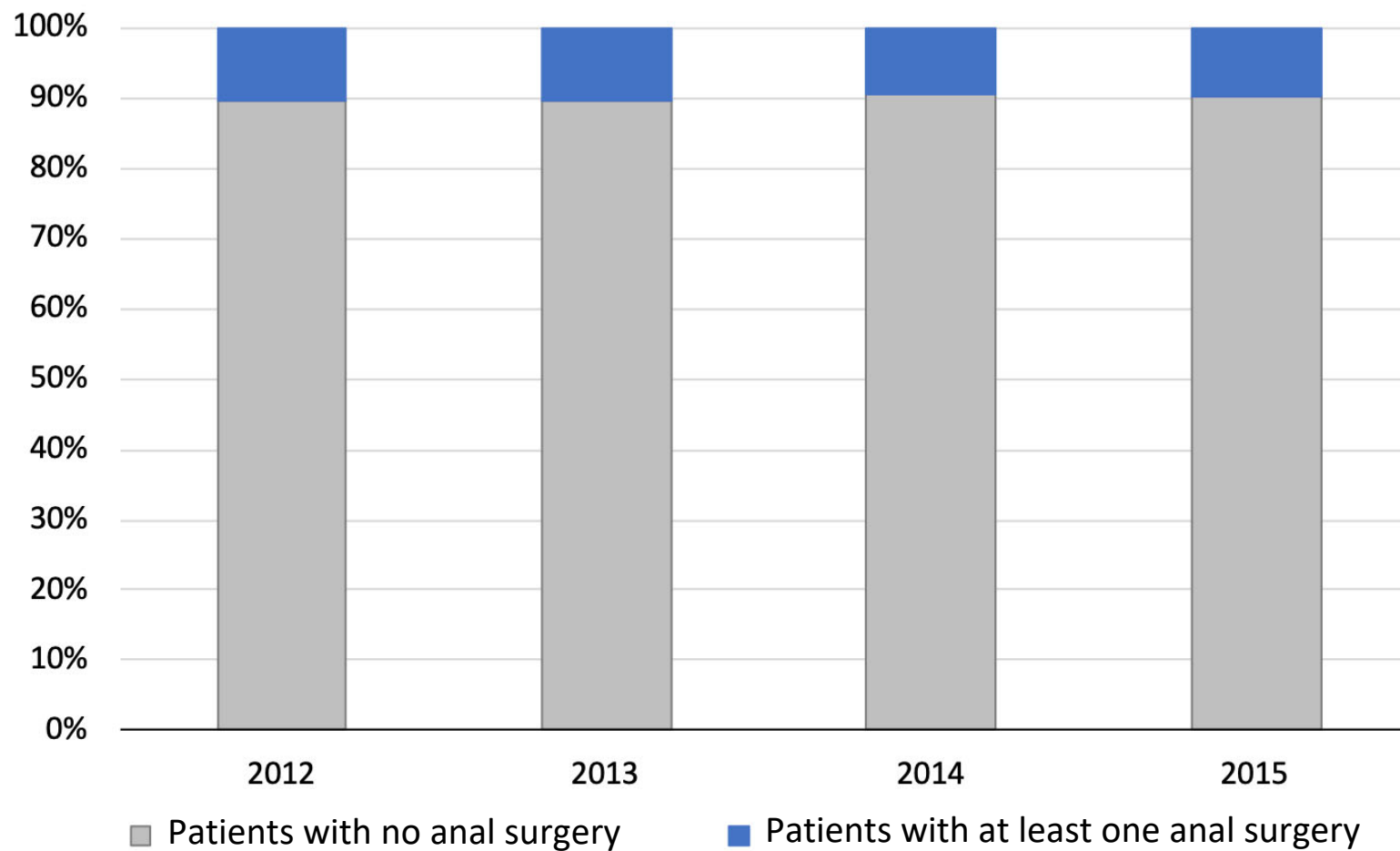
## RESULTS: characteristics of included patients





