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Sessione

“Patologie cardiovascolari/Esercizio fisico”

Psychological effects of Apixaban in an elderly population. An insight from the multicenter, prospective, observational APULEIO Study

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Conflict of Interest

The Authors have no personal conflict of interest to declare about this presentation.

The APULEIO Study was, however, designed and conducted with the support of BMS / Pfizer.

Analysis of data was performed by MediNeos Observational Research.

The interpretation of the results, the drafting of the manuscript and the drawing of the figures and the slides were independently done by the Authors.

Introduction

- ✓ NOACs, because of their pharmacological **characteristics** and the favorable **risk-benefit profile** are the preferred choice for oral anticoagulant therapy (OAT)
- ✓ Some important questions still exist about NOACs therapy; among these, **adherence** is one of the most relevant
- ✓ **Patients reported outcomes** (PROs) - the individual interactions with disease and drug therapy - could help to improve treatment adherence
- ✓ Treatment effects on **quality of life** (HRQL) and **functional status** are relevant knowledge gaps in CV care of **older patients**
- ✓ Importantly, evidence on NOACs about these topics **are limited**

The primary objective of the APULEIO study was to evaluate the effects of apixaban on patients' satisfaction to therapy, HRQL and depressive symptoms in a real-world setting

Methods

- ✓ APULEIO was a **multicentre, prospective, observational**, two-cohort study including patients eligible to OAT for either **NVAF** or **DVT/PE**
- ✓ Italian participating centres – N=43; enrolment period: April 22nd, 2016 - January 31st, 2017
- ✓ Patients, **starting apixaban** treatment, were followed-up at **3** and **6** months
- ✓ The **Anti-Clot Treatment Scale** (ACTS) was used to assess patient satisfaction
- ✓ HRQL was evaluated with the 12-Item **Short Form Health Survey** (SF-12)
- ✓ Depressive symptoms were measured with the **Beck Depression Inventory-II** (BDI-II)
- ✓ Frailty and disability status were assessed with the **FIND questionnaire**

Clinical characteristics of the APULEIO study population

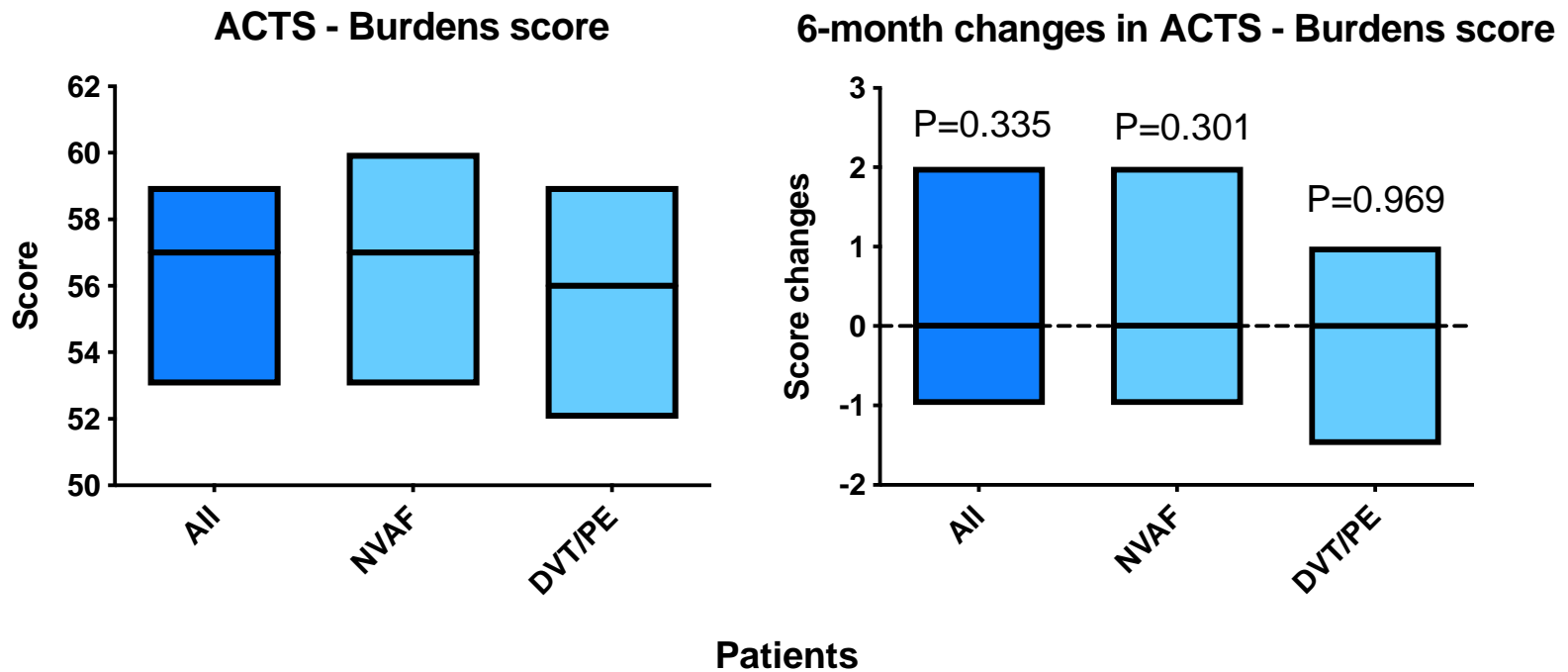
	All (N=371)	AF (N=285)	DVT/PE (N=86)	P
<u>Age (years)</u>	76 (70 - 82)	<u>76 (71 - 82)</u>	<u>71 (59 - 78)</u>	<0.0001
Men (N, %)	200 (53.9)	153 (53.7)	47 (54.7)	0.902
BMI (Kg/m ²)	27 (24.4 - 29.8)	27 (24.2 - 29.8)	26.9 (24.8 - 30)	0.702
<u>Disease length (m)</u>	1.5 (0.8 - 30.8)	<u>1.9 (0.8 - 42.9)</u>	<u>0.9 (0.7 - 2.0)</u>	0.0002
CHA ₂ DS ₂ -VASc (score)	/	4.0 (3.0 - 5.0)	/	/
HASBLED (score)	/	2.0 (1.0 - 3.0)	/	/
<u>Comorbidities (N, %)</u>	328 (88.4)	<u>270 (94.7)</u>	<u>58 (67.4)</u>	<0.0001
<u>CCI (score)</u>	1 (0 - 2)	<u>1 (0 - 2)</u>	<u>0 (0 - 1)</u>	0.0105

