Tavola Rotonda: evoluzione nella gestione dell'IPF

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La media dei pazienti è in normo/sovrappeso alla diagnosi

Baseline characteristics by weight loss ≤5% and >5% over 52 weeks

	Weight loss ≤5%		Weight loss >5%	
	Nintedanib (n=409)	Placebo (n=338)	Nintedanib (n=226)	Placebo (n=83)
Age, years, mean (SD)	66.0 (8.1)	66.4 (8.1)	67.7 (8.0)	69.0 (6.3)
Male, n (%)	338 (82.6)	276 (81.7)	166 (73.5)	57 (68.7)
Weight, kg, mean (SD)	79.2 (16.2)	79.5 (16.4)	79.4 (17.2)	75.5 (16.6)
BMI, kg/m^2, mean (SD)	27.9 (4.4)	27.8 (4.5)	28.5 (4.9)	26.9 (4.7)
Race, n (%)				
White	229 (56.0)	198 (58.6)	131 (58.0)	49 (59.0)
Asian	127 (31.1)	102 (30.2)	64 (28.3)	25 (30.1)
Black	0	0	2 (0.9)	0
Missing*	53 (13.0)	38 (11.2)	29 (12.8)	9 (10.8)
Time since diagnosis, years, mean (SD)	1.6 (1.4)	1.5 (1.3)	1.7 (1.4)	1.7 (1.3)

*In France, regulation did not permit the collection of data on race.

- Poster to be presented by Bruno Crestani at the European Respiratory Society Congress, Madrid, Spain, 28 September–2 October 2019

La perdita di peso è associata a maggiori effetti collaterali GI (NS); alta prevalenza anche nei placebo di perdita di peso

Adverse events in subgroups by weight loss ≤5% and >5% over 52 weeks

	Weight loss ≤5%		Weight loss >5%	
	Nintedanib (n=409)	Placebo (n=338)	Nintedanib (n=226)	Placebo (n=83)
Adverse events	388 (94.9)	299 (88.5)	219 (96.9)	79 (95.2)
Most frequent adverse events*				
Diarrhoea	220 (53.8)	56 (16.6)	172 (76.1)	22 (26.5)
Progression of IPF†	34 (8.3)	41 (12.1)	29 (12.8)	20 (24.1)
Dyspnoea	21 (5.1)	38 (11.2)	28 (12.4)	10 (12.0)
Nausea	90 (22.0)	19 (5.6)	66 (29.2)	9 (10.8)
Pneumonia	24 (5.9)	17 (5.0)	9 (4.0)	9 (10.8)
Nasopharyngitis	47 (11.5)	57 (16.9)	40 (17.7)	11 (13.3)
Decreased appetite	27 (6.6)	12 (3.6)	41 (18.1)	12 (14.5)
Cough	56 (13.7)	46 (13.6)	29 (12.8)	11 (13.3)
Bronchitis	45 (11.0)	33 (9.8)	22 (9.7)	12 (14.5)
Vomiting	42 (10.3)	9 (2.7)	32 (14.2)	2 (2.4)
Upper respiratory tract infection	39 (9.5)	35 (10.4)	19 (8.4)	7 (8.4)
Abdominal pain	33 (8.1)	8 (2.4)	23 (10.2)	2 (2.4)
Weight decreased	18 (4.4)	3 (0.9)	44 (19.5)	12 (14.5)

←??!!

Data are n (%) of patients with ≥1 such adverse event reported over 52 weeks plus a 4-week post-treatment follow-up period. *Adverse events by MedDRA preferred term reported in ≥10% of patients in ≥1 of the subgroups shown. †Corresponds to MedDRA term 'IPF', which included disease worsening and acute exacerbations.