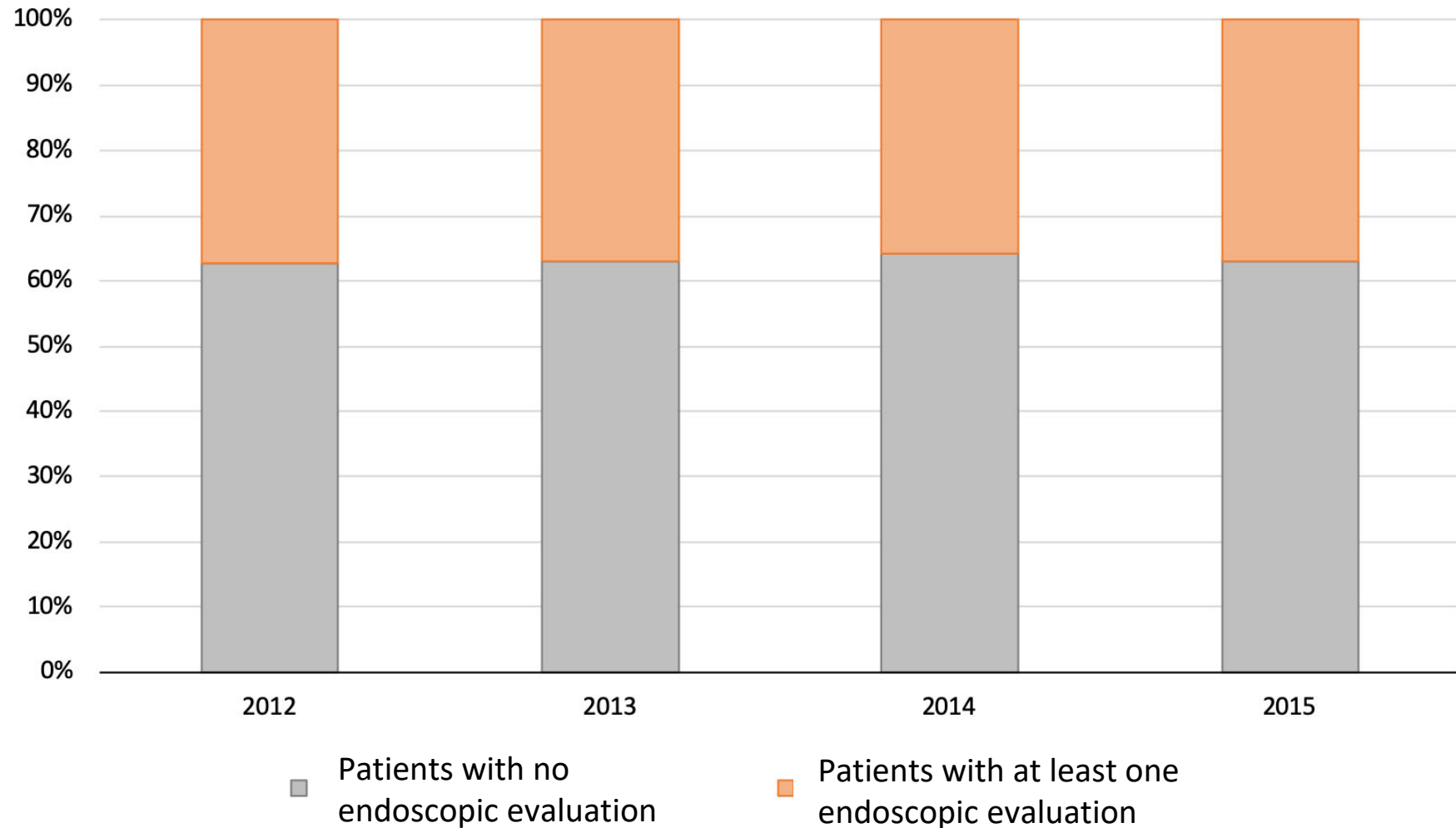
## ***RESULTS: anal surgeries***

**Distribution of patients with at least one anal surgery (%)**

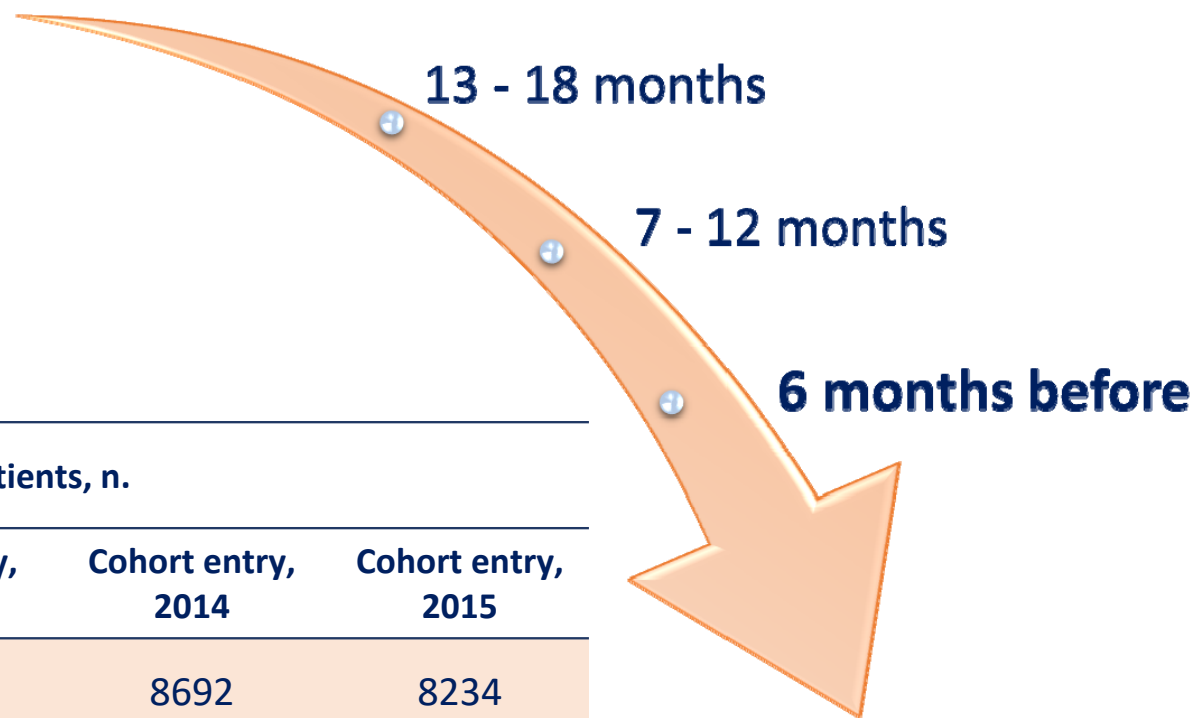


## ***RESULTS: endoscopic evaluations***

**Distribution of patients with at least one endoscopic evaluation (%)**

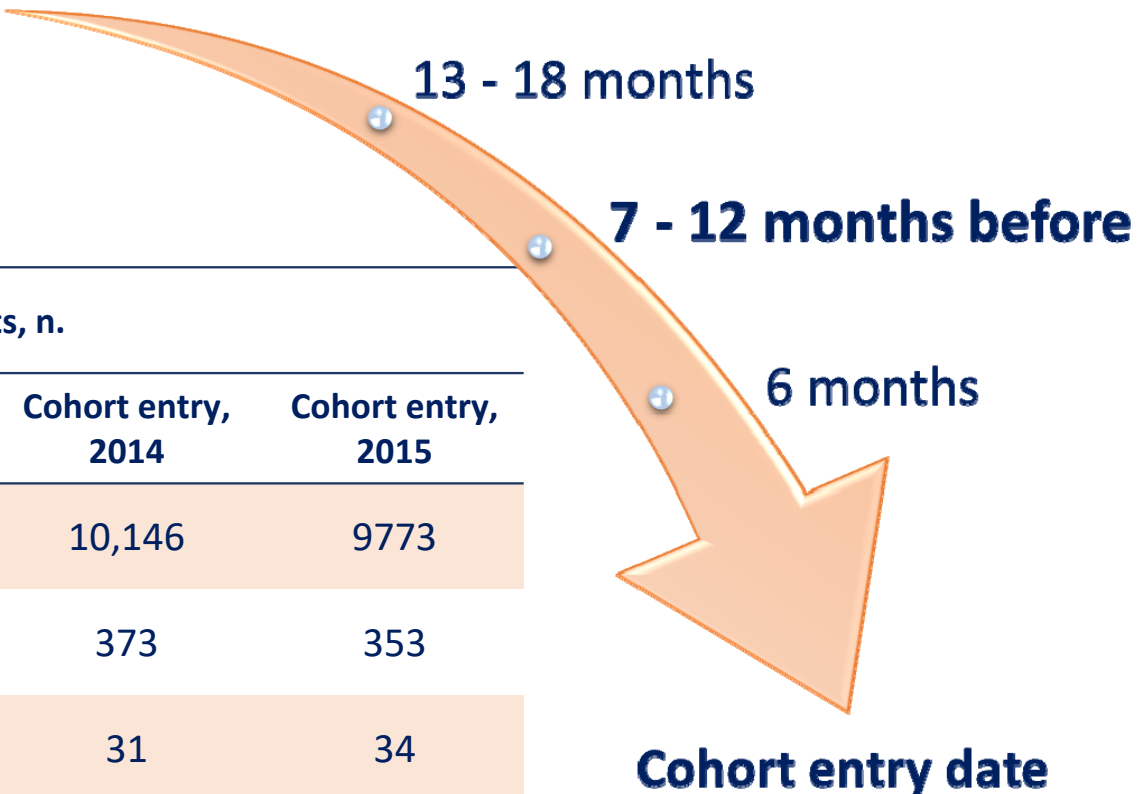


## **RESULTS: endoscopic evaluations**



Endoscopic evaluation, n.	Patients, n.			
	Cohort entry, 2012	Cohort entry, 2013	Cohort entry, 2014	Cohort entry, 2015
0	7710	8375	8692	8234
1	1598	1724	1682	1741
2	155	207	169	173
>3	19	21	10	16

## ***RESULTS: endoscopic evaluations***



Endoscopic evaluation, n.	Patients, n.			
	Cohort entry, 2012	Cohort entry, 2013	Cohort entry, 2014	Cohort entry, 2015
0	9125	9947	10,146	9773
1	320	342	373	353
2	29	35	31	34
>3	8	3	3	4

## ***RESULTS: endoscopic evaluations***

Endoscopic evaluation, n.	Patients, n.			
	Cohort entry, 2012	Cohort entry, 2013	Cohort entry, 2014	Cohort entry, 2015
0	9196	10,005	10,246	9866
1	264	302	278	282
2	20	18	29	13
>3	2	2	-	3

