Acceptability of adjuvant chemotherapy in women aged 70 and older after surgery for ER-positive HER2-negative breast cancer selected with a high genomic grade index: results from the ASTER 70s/Unicancer trial

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Background

Women aged 70 and older (70+) with early-stage ER-positive/HER2-negative breast cancer (BC) represent a heterogeneous population with variable levels of frailty and treatment tolerance. In the ASTER 70s trial, patients with a high genomic grade index (GGI) were identified at higher risk and were randomised in a 1:1 ratio to chemotherapy (CT) followed by hormonotherapy (HT) or HT alone as standard treatment. However, the addition of adjuvant CT to HT did not improve overall survival (OS) nor invasive disease-free survival (iDFS) and breast cancer-specific survival.[1] In this age group, the clinical relevance of CT relies not only on its efficacy, but also on its acceptability, which can be influenced by toxicity, health-related quality of life (HRQoL), geriatric characteristics and individual preferences. Understanding the acceptability of CT is essential to inform treatment decisions in frail or elderly patients with high-risk luminal BC.

Study objective

To assess the acceptability of adjuvant CT among women 70+ randomised to CT in the ASTER 70s trial

- Association of CT acceptability with occurrence of adverse events (AEs) or serious adverse events (SAEs)
- Association of CT acceptability with geriatric parameters and HRQoL at baseline
- Patient willingness to recommend CT to peers
- Changes in acceptability over 4 years of follow-up

Methods for acceptability assessment

Patients randomized to CT received 4 cycles of anthracycline- or taxane-based regimens q3w in addition to HT

A self-administered acceptability questionnaire, adapted from the GERICO 06 trial,[2] was completed:

- At the end of CT
- Then annually for 4 years

Patients were asked:

- Whether CT was "acceptable" given the announced benefit
- If not, main reason for being "not acceptable"
- Whether they would recommend CT to a relative in a similar situation

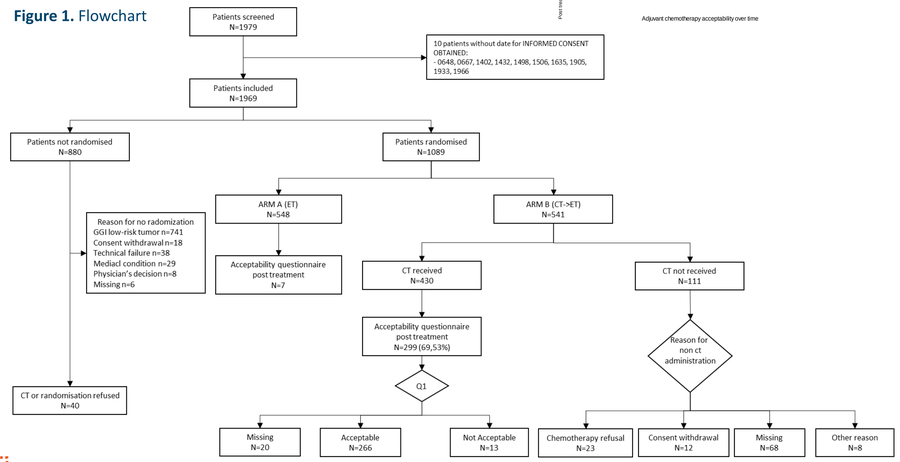
Analyses assessed associations between acceptability, toxicity, geriatric parameters, HRQoL and clinical outcomes

Study population

Study population and flowchart ***(Figure 1)***

- 1,969 women ≥70 years screened for tumour GGI
- 1,089 (55%) with high GGI randomised
- 541 (49.7%) assigned to CT by randomisation
  - ✓ 111 (20.5%) did not receive any CT (20.7% refusal; others: consent withdrawals, technical failures, medical contraindication, physician's decision, unknown reason)
  - ✓ 430 (79.5%) initiated CT, with 44 (10.2%) discontinuing it before cycle 4
    - 299 (69.5%) completed 1st acceptability questionnaire
    - Patient and tumour characteristics, geriatric parameters and HRQoL at baseline, and survival were comparable between questionnaire responders and non-responders

Figure 1. Flowchart



Key results

CT acceptability at completion of CT

- ➢ "Acceptable" 95.3% of patients (266/279)
- ➢ "Unacceptable" 4.7% of patients (13/279)
- ➢ Correlation with occurrence of SAEs under CT (15% versus 46%, respectively; p < 0.05)