Continuous variables are expressed as median and interquartile range.

Comorbidities: patients with at least one comorbid condition; **CCI:** Charlson Comorbidity Index; **Disease length (m):** disease length in months

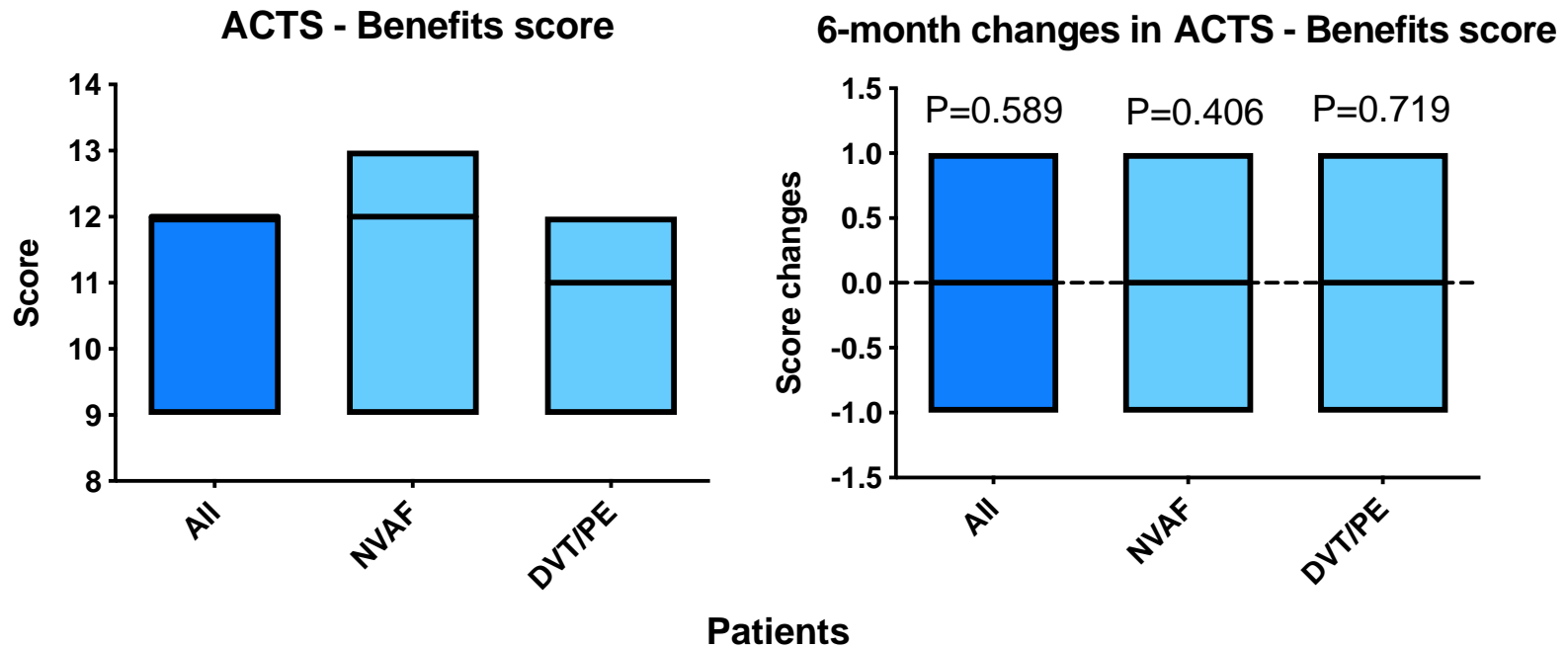
Daily dosage of apixaban: 10 mg (IQR(10;10))