**13 - 18 months before**

**7 - 12 months**

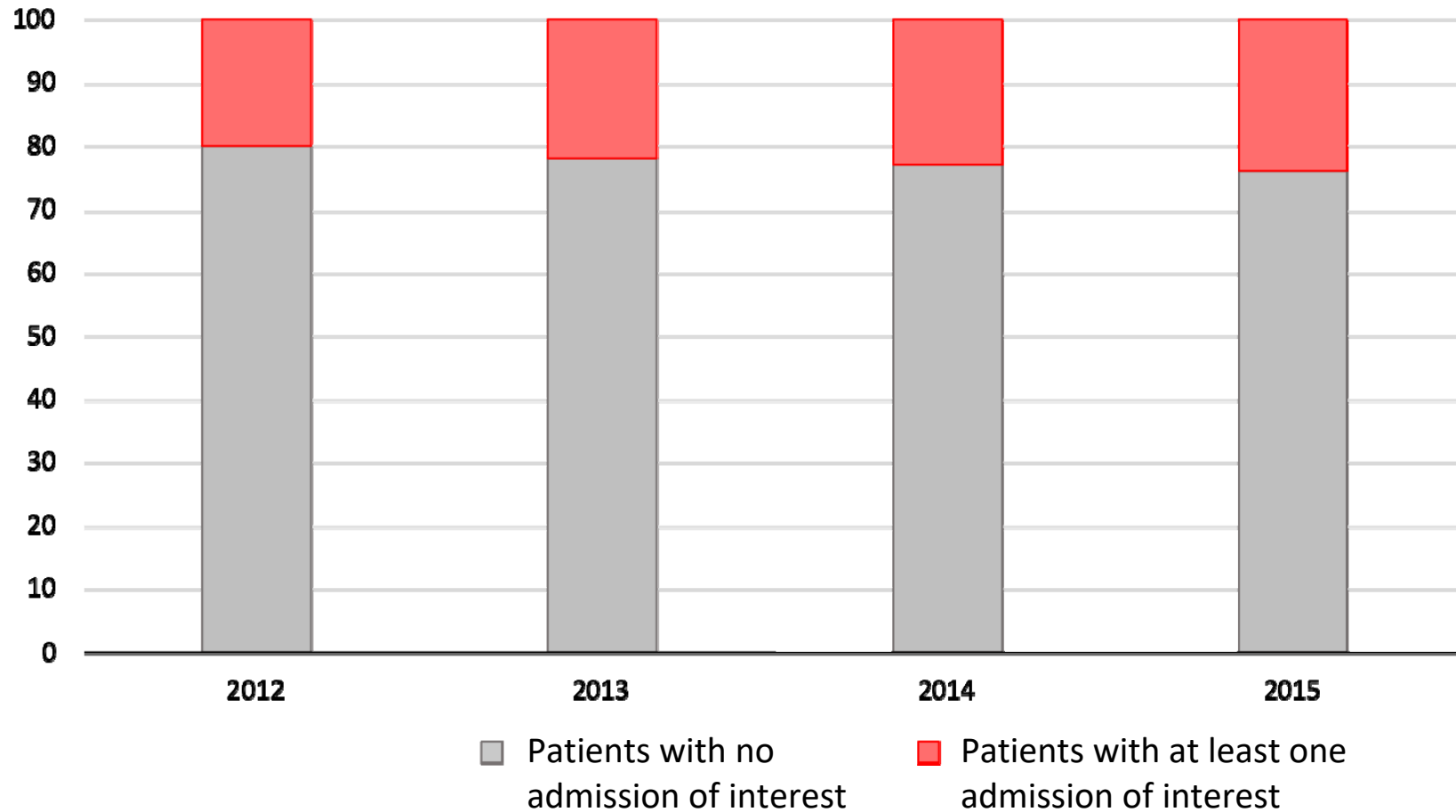
**6 months**

**Cohort entry date**



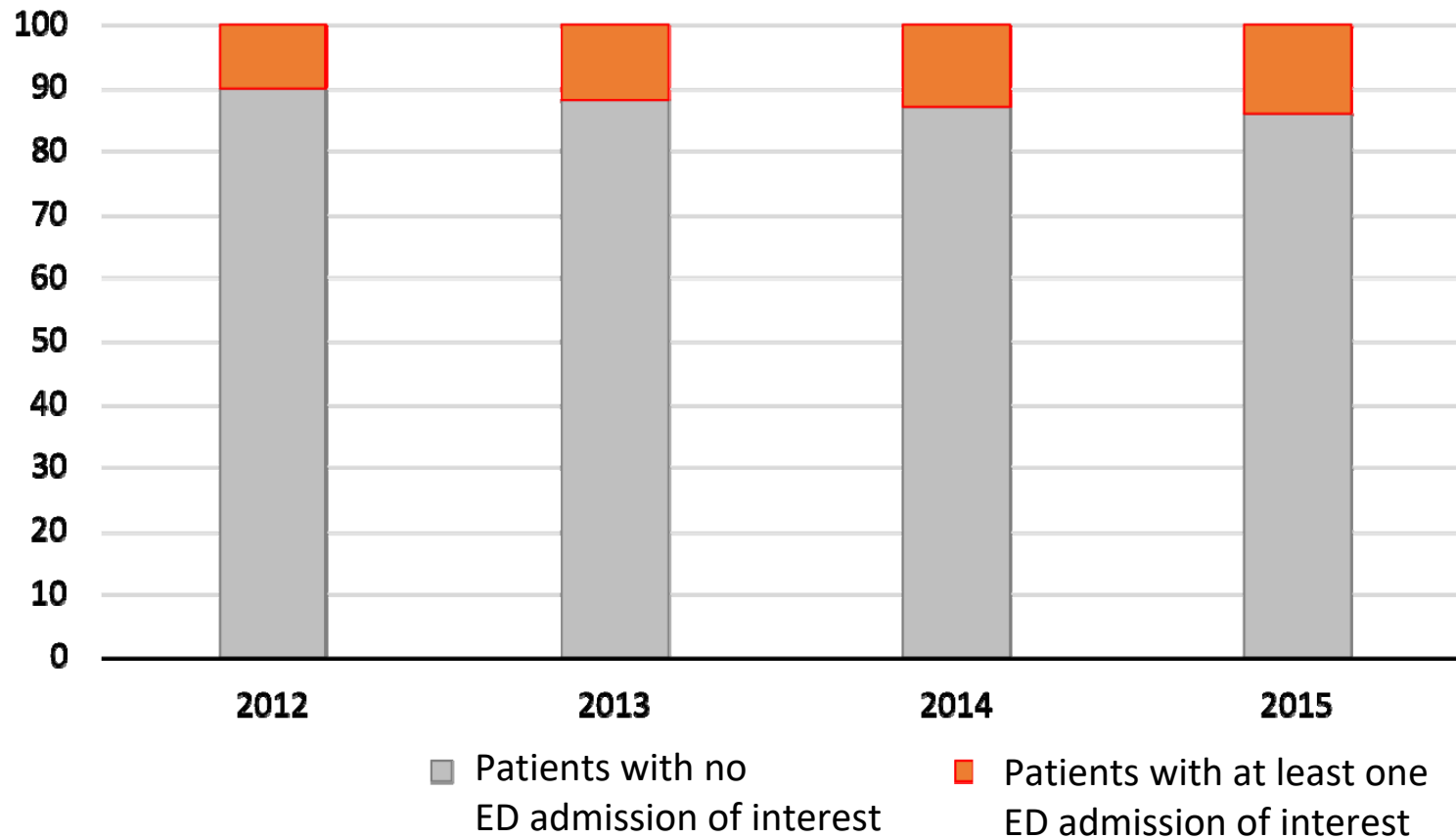
## ***RESULTS: hospital admissions for gastroenterological events***

**Distribution of patients with at least one Emergency Department admission or hospitalization for gastroenterological events (%)**



## ***RESULTS: Emergency Department admissions***

**Distribution of patients with at least one Emergency Department admission for gastroenterological events (%)**



## **RESULTS: Emergency Department admissions**

### 5 years before

- only 1 access: 9%-13% of patients
- 2 accesses: 1%-3% of patients
- 3 accesses: 0.4%-0.7% of patients

### 3 years before

- only 1 access: 9%-12% of patients
- 2 accesses: 1%-3% of patients
- 3 accesses: 0.4%-0.5% of patients

