AUC BASED-METHOD TO ESTIMATE OVERALL SURVIVAL BENEFIT OF INAVOLISIB + PALBOCICLIB + FULVESTRANT VERSUS PALBOCICLIB + FULVESTRANT

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BACKGROUND AND IMPORTANCE

Inavolisib has recently been approved in combination with palbociclib and fulvestrant for the treatment of adult patients with PIK3CA-mutated, oestrogen receptor (ER)-positive, HER2-negative, locally advanced or metastatic breast cancer, following recurrence during or within 12 months after completing adjuvant endocrine therapy

Pivotal **INAVO120 trial** → Benefit overall survival (OS) inavoliisb + palbociclib + fulvestrant vs placebo + palbociclib + fulvestrant: 34.0 vs 27.0 months (7.0-month difference) and a hazard ratio of 0.67 (95% CI, 0.48–0.94), with data maturity of 47.4%

→ The median OS may not fully represent clinical benefit, as it reflects only a single point on the survival curve and does not capture differences occurring earlier or later in follow-up

AIM AND OBJETIVES

The aim of this study was to apply the modified Seruga–Fénix area under the curve (AUC) method to estimate mean OS from Kaplan–Meier data of the inavolisib trial and to compare the results with the median OS reported in the pivotal study

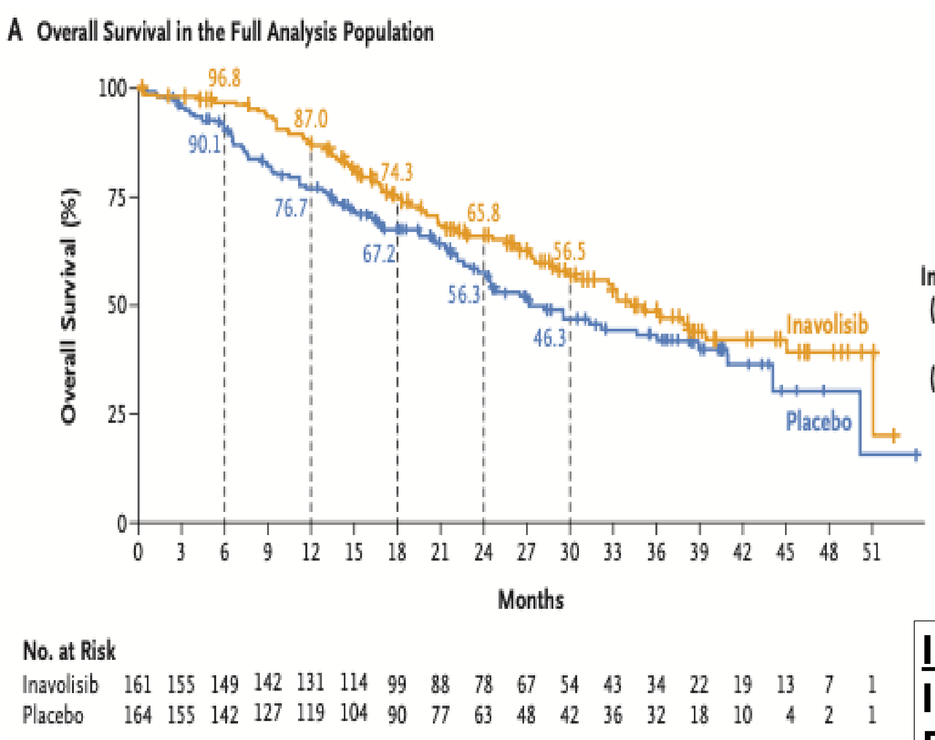
MATERIALS AND METHODS

Kaplan-Meier curves from INAVO120 were digitized using **WebPlotDigitizer** v5 → AUCs were calculated for **inavolisib** and **control arm**

The **reference area** was defined as the rectangle bounded by the y-axis, the vertical cut-off line representing the minimum number of patients at risk (≥10 per group or ≥30 in total), and the upper boundary of the survival curve

Mean OS values obtained were compared with the published medians to assess possible over- or underestimation of survival benefit

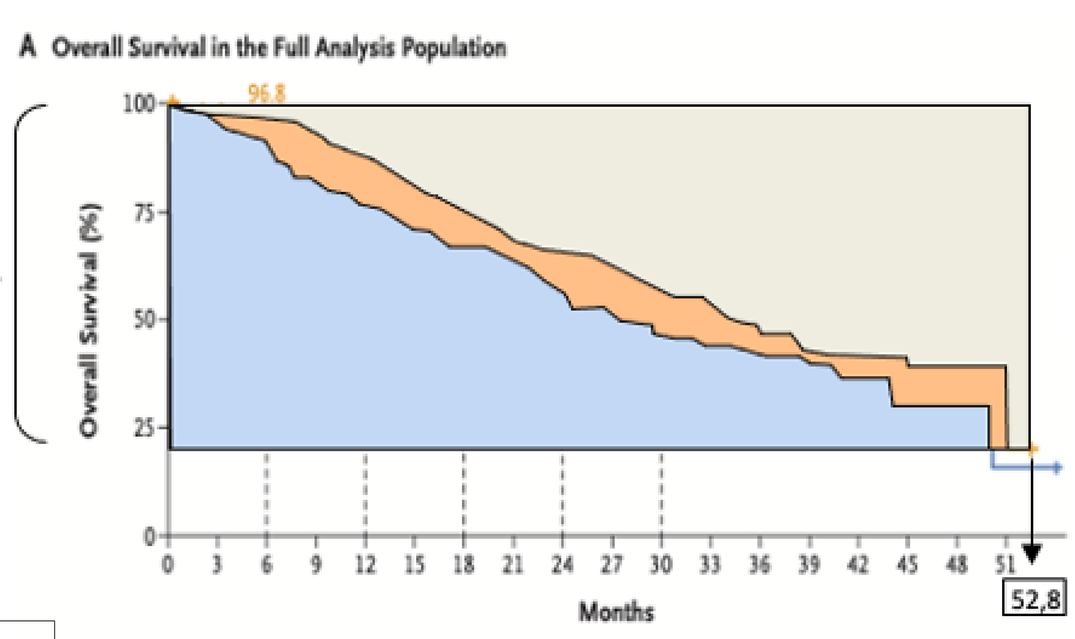
RESULTS



	No. of Deaths (%)	Median Overall Survival (95% CI) mo
Inavolisib (N=161)	72 (44.7)	34.0 (28.4–44.8)
Placebo (N=164)	82 (50.0)	27.0 (22.8–38.7)

Stratified hazard ratio for death, 0.67 (95% CI, 0.48–0.94)
P=0.02

79,74%



INAVO120 trial median OS
Inavolisib + P + F: 34,0 months
Placebo + P + F: 27,0 months
Difference: 7,0 months

Mean OS RMST
Inavolisib + P + F: 29,27 months
Placebo + P + F: 24,37 months
Difference: 4,90 months

Total reference time: 52,8 months
Registered population: 79,74% with shorter OS
Data extraction: WebPlotDigitizer v5
Seruga method – Fénix modification

CONCLUSION AND RELEVANCE

- ✓ Inavolisib achieved a mean OS of 29.27 months compared with 24.37 months for the control arm in the AUC-based method
- ✓ Compared with the pivotal trial (34 vs 27 months), the AUC-based method showed a smaller survival difference, suggesting that the pivotal trial measurements may be overestimating the clinical benefit.

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