Three-month ACTS Burdens scores in the APULEIO patients by indication to OAT (left), and their changes at the 6-month follow-up visit (right). Boxes indicate the median with the 25th and the 75th percentile



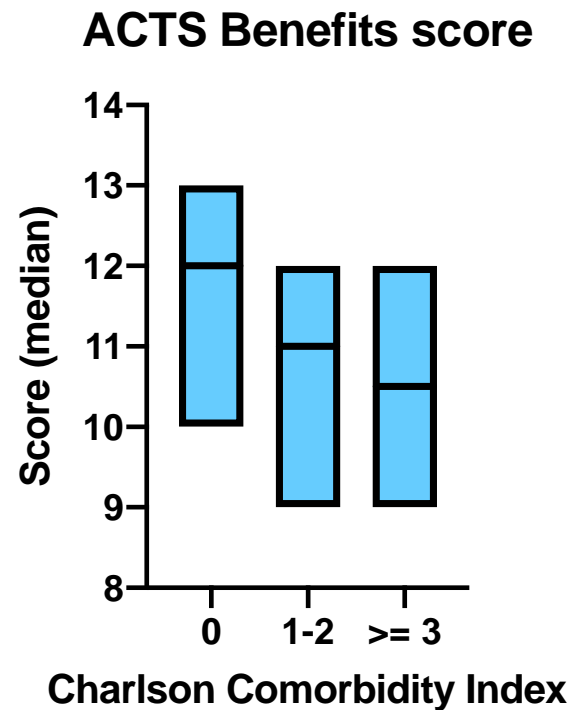
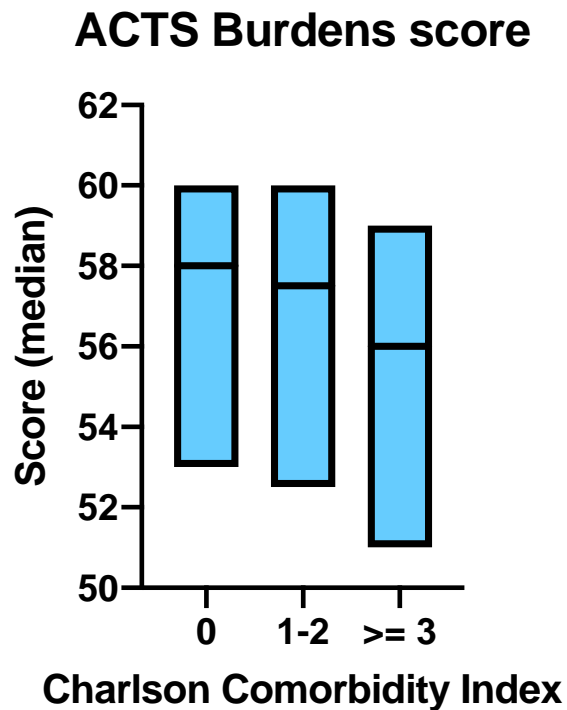
P is for the difference between the 6- and the 3-month values of each group of patients