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La maggiore età all'inizio della terapia è associata a **maggiori effetti indesiderati GI**

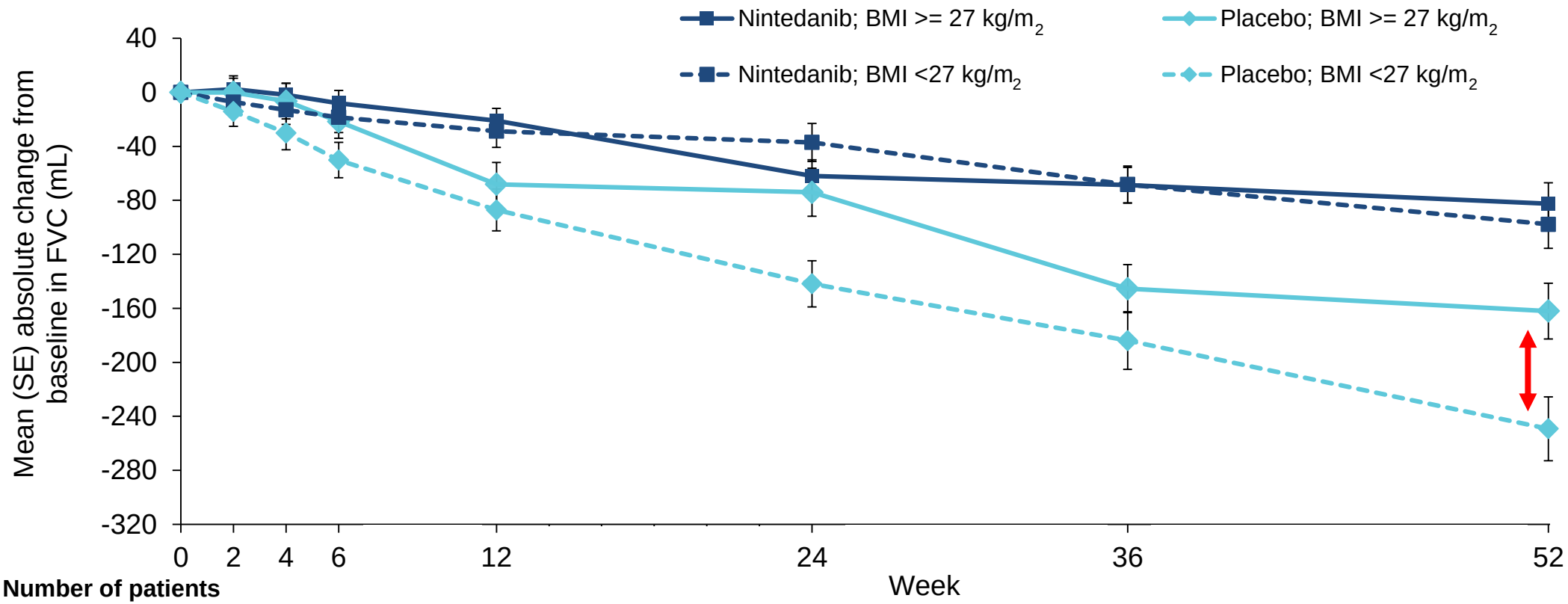
Adverse events leading to treatment discontinuation by age <75 versus ≥75 years at baseline

	Age <75 years		Age ≥75 years	
	Nintedanib (n=717)	Placebo (n=647)	Nintedanib (n=178)	Placebo (n=148)
Adverse events leading to treatment discontinuation	115 (16.0)	70 (10.8)	47 (26.4)	18 (12.2)
Most frequent adverse events leading to treatment discontinuation*				
Diarrhoea	30 (4.2)	1 (0.2)	12 (6.7)	0
Progression of IPF†	14 (2.0)	28 (4.3)	4 (2.2)	2 (1.4)
Nausea	13 (1.8)	0	6 (3.4)	0
Decreased appetite	8 (1.1)	1 (0.2)	4 (2.2)	1 (0.7)

Data are n (%) of patients with ≥1 such event. *Adverse events leading to treatment discontinuation in >2% of patients in any of these subgroups are shown.
†Corresponded to MedDRA term 'IPF', which included disease worsening and acute exacerbations of IPF.

