SZPITAL UNIWERSYTECKI
im. Karola Marcinkowskiego
w Zielonej Górze Sp.zo.o.

Rak gruczołu krokowego - dane z kongresu ESMO 2021

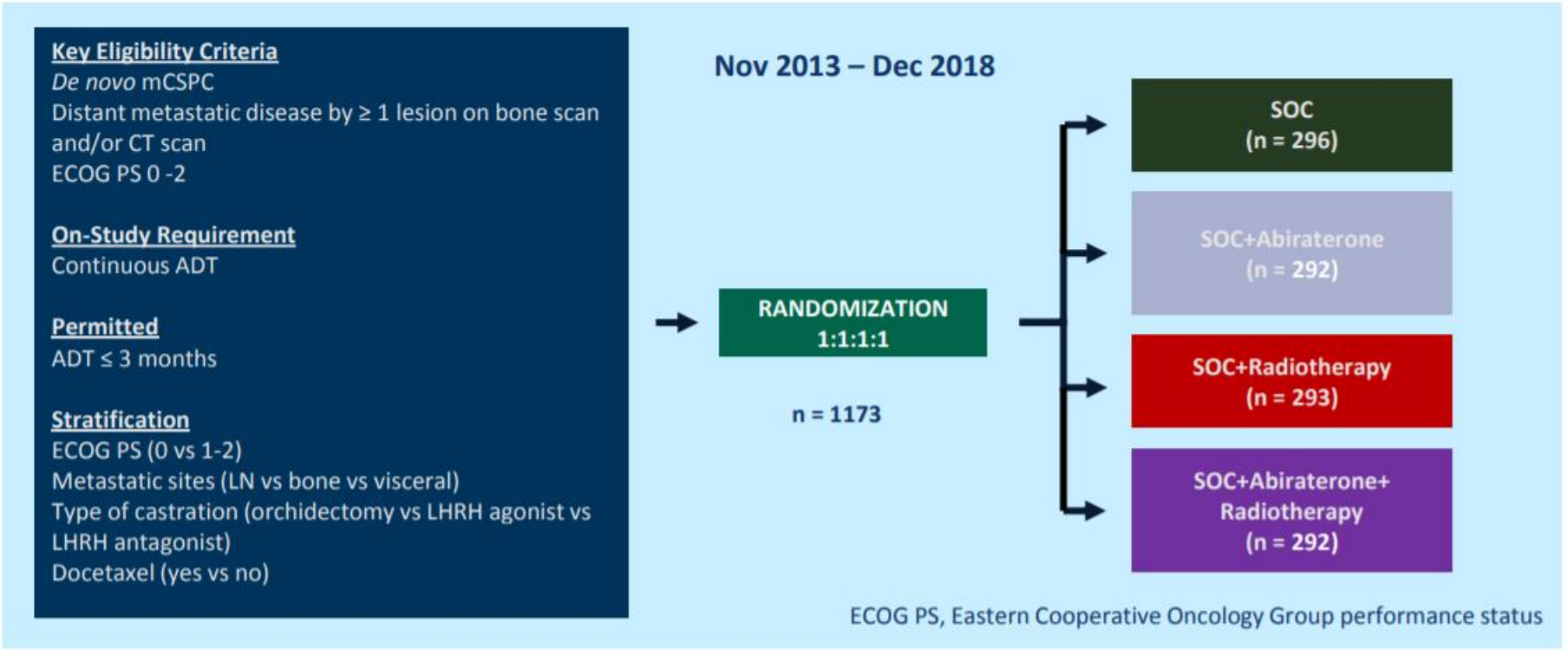
BB-PL
INTERREG V A
2014-2020

„Redukować bariery - wspólnie wykorzystywać silne strony /
Barrieren reduzieren – gemeinsame Stärken nutzen”

Unia Europejska
Europejski Fundusz
Rozwoju Regionalnego

ESMO 2021: Badanie fazy 3 u mężczyzn z rakiem gruczołu krokowego wrażliwym na kastrację z przerzutami de novo: całkowite przeżycie z octanem abirateronu plus prednizonem w badaniu PEACE-1

Design of PEACE-1 (2x2)



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PEACE-1

- ZASTOSOWANE TERAPIE:
- 1. standardowa ADT
- +/- 6x DxL 75mg/m2
- - 2013 - 2015 – sama deprywacja androgenowa
- - 2015 - 2017 - możliwe dodanie DXL
- - 2017 - 2018 - obowiązkowe dodanie DXL
-
- 2. Eksperymentalna
- - abirateron (+ 6x DXL) - do progresji lub nieakceptowalnej toksyczności
- - RT 74 Gy/37fr

