FR-POPEA: French Real-world-data of Peri-Operative Pembrolizumab KN522 regimen in Extreme Ages subgroups (<30 y.o and >70 y.o) with high-risk TNBC

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Introduction

- Pembrolizumab added peri-operatively improves pathological complete response (pCR) and survival in early triple negative breast cancer (TNBC) (KEYNOTE-522 trial).[1]
- Age extremes are underrepresented in RCTs; real-world evidence is needed.
- FR-POPEA (French Real-world-data of Peri-Operative Pembrolizumab KN522 regimen in Extreme Ages subgroups) assessed feasibility, toxicity and pCR in the youngest (<30 y) and oldest (≥70 y) subgroups within the French KN522 Early Access Program (EAP).

Objective

Describe baseline characteristics, treatment patterns, safety, and pCR rates in patients at the youngest and oldest stages of life treated with the KN522 regimen in real life.

Methods

- Prospective observational cohort from the French KN522 EAP (Apr 2022–Nov 2024).
- Inclusion: adults with stage II–III TNBC (including estrogen receptor 1–9% per French guidelines).
- Data source: physician-completed EAP forms; follow-up until EAP end or treatment end.
- Age cohorts: youngest <30 y (control ≥30 y); oldest ≥70 y (control <70 y).

Cohorts

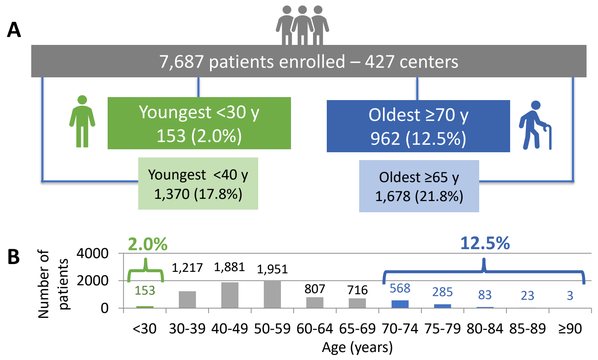


Figure 1: Study cohorts. A Flowchart, and B. Age distribution at treatment access request.

Results – Youngest patients (<30 y) – Key findings

- n = 153 (2.0% of the cohort).

Medical history

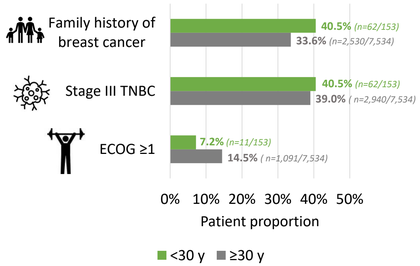


Figure 2: Clinical characteristics at baseline (<30 vs ≥30 years old).

Treatment, surgery, & pCR

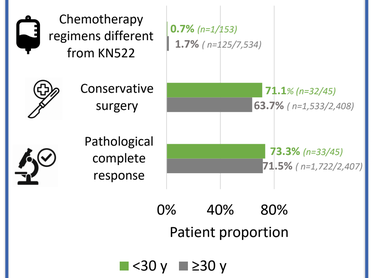


Figure 3: Treatment patterns, surgical outcomes, and pCR (<30 vs ≥30 years old).

Interruptions & discontinuations

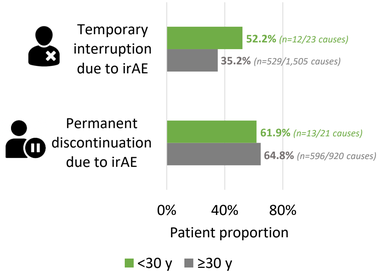


Figure 4: Pembrolizumab interruptions and discontinuations (<30 vs ≥30 years old).

- The youngest patients (<30 years) had a higher family history of breast cancer (40.5% *vs* 33.6%), similar stage distribution, and lower ECOG ≥1 rate.
- pCR and breast-conserving surgery rates were similar or slightly higher in the youngest patients.
- The proportion of interruptions attributed to irAEs was higher in the youngest patients; however, this is not reflected on discontinuation rate due to irAE wich was similar between the 2 populations.

Results – Oldest patients (≥70 y) – Key findings

- n = 962 (12.5% of the cohort). Notable absolute counts: 106 patients had between 80 and 89 years old and 3 patients had more than 90 years old.

Medical history

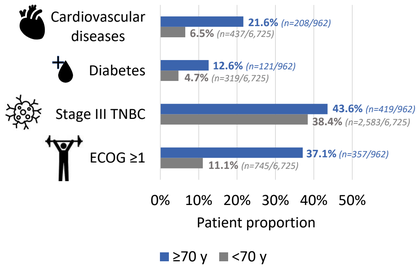


Figure 5: Clinical characteristics at baseline (<70 vs ≥70 years old).

Treatment, surgery, & pCR

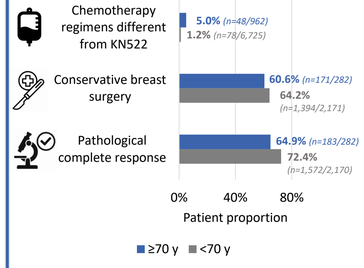


Figure 6: Treatment patterns, surgical outcomes, and pCR (<70 vs ≥70 years old).

Interruptions & discontinuations

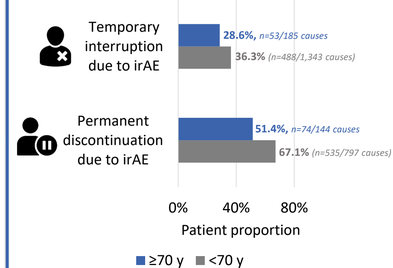


Figure 7: Pembrolizumab interruptions and discontinuations (<70 vs ≥70 years old).

- In this oldest sub-group, a KN-522 chemotherapy regimen was planned for 95% of patients.
- The oldest patients (≥70 years) presented a higher comorbidity burden and worse ECOG status compared with younger patients (<70 years old).
- The oldest patients had lower pCR and breast-conserving surgery rates and a lower rate of interruptions or discontinuations due to irAES compared with those <70 years.

Conclusions

- FR POPEA is the largest real-world assessment of the KEYNOTE-522 regimen in youngest and oldest patients.
- The results support the feasibility, acceptable safety profile, and effectiveness of perioperative pembrolizumab across age extremes in routine practice.
- The lack of systematic BRCA data and geriatric assessments are limitations; nevertheless, the findings are reassuring and complementary to KEYNOTE-522.

Limitations

- Data are from an observational EAP, and potential reporting bias may exist.
- Missing data include BRCA status, formal geriatric assessment, and detailed AE grading in all cases.

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Abbreviations

EAP: Early Access Program
ECOG: Eastern Cooperative Oncology Group
irAE: Immune-related adverse event
KN522: KEYNOTE-522 clinical trial
pCR: Pathological complete response
TNBC: triple negative breast cancer

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