IL PESO CORPOREO ALL'INIZIO DELLA TERAPIA NON CONDIZIONA L'ANDAMENTO FUNZIONALE

Change from baseline in FVC (mL) over 52 weeks by baseline BMI below and at least the median

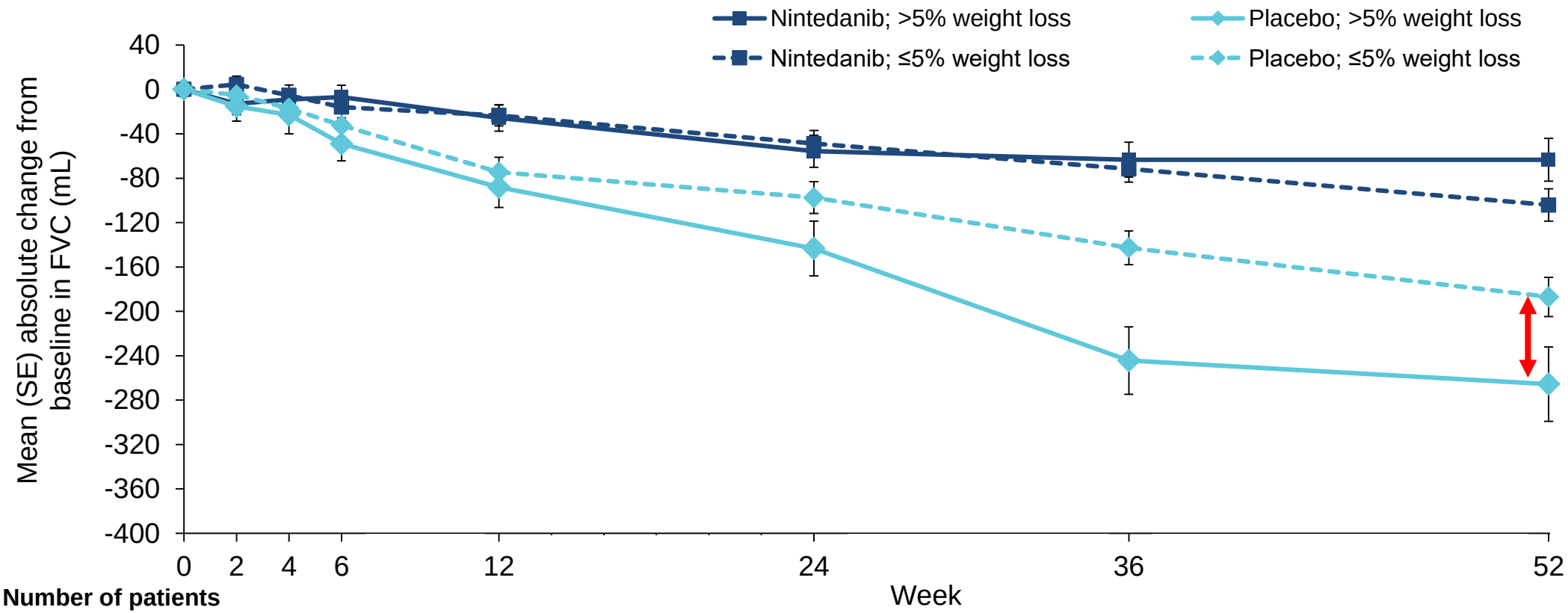


Number of patients								
BMI ≥27 kg/m²								
Nintedanib	360	352	348	345	348	338	327	300
Placebo	215	212	207	207	209	203	201	183
BMI <27 kg/m²								
Nintedanib	278	274	268	268	256	249	242	219
Placebo	208	205	201	200	194	192	182	162

- Poster to be presented by Stéphane Jouneau at the European Respiratory Society Congress, Madrid, Spain, 28 September–2 October 2019

LA PERDITA DI PESO **NON** INFLUENZA L'EVOLUZIONE FUNZIONALE *(AD 1 ANNO)*

Change from baseline in FVC (mL) in subgroups by weight loss ≤5% and >5% over 52 weeks