- SOC – standard od care

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Charakterystyka pacjentów:

Patient characteristics (ADT+docetaxel population)

		SOC (+/- RXT) + Abiraterone (n = 355)	SOC (+/- RXT) (n = 355)
Median age, year (IQR)		66 (60–70)	66 (59–70)
ECOG PS score, n (%)	0 1-2	250 (70) 105 (30)	246 (69) 109 (31)
Gleason score at initial diagnosis, n (%)	≤ 7 ≥ 8	79 (23) 270 (77)	71 (21) 276 (79)
Median time from diagnosis, month (IQR)		2.2 (1.6-3.0)	2.2 (1.4-2.9)
Metastatic sites, n (%)	Lymph nodes only Bone without visceral Visceral	27 (8) 287 (81) 41 (12)	29 (8) 279 (79) 47 (13)
Disease burden, n (%)	Low High	131 (37) 224 (63)	123 (35) 232 (65)
Median baseline PSA, ng/mL (IQR)		13.7 (2.4-58.9)	12.0 (3.0-59.9)
Docetaxel, n (%)	Yes No	355 (100) 0 (0)	355 (100) 0 (0)

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Toksyczność:

Grade 3-5 Toxicity on study treatments (ADT+docetaxel safety population)

Toxicity, n (%)	SOC (+/- RXT) + Abiraterone (n=346)	SOC (+/- RXT) (n=350)
Neutropenia	34 (10)	32 (9)
Febrile neutropenia	18 (5)	19 (5)
Liver	20 (6)	2 (1)
Hypertension	76 (22)	45 (13)
Hypokalemia	11 (3)	1 (0)
Cardiac	6 (2)	5 (1)
Fatigue	10 (3)	15 (4)
Gastro-intestinal	14 (4)	18 (5)
Grade 5	7 (2)	3 (1)

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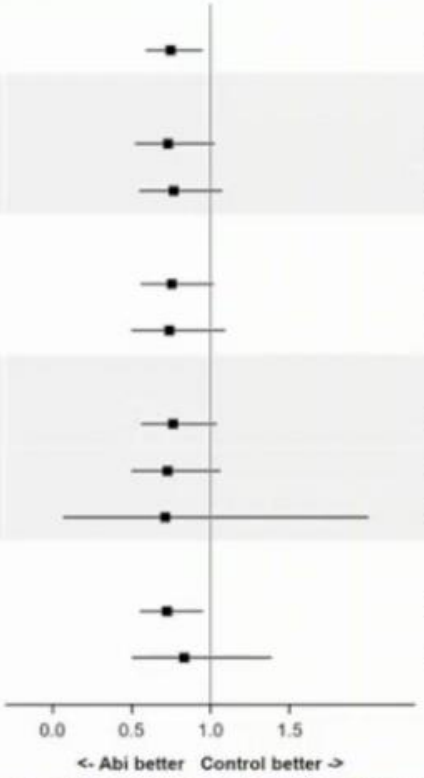
Analiza podgrup:

Subgroup analysis of OS: Abiraterone effect ADT+docetaxel (+/-RXT) population

Subgroup	N Events/N Pts Abi	N Events/N Pts Control	Hazard Ratio	Hazard Ratio	pvalue
Overall	121/355	151/355		0.75 [0.59-0.95]	
Radiotherapy					0.85
No				0.73 [0.52-1.03]	
Yes				0.76 [0.54-1.07]	
Performance Status					0.93
0	76/250	93/246		0.75 [0.56-1.02]	
1-2	45/105	58/109		0.74 [0.50-1.09]	
Type of castration					0.98
LHRH agonist	72/219	88/222		0.76 [0.56-1.04]	
LHRH antagonist	47/134	62/132		0.73 [0.50-1.06]	
Surgical castration	2/ 2	1/ 1		0.71 [0.06-7.91]	
Metastatic burden					0.64
High	92/224	120/232		0.72 [0.55-0.95]	
Low	29/131	31/123		0.83 [0.50-1.38]	