Three-month ACTS Benefits scores in the APULEIO patients by indication to OAT (left), and their changes at the 6-month follow-up visit (right). Boxes indicate the median with the 25th and the 75th percentile



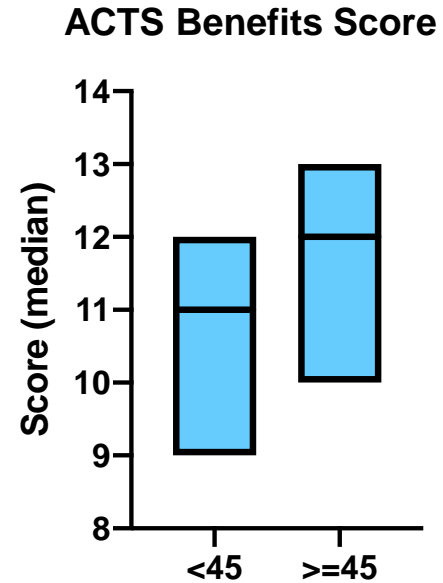
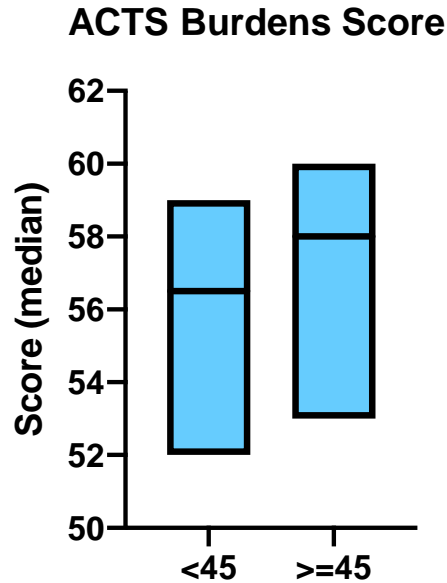
P is for the difference between the 6- and the 3-month values of each group of patients

Six-month ACTS Burdens and Benefits scores by Charlson Comorbidity Index in all APULEIO patients

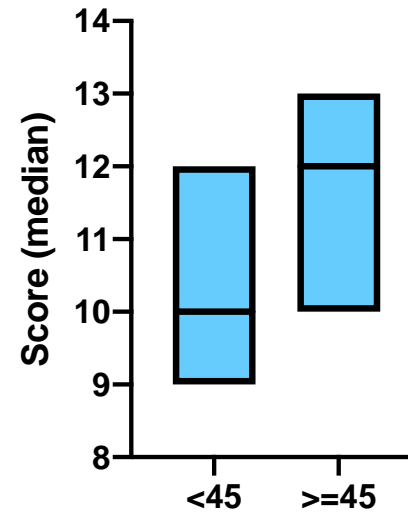
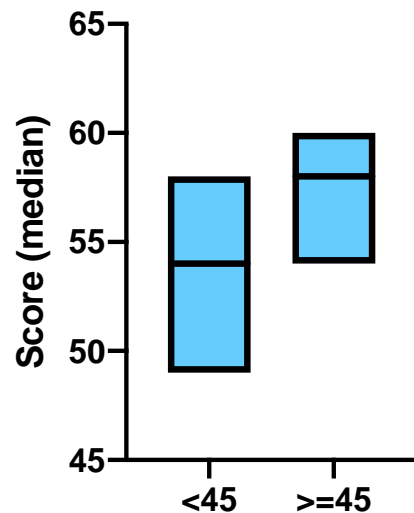


Six-month ACTS Burdens and Benefits scores by SF-12 Physical and Mental Health composite scores groups in all APULEIO patients