Number of patients								
>5% weight loss								
Nintedanib	226	226	224	221	220	219	213	195
Placebo	83	82	81	81	82	82	79	70
≤5% weight loss								
Nintedanib	409	400	392	392	384	368	356	324
Placebo	338	335	327	326	321	313	304	275

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32 pazienti che eseguivano esame BIA dopo il riscontro di perdita di peso (> 5%): tendenza alla MN : 13 pz. (40%) MN: 3 (9%)

Grafico 4.2a - *Variazione del peso corporeo dal periodo antecedente il trattamento e durante il follow up nel periodo di trattamento con Pirfenidone (Esbriet).*

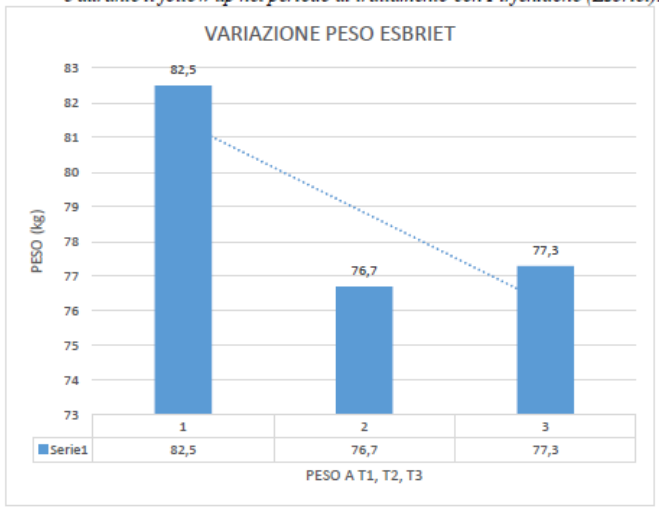


Grafico 4.2b - *BMI a confronto dal periodo antecedente la terapia e durante il follow up dopo inizio con Pirfenidone (Esbriet).*

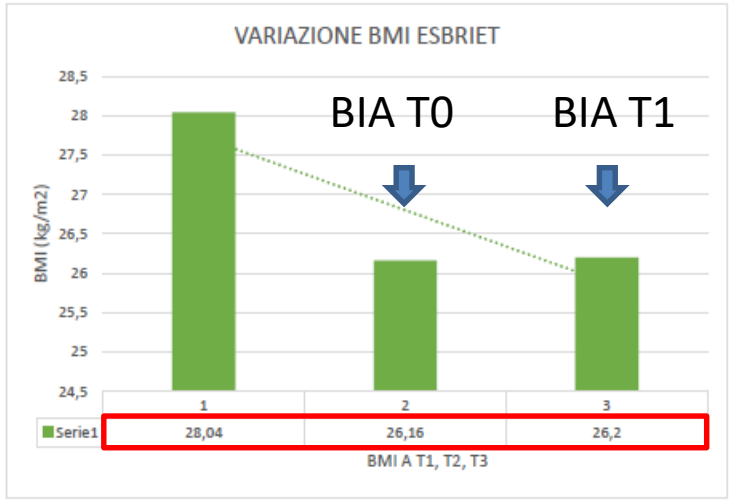


Grafico 4.3a- *Variazione del peso corporeo dal periodo antecedente il trattamento e durante il follow up nel periodo di trattamento con Nintedanib (Ofev) .*