Willingness to recommend CT

- ➢ 94.2% patients would recommend CT to a relative facing the same decision

CT acceptability and recommendation for CT

- ➢ Stable over 4 years ***(Figure 2)***

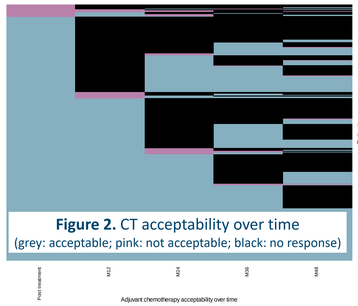


Figure 2. CT acceptability over time
(grey: acceptable; pink: not acceptable; black: no response)

Factors reducing CT acceptability over time *(Figure 3)*

(acceptable versus acceptable → not acceptable since 1st post-CT assessment)

- ➢ Increasing age
- ➢ High Lee prognostic score (4-year mortality estimate)
- ➢ Low baseline IADL score

Baseline factors associated with decreasing CT acceptability *(Figure 4)*

- ➢ Poorer functional scores: cognitive (role & social NS)
- ➢ Symptoms: pain (dyspnea & appetite loss NS)

Survival according to CT acceptability

- ➢ No difference ***(Figures 5 and 6)***

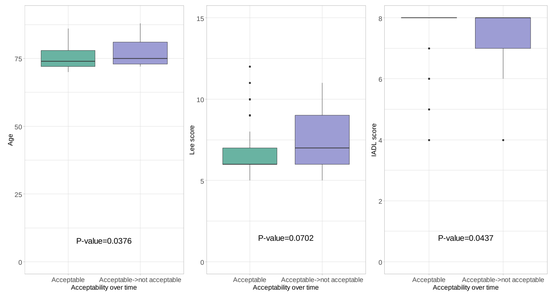


Figure 3. Factors reducing CT acceptability over time

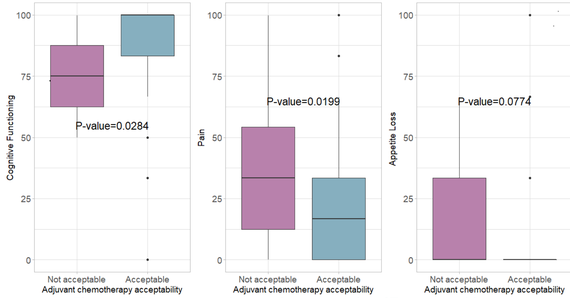


Figure 4. Factors associated with decreasing CT acceptability

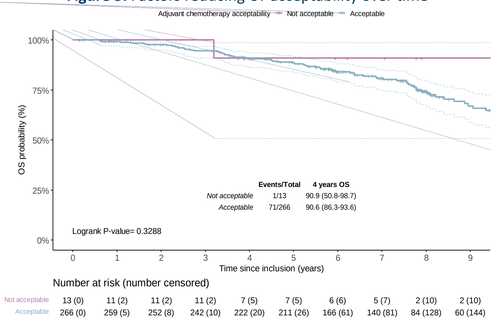


Figure 5. OS in patients according to acceptability of CT

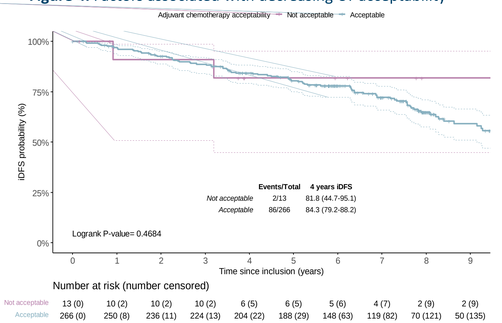


Figure 6. iDFS in patients according to acceptability of CT

Conclusions

It is difficult to assess the acceptability of a treatment, which depends largely on its safety and, consequently, its intensity in relation to increasing frailty with age. The acceptability of CT appears also to be influenced by factors such as age and HRQoL, which must be taken into account when developing hypotheses in clinical trials, especially in elderly subjects. Relevant absolute thresholds should be revisited with patients.

References

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2. Brain EG, Mertens C, Girre V, et al. Impact of liposomal doxorubicin-based adjuvant chemotherapy on autonomy in women over 70 with hormone-receptor-negative breast carcinoma: A French Geriatric Oncology Group (GERICO) phase II multicentre trial. Crit Rev Oncol Hematol 2011; 80: 160–70.

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