Physical Health Composite Score

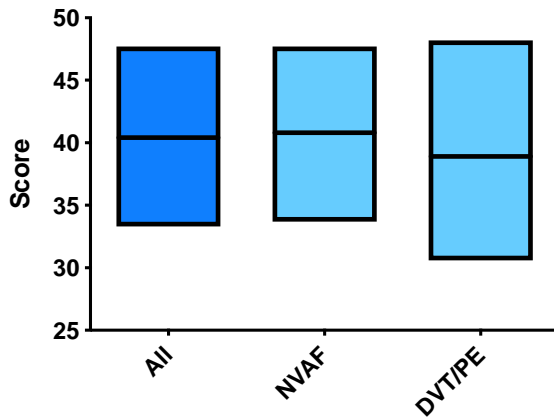


Mental Health Composite Score

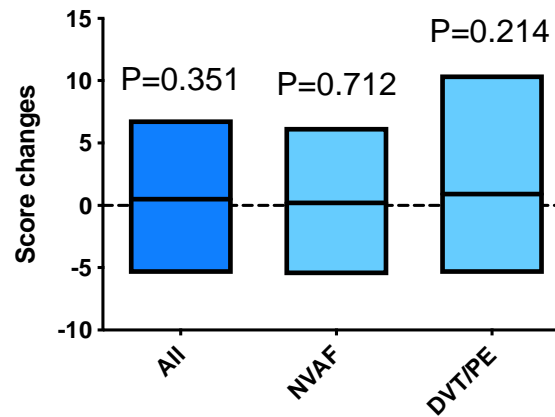


Baseline SF-12 Physical composite scores with their changes at the 3- and at the 6-month follow-up visits. Boxes indicate the median with the 25th and the 75th percentile

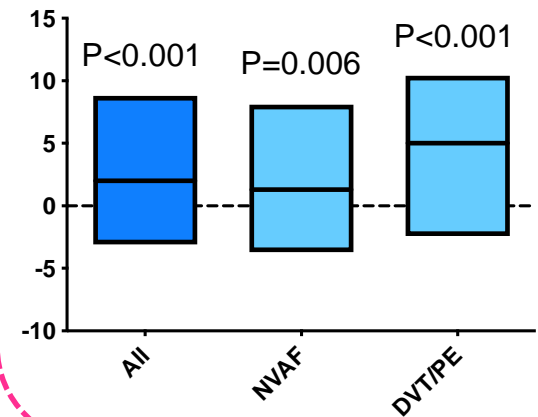
Baseline SF-12 – Physical Health composite score (CS)



SF-12 – Physical Health CS: 3-month changes



SF-12 – Physical Health CS: 6-month changes

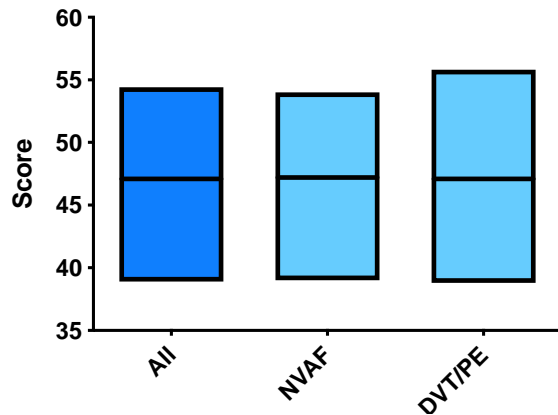


Patients

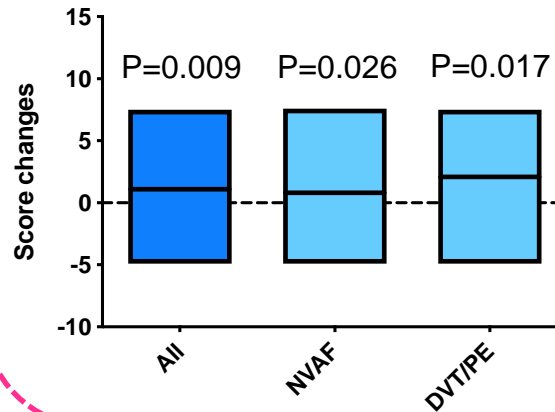
P is for the difference between baseline and the 3- or the 6-month values of the SF-12 score by group

Baseline SF-12 Mental composite scores with their changes at the 3- and at the 6-month follow-up visits. Boxes indicate the median with the 25th and the 75th percentile

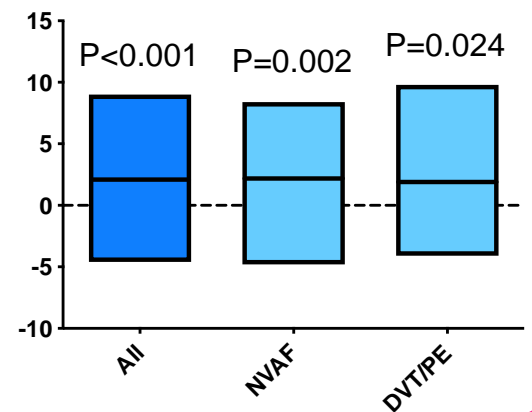
Baseline SF-12 – Mental Health composite score (CS)