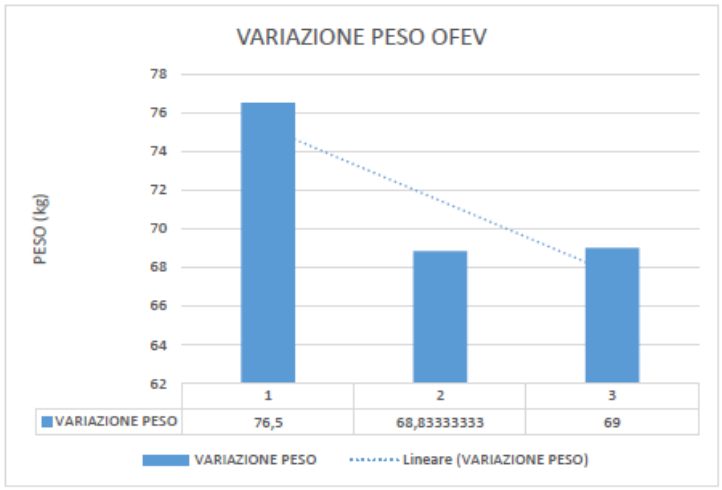
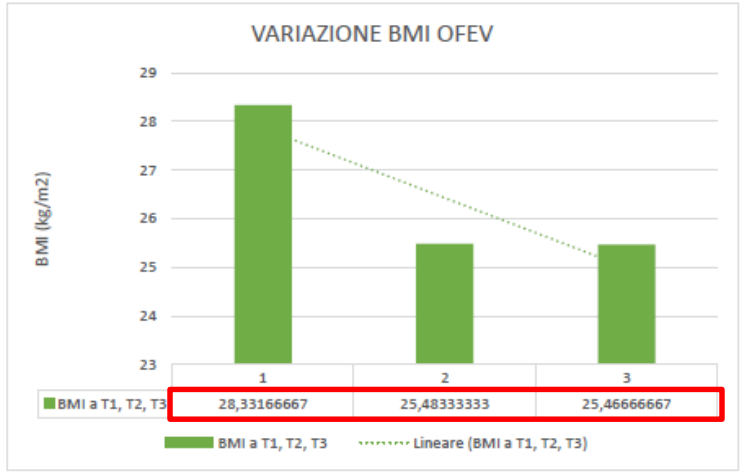
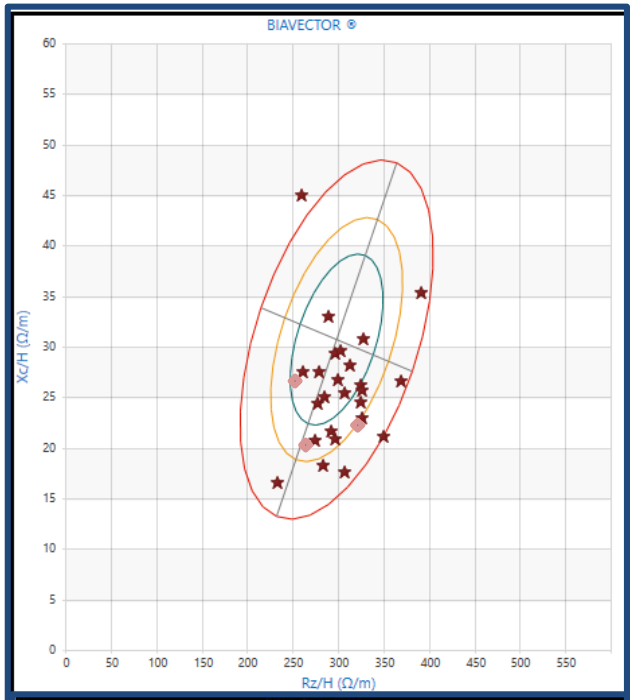
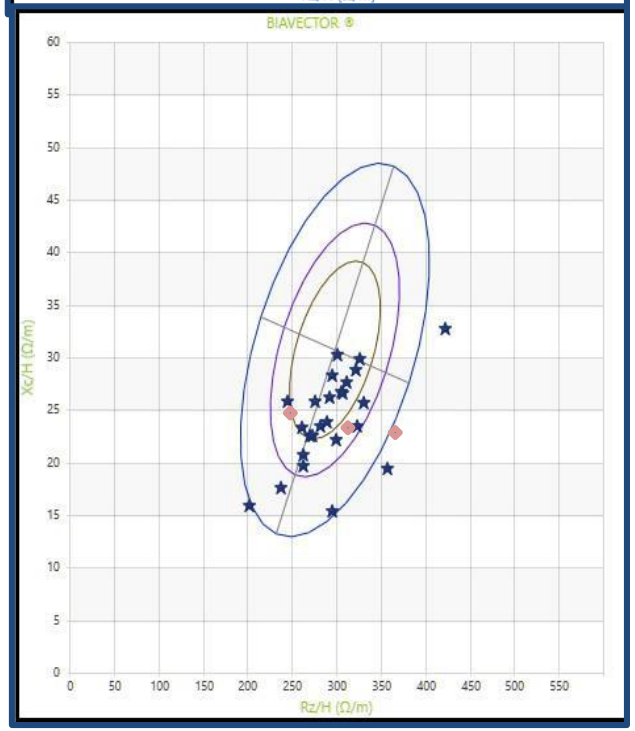


