From Keynote522 to real world evidence: The use of Pembrolizumab in early triple-negative breast cancer

Jonas Roth[1], Jana Albers[1], Michael Gerken[2], Olaf Ortmann[1], Stephan Seitz[1]
1 *Department of Gynecology and Obstetrics, University of Regensburg, 93053 Regensburg, Germany, CCC-WERA, NCT-WERA*
2 *Tumor Center Regensburg, University of Regensburg, 93053 Regensburg, Germany*

SAN ANTONIO BREAST CANCER SYMPOSIUM®
DECEMBER 10–13, 2024
SABCS.ORG

Abstract

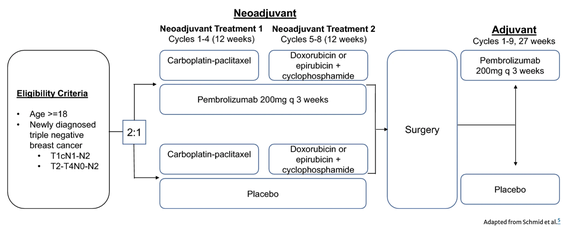
The KEYNOTE-522 trial demonstrated significantly higher rates of pathological complete response (pCR) with the addition of pembrolizumab to neoadjuvant chemotherapy in patients with early triple-negative breast cancer (TNBC). In this analysis, we aimed to evaluate whether real-world data support the benefit of adding immunotherapy to neoadjuvant chemotherapy for patients with early-stage TNBC. Additionally, we analyzed several subgroups to identify whether specific patient populations derive greater benefit from immunotherapy.

Data were collected at the Tumor Center Regensburg. We included 160 patients diagnosed with non-metastatic TNBC between January 2020 and May 2025 at the Comprehensive Cancer Center Regensburg. Of these, 88 patients received neoadjuvant chemotherapy plus pembrolizumab, while 72 patients received chemotherapy alone. We observed pCR rates of 61.4% in the chemotherapy plus pembrolizumab group compared to 51.4% in the chemotherapy-only group, demonstrating an absolute increase of 10% favoring the addition of pembrolizumab.

Subgroup analyses revealed that patients with a high Ki-67 score, particularly above 35%, achieved significantly higher pCR rates. Patients with BRCA mutations also showed markedly higher pCR rates in the pembrolizumab arm. Interestingly, younger patients demonstrated significantly higher pCR rates in both treatment arms compared to older patients. Detailed subgroup analyses will be presented.

This real-world study demonstrates that the addition of pembrolizumab in routine clinical practice is associated with improved pCR rates, showing an absolute difference of 10%. Moreover, it suggests that specific subgroups may particularly benefit from immunotherapy. However, larger real-world studies are needed to enable more robust subgroup analyses.

Keynote522 study



Patient characteristics

		neoadjuvante Chemotherapie mit Pembrolizumab			
		NACT + Pembrolizumab		NACT	
		Anzahl	Anzahl als Spalten (%)	Anzahl	Anzahl als Spalten (%)
Diagnosealter	<40,0	14	15.9%	10	13.9%
	40,0-49,9	25	28.4%	15	20.8%
	50,0-59,9	21	23.9%	20	27.8%
	60,0+	28	31.8%	27	37.5%
betroffene Brustseite	L	41	46.6%	38	52.8%
	R	47	53.4%	33	45.8%
	R+L	0	0.0%	1	1.4%
Menopausenstatus	prämenopausal	29	33.0%	18	25.0%
	perimenopausal	7	8.0%	4	5.6%
	postmenopausal	52	59.1%	50	69.4%
	k.A.	0	0.0%	0	0.0%
cT Tumorgröße	T0/is	0	0.0%	0	0.0%
	T1	15	17.0%	28	38.9%
	T2	63	71.6%	40	55.6%
	T3	6	6.8%	1	1.4%
	T4	4	4.5%	3	4.2%
	k.A.	0	0.0%	0	0.0%
cN Nodalstatus	N0	47	53.4%	55	76.4%
	N+	41	46.6%	17	23.6%
	k.A.	0	0.0%	0	0.0%
Ki67%	<20%	7	8.0%	6	8.3%
	20,0-34,9%	15	17.0%	16	22.2%
	>=35,0%	66	75.0%	50	69.4%
	k.A.	0	0.0%	0	0.0%
pL Lymphinvasion	L0	80	90.9%	66	91.7%
	L1	8	9.1%	4	5.6%
	LX/k.A.	0	0.0%	2	2.8%
pV Veneninvasion	V0	87	98.9%	69	95.8%
	V1	1	1.1%	1	1.4%
	VX/k.A.	0	0.0%	2	2.8%
BRCA-Mutation	Nein	58	65.9%	30	41.7%
	Ja	17	19.3%	14	19.4%
	k.A.	13	14.8%	28	38.9%

Results

pCR rates – all patients

	NACT + Pembro	NACT	p-value
number of patients achieving pcR	88	72	
% of patients achieving pCR	61,4	51,4	0,205

pCR rates – NACT + Pembro depending on BRCA

	BRCAmut	BRCAwt	K.A.	p-value
number of patients achieving pcR	17	58	13	
% of patients achieving pCR	88,2	55,2	53,8	0,04

Logistic regression

Pembro + NACT			
Label	OR	Ci low	Ci high
Age	1,02	0,631	1,648
Grading	1,685	0,995	2,854
Ki67	1,583	0,689	3,638
BRCA mutation	0,966	0,829	1,125
NACT			
Age	0,279	0,141	0,554
Grading	0,933	0,687	1,268
Ki67	1,277	0,538	3,028
BRCA mutation	1,158	0,998	1,343

Results

Interaction term age x therapy
OR 0,48; p=0,035

Summary

- KEYNOTE522-regime shows higher pCR rates than chemotherapy only regimes
- In chemotherapy only regimes young patients show significantly higher pCR rates than older patients
- Keynote-522-regime shows no age-dependent effect on achieving pCR
- BRCA-mutation carriers show higher pCR rates

Conclusions

- Real world data confirms the results of Keynote522 study
- Especially older patients benefit from adding immunotherapy to chemotherapy in neoadjuvant setting
- Patients with BRCA-mutations show significantly higher pCR rates than patients without mutations
- Bigger real world data analysis are needed to identify subgroups that benefit most from Keynote522-regime

Contact

Jonas Roth
Department of Gynecology and Obstetrics, University Medical Center Regensburg, 93053 Regensburg, Germany
Email: Jonas.roth@ukr.de

This presentation is the intellectual property of the author/presenter. Unpublished data. Please do not post!

© Poster Template by Genigraphics® 1.800.790.4001 www.genigraphics.com