SF-12 – Mental Health CS: 3-month changes



SF-12 – Mental Health CS: 6-month changes

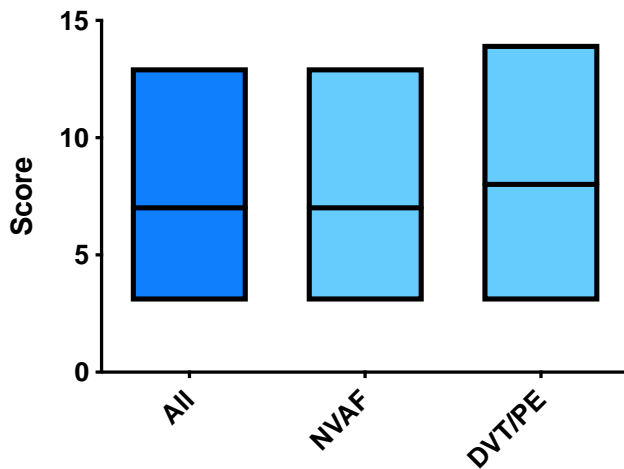


Patients

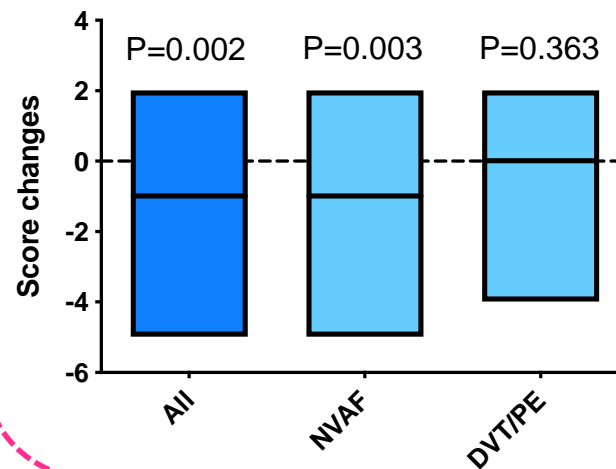
P is for the difference between baseline and the 3- or the 6-month values of the SF-12 score by group

Baseline BDI-II General Depression symptoms intensity scores with their changes at the 3- and at the 6-month follow-up visits. Boxes indicate the median with the 25th and the 75th percentile

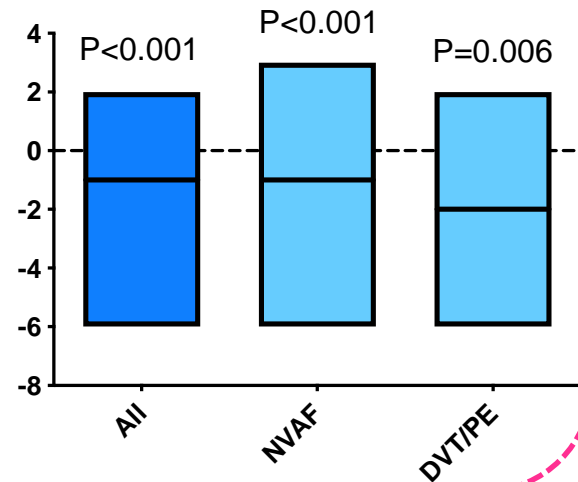
Baseline BDI-II – General Depression symptoms intensity score



BDI-II – 3-month changes



BDI-II – 6-month changes



Patients

P is for the difference between baseline and the 3- or the 6-month values of the BDI-II score by group

Conclusions

- ✓ The APULEIO study, aimed at evaluating PROs - still now relatively unexplored with apixaban - seem to strengthen the evidence of the efficacy of the drug also in this new perspective
- ✓ For the first time, and independently of the indication, it was shown that after 6 months of treatment, the drug is not associated with the compromise of patients' satisfaction
- ✓ Some differences in response exist due to the presence of comorbidities and baseline HRQL
- ✓ Importantly, with therapy, HRQL improves and the burden of depressive symptoms reduces
- ✓ Further studies are needed to confirm our findings, and to verify the existence of a similar behavior among the other oral anticoagulants