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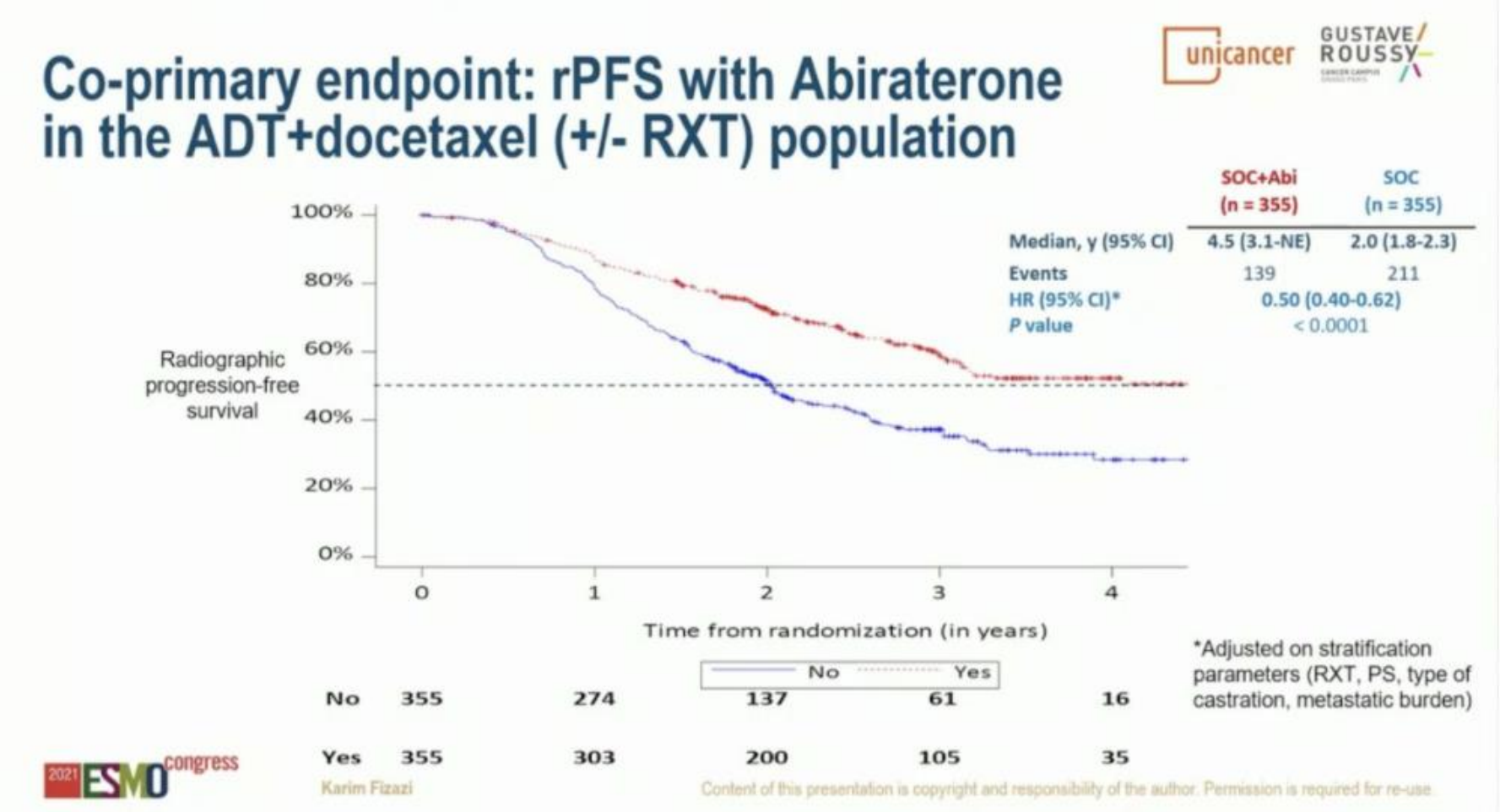
Wyniki PFS: Dodatek abirateronu do standardowej terapii DXL poprawia czas przeżycia wolny od progresji o 50%



