

LBA28

Compression therapy using normal-sized surgical gloves for prevention of paclitaxel-induced peripheral neuropathy in breast cancer: Results from the multicenter randomized AIUR trial

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Background

Cryotherapy and compression gloves are device-dependent and uncomfortable, both limiting adherence. Normal-sized surgical gloves are neither and are put on in seconds. Prior compression studies, including POLAR, used self-controlled designs and investigator-rated outcomes that underestimate patient-perceived symptoms; a double-blind RCT was negative. AIUR is the first parallel-group RCT of this approach with a patient-reported outcome (PRO) primary endpoint.

Methods

Stage II-III breast cancer patients receiving ≥12 weeks of paclitaxel were randomized 1:1 to two normal-sized surgical gloves (30 min before to 30 min after infusion) or no intervention at seven centers in South Korea (NCT05771974). Primary endpoint: proportion with a FACT-NTX 11-item increase ≥5 points at end of paclitaxel. Secondary: change in FACT-NTX total score and NCI-CTCAE. Hand and foot sub-scores were compared; the ungloved feet served as internal control.

Results

104 patients were randomized (52/arm). The primary endpoint was not significant; the effect was confined to the upper extremities (Table); arm-by-region interaction P<0.001 (permutation P<0.001). All four upper-extremity items and fingertip pain were significant (BH q<0.05); no lower-extremity, systemic or non-neural hand item was. CTCAE grade ≥2 sensory neuropathy 58.7% vs 82.2% (P=0.02). No serious adverse events; 44 of 48 assessable patients (92%) rated the gloves satisfactory or better.Table: LBA28

Key endpoints, baseline to target

Change to target	Glove Control Difference (95% CI) <i>P</i>				
Poor outcome, %	74.5	82.6	-8.1	(-24.7, 8.5)	0.45
FACT-NTX 0-44	+9.7	+13.7	-3.9	(-7.5, -0.4)	0.03
Upper-extremity 0-16	+2.9	+6.1	-3.20	(-4.93, -1.48)	<0.001
Lower-extremity 0-12	+5.3	+5.5	-0.22	(-1.69, 1.25)	0.77

Conclusions

AIUR did not meet its prespecified primary endpoint. Exploratory analyses showed an effect confined to the gloved hands and absence in the ungloved feet, so a total score combining both regions may dilute a hand-directed effect. The same approach extends readily to the feet and merits further evaluation in a trial assessing each region separately with prespecified PRO endpoints.

Clinical trial identification

NCT05771974 (registered March 16, 2023); KCT0008371 (registered April 6, 2023).

Legal entity responsible for the study

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Disclosure

All authors have declared no conflicts of interest.

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