### 1 year before

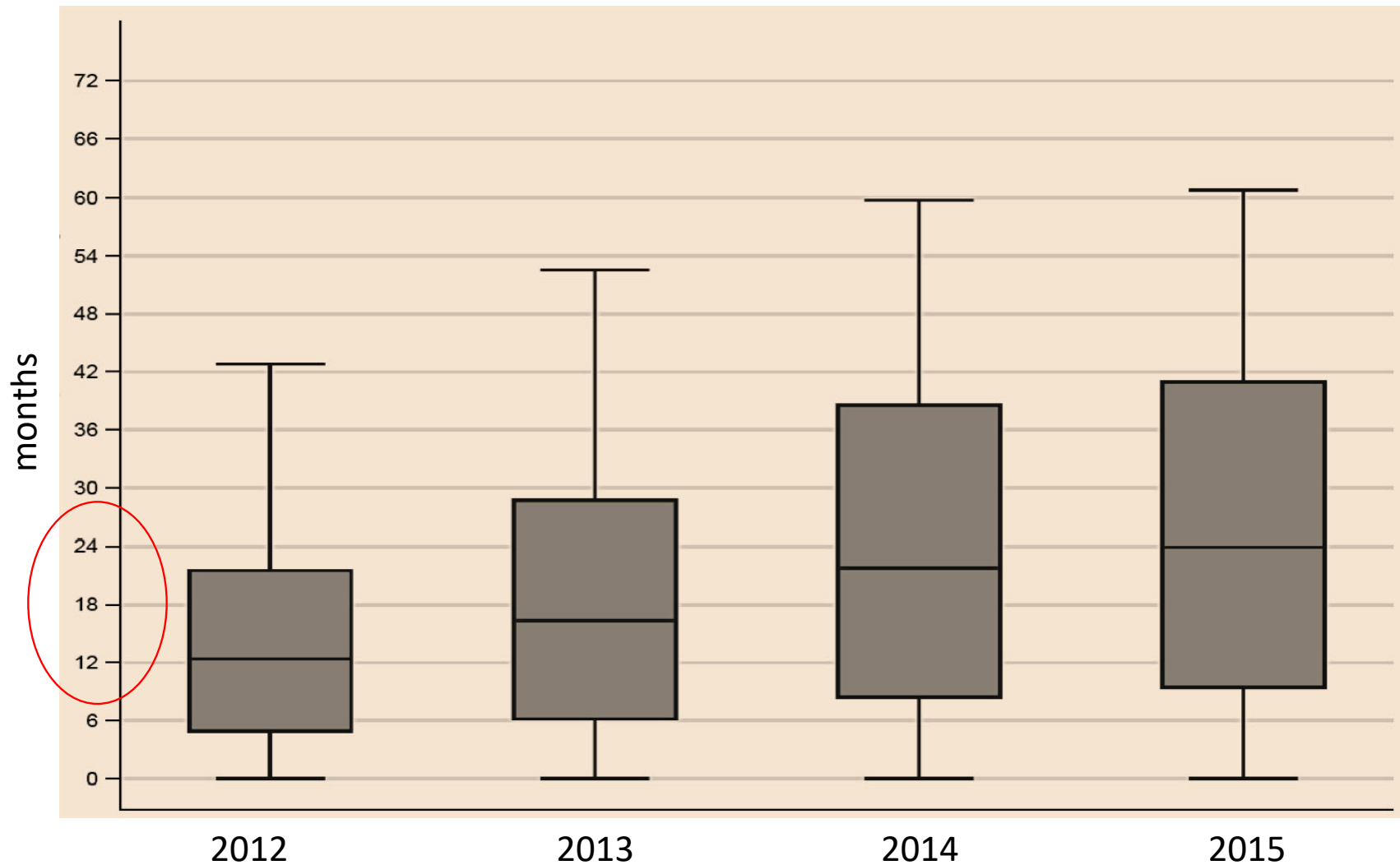
- only 1 access: 8%-10% of patients
- 2 accesses: 1%-1.5% of patients
- 3 accesses: <0.3% of patients

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***RESULTS: mean time to the first Emergency Department admission for gastrointestinal events***

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## ***DISCUSSION***

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- ✓ Out of the included patients, it was recorded at least one gastroenterological event **from 12 to 24 months** before the cohort entry
- ✓ However many limitations don't allow highlighting further conclusions, but they point out the need to re-designe the study, as regard:
  - selection criteria of patients
  - covariates
  - endpoints

## ***DISCUSSION: selection criteria of patients***

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### **✓ Actual:**

- the first prescription of budesonide and mesalazine

### **✓ Future:**

- at least three prescriptions of the index drugs
- the stratification of diagnostic delay in 0 - 6 months
- the stratification of patient exposure for single index drug



- Do the Tuscan Inflammatory Bowel Disease patients have history of gastroenterological events before IBD diagnosis?
- How long is this time period?
- What is its clinical impact?

*Prof. Blandizzi C.*

*Dott. Tuccori M .*

*Dott.ssa Ferraro S.*

*Dott.ssa Valdiserra G.*

*Dott. Cappello E.*

*Dott. Costa F.*

*Dott. Bertani L.*

***Thanks!***

*Dott.ssa Lucenteforte E.*

*Dott.ssa Gini R.*

*Dott.ssa Bartolini C.*

*... and you*