Grafico 4.3b - *BMI a confronto dal periodo antecedente la terapia e durante il follow up dopo inizio con Nintedanib (Ofev).*



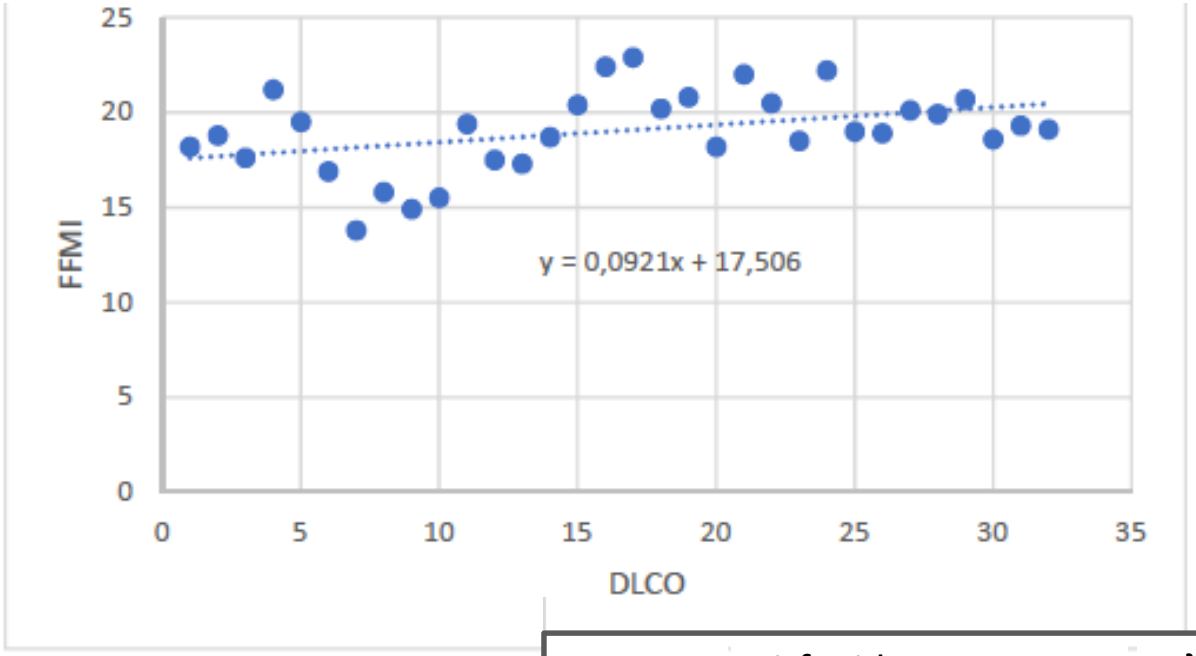


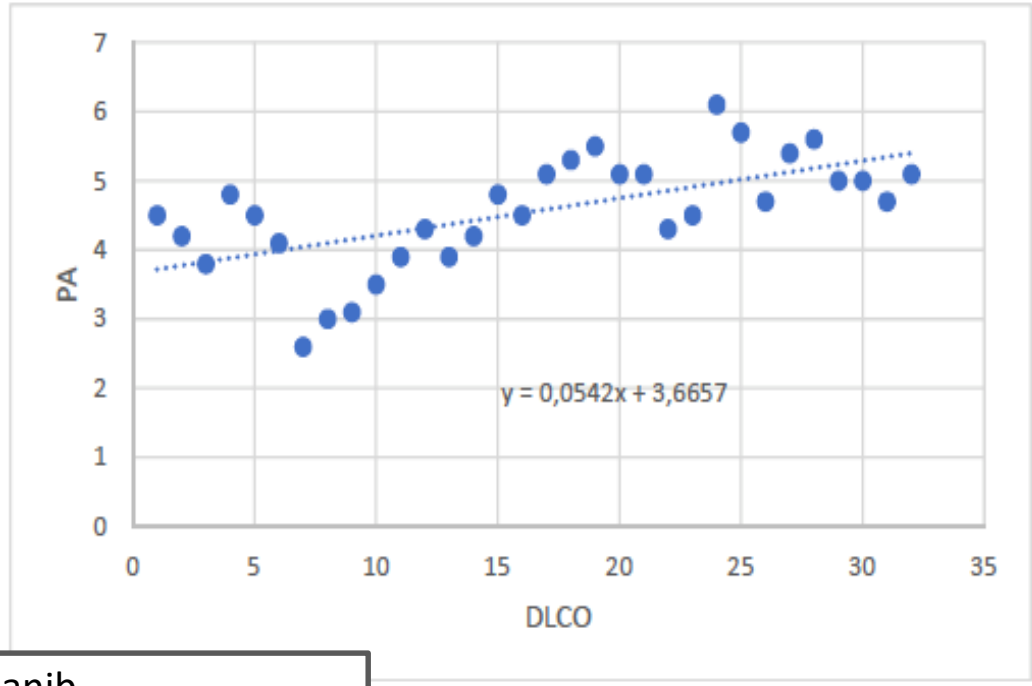
T0

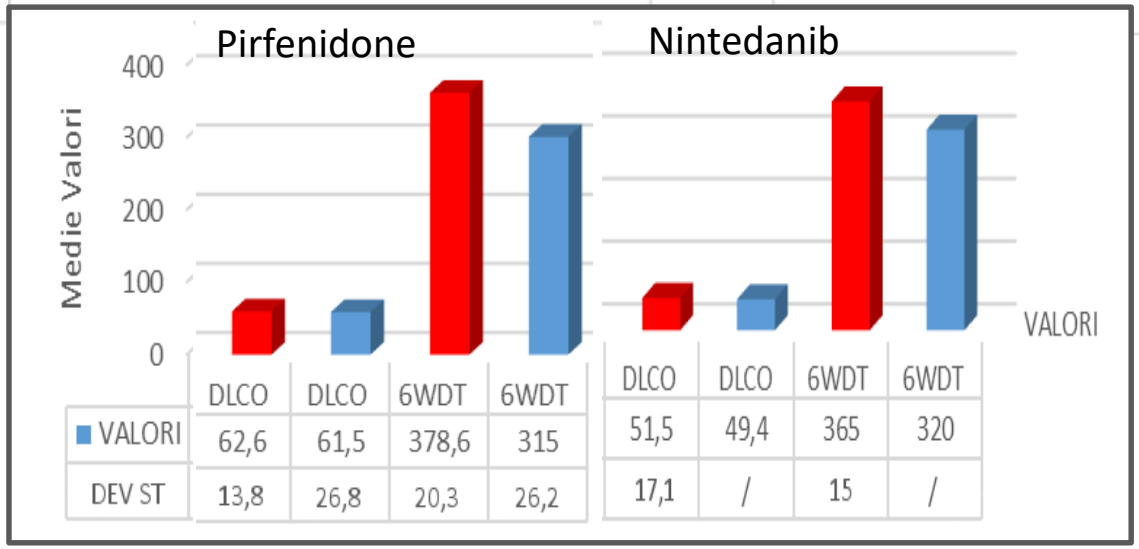


T1
(6mesi)

La perdita di massa magra (in termini di ridotto FFMI e Angolo di fase), e non il BMI, correla con la riduzione della capacità di diffusione (a T0: riscontro di calo ponderale);







I pazienti MN hanno una significativa minore capacità di esercizio (p<05) rispetto ai NN