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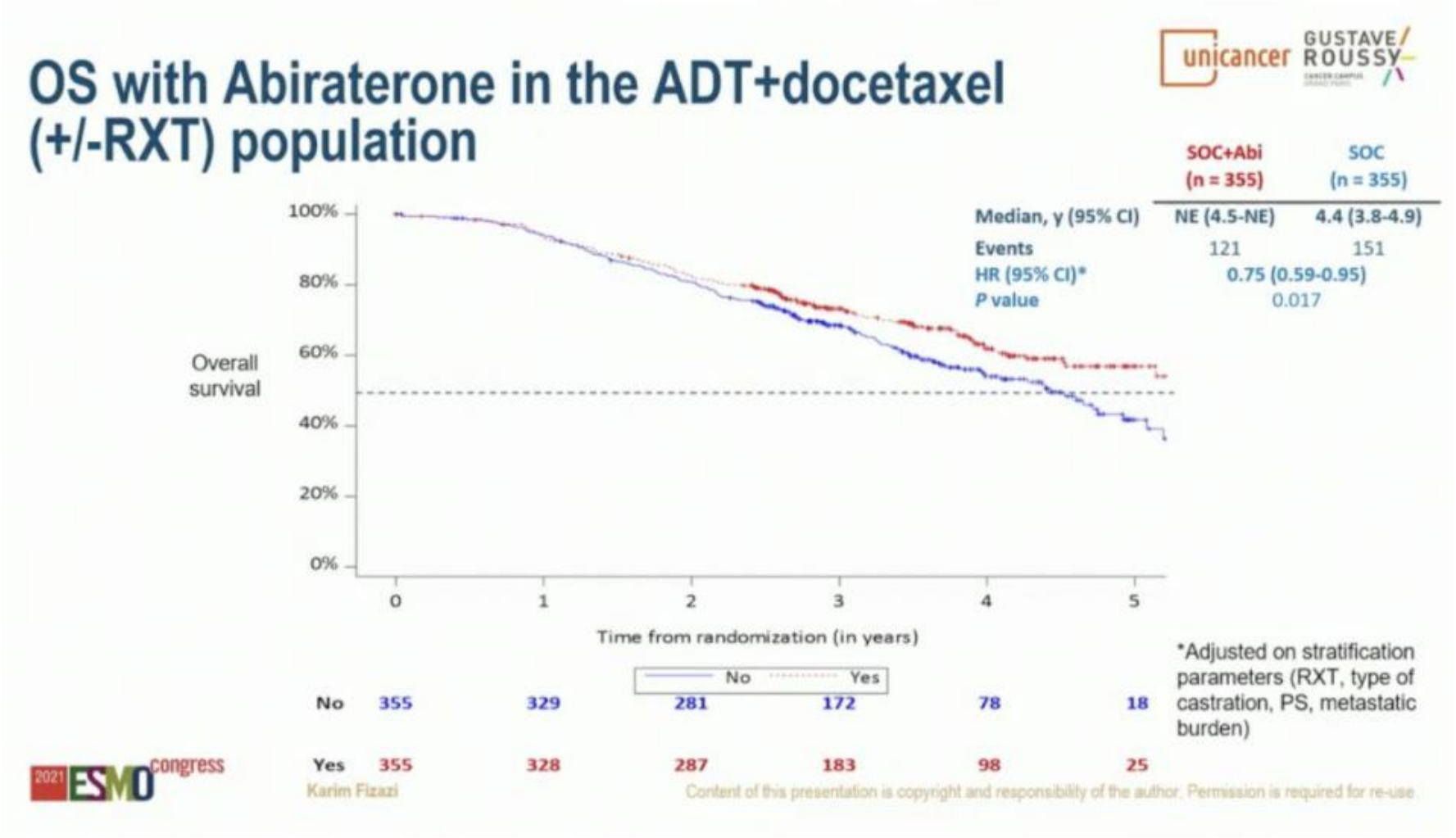
Wyniki OS: 25% redukcja ryzyka zgonu



