PS1-01-04 Efficacy of cryotherapy using frozen gloves and socks to prevent docetaxel-induced onycholysis in early breast cancer patients undergoing sequential (neo)adjuvant (F)EC and docetaxel treatment: The Banquise randomized controlled trial

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Introduction

- The use of docetaxel in the (neo)adjuvant treatment of early-stage breast cancer (eBC) is frequently linked to notable nail toxicities, which can negatively impact quality of life (QoL) and potentially lead to treatment delays[1,2].
- Cryotherapy, involving the use of frozen gloves and socks, is used as a strategy to decrease docetaxel-induced nail toxicity[3,4].
- Strong evidence supporting its efficacy at lower cumulative doses of docetaxel and its overall tolerability remains limited.

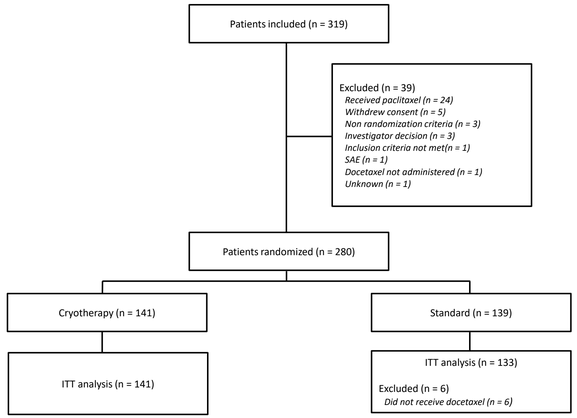
Material and methods

- BANQUISE trial was a randomized, open-label, multicenter study investigating the efficacy of cryotherapy in eBC patients receiving three cycles of (neo)adjuvant docetaxel (100 mg/m²) following three cycles of (F)EC 100.
- Participants were randomized after completing three cycles of (F)EC to either the cryotherapy group, with frozen gloves and socks applied 15 minutes before and removed 15 minutes after the docetaxel infusion, or to the control group.
- The primary endpoint was the incidence of nail toxicity grade ≥ 2 between the first dose of docetaxel and eight weeks after the last dose of docetaxel, assessed using CTCAE v4.0 criteria by investigators.
- Secondary endpoints included a docetaxel nail toxicity (DNT)* score assessed by a blinded dermatologist at weeks 8 and 24 using photographs. Cryotherapy tolerability, and patient-reported outcomes (PROs) were measured at each cycle and week 8 and 24 after last dose of docetaxel by the EORTC QLQ-C30 and BR23 questionnaires.
- Statistical analyses used X^2 and t-tests, with significance set at $p<0.05$.

**DNT score : this score integrates the CTCAE V4.0 grade and the number of affected fingers, assigning 1 point per digit for grade 1 toxicity and 5 points per digit for grade 2 toxicity[5].*

Results

Patients flow diagram

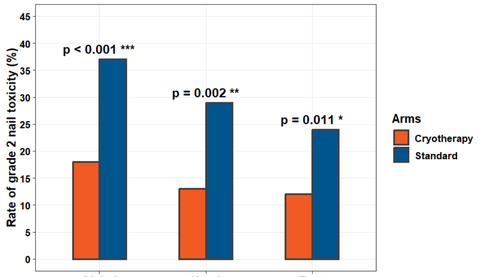


Characteristics of the patients

	Cryotherapy, n = 141	Standard, n = 133	Overall, n = 274
Age (years)			
Median (range)	53 (29–78)	54 (27–78)	54 (27–78)
Concomitant treatment			
No	68 (48%)	61 (46%)	129 (47%)
Yes	73 (52%)	72 (54%)	145 (53%)
Docetaxel courses			
C1 performed	141 (100%)	133 (100%)	274 (100%)
C2 performed	135 (96%)	129 (97%)	264 (96%)
C3 performed	128 (91%)	122 (92%)	250 (91%)
Docetaxel dose reduction			
C1	0 (0%)	1 (0.8%)	1 (0.4%)
C2	21 (16%)	24 (19%)	45 (17.0%)
C3	28 (22%)	30 (25%)	58 (23.2%)
Docetaxel dose delay			
C1	5 (3.5%)	1 (0.8%)	6 (2.2%)
C2	1 (0.7%)	4 (3.1%)	5 (1.9%)
C3	0 (0%)	2 (1.6%)	2 (0.8%)
Docetaxel total dose (mg)			
Mean (SD)	471 (95)	467 (80)	469 (88)

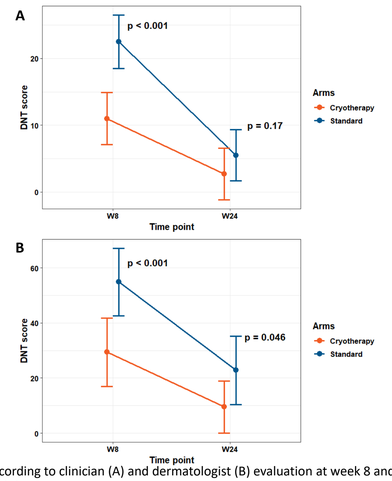
Abbreviation: SD, standard deviation.

Incidence of nail toxicity



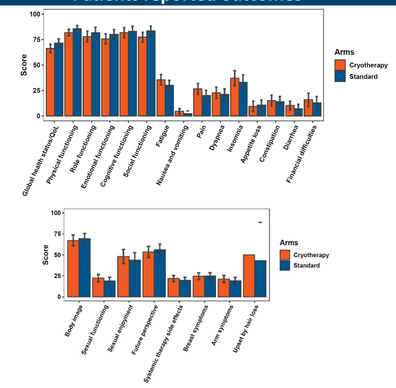
Incidence of grade ≥2 nail toxicity according to CTCAE V4.0 at week 8 after the final docetaxel dose.

DNT score evaluation



DNT score according to clinician (A) and dermatologist (B) evaluation at week 8 and 24 after the final docetaxel dose.

Patients reported outcomes



EORTC QLQ-C30 (A) and QLQ-BR23 (B) at week 8 after the final docetaxel dose.

Tolerance

	Frozen gloves, n = 141	Frozen socks, n = 141
Discomfort		
Absence	1 (0.7%)	2 (1.5%)
Minimal	21 (15%)	9 (6.6%)
Moderate	60 (43%)	67 (49%)
Severe	57 (41%)	58 (43%)
Pain		
Absence	11 (7.9%)	12 (8.7%)
Minimal	26 (19%)	14 (10%)
Moderate	54 (39%)	54 (39%)
Severe	48 (35%)	58 (42%)

Conclusions

- Cryotherapy with frozen gloves and socks significantly decreased the incidence and severity of docetaxel-induced nail toxicity in patients with early breast cancer at lower cumulative dose.
- Although tolerability remains a limitation, patient-reported quality of life was preserved. The BANQUISE trial supports cryotherapy as an effective, feasible intervention to enhance docetaxel tolerability in the (neo)adjuvant setting.

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