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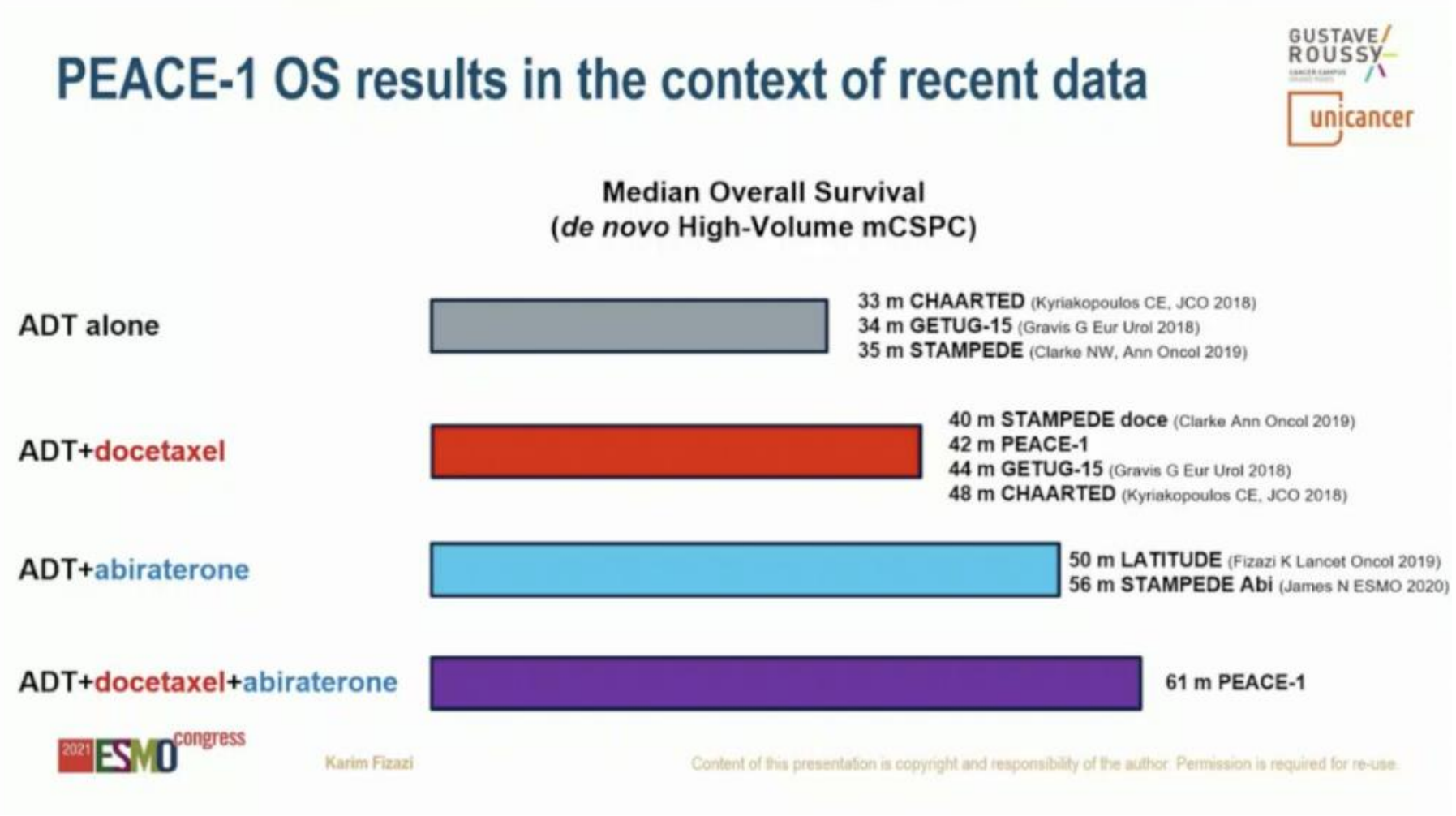
Czy te wyniki zmienią praktykę kliniczną?



PEACE-1

- PEACE-1 to pierwsze badanie pokazujące, że dodatek nowoczesnego leczenia hormonalnego od samego początku postępowania standardowego (DXL + ADT) wykazuje korzyści.
- W celu ograniczenia toksyczności finansowej NCCN zezwala na stosowanie abirateronu w dawce 250 mg przyjętego razem z posiłkiem
- Źródła:
- 1) Prospective International Randomized Phase II Study of Low-Dose Abiraterone With Food Versus Standard Dose Abiraterone In Castration-Resistant Prostate Cancer (Russell Z Szmulewitzhttps://pubmed.ncbi.nlm.nih.gov/29590007/
- 2) Low-Dose Abiraterone in Metastatic Prostate Cancer: Is It Practice Changing? Facts and Facets https://ascopubs.org/doi/pdf/10.1200/JGO.19.00341

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A randomized phase 2 non-inferiority study of 75 patients with M1 CRPC compared 1000 mg/day abiraterone after an overnight fast with 250 mg/day after a low-fat breakfast.[642] The primary endpoint was log change in PSA, with secondary endpoints of PSA response (≥50%) and PFS. The primary endpoint favored the low-dose arm (log change in PSA, -1.59 vs. -1.19), as did the PSA response rate (58% vs. 50%), with an equal PFS of 9 months in both arms. Noninferiority of the low dose was established according to the predefined criteria. Therefore, abiraterone can be given at 250 mg/day administered following a low-fat breakfast, as an alternative to the dose of 1000 mg/day after an overnight fast in patients who will not take or cannot afford the standard dose. The cost savings may reduce financial toxicity and improve compliance. Food impacts absorption unpredictably; side effects should be monitored and standard dosing (1000 mg on empty stomach) utilized if excess toxicity is observed on modified dosing (250 mg with food).

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- Dziękuję za uwagę