39P - A validation study of a self-testing capillary kit, the rhelise™ kit for therapeutic dose monitoring (TDM) of tamoxifen, Z-endoxifen, and 4-hydroxytamoxifen in breast cancer patients (ID 259)

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Background

Tamoxifen is a highly effective drug in reducing the risk of death from breast cancer. Our aim was to validate and explore the feasibility of regularly monitoring the levels of tamoxifen (TAM), 4-hydroxytamoxifen (4HT), and Z-endoxifen (Z-END) using capillary blood sampling.

Methods

In this single-centre, prospective study, we included women with stage 0-3 breast cancer who received adjuvant tamoxifen at a daily dose of 20 mg for a minimum of 2 months.

LC-MS/MS was used to analyse TAM, 4HT, and Z-END concentrations in both venous whole blood and plasma and capillary blood samples collected using the rhelise™ kit.

Study design

Capillary blood samples were taken at baseline, 1 week, 2 weeks, and 3 weeks, while venous blood samples were taken at baseline and week 3. A research nurse conducted the first capillary blood test and the patient the following three tests. Participants were asked to provide one vial of capillary blood using the rhelise™ kit at each time point and two samples of conventional venous blood for blood and plasma at baseline and week 3.

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Primary Objective:

The primary objective of this study is to validate the rhelise™ kit for monitoring TAM, 4HT, and Z-END by testing the equivalence between the concentrations found in the capillary sample and the venous blood sample (gold standard).

Secondary Objective:

To validate the user acceptability and feasibility of self-testing the capillary kit by comparing the capillary blood test concentrations of TAM, 4HT, and Z-END taken by the patient to the capillary sample taken by the research nurse.

Baseline sample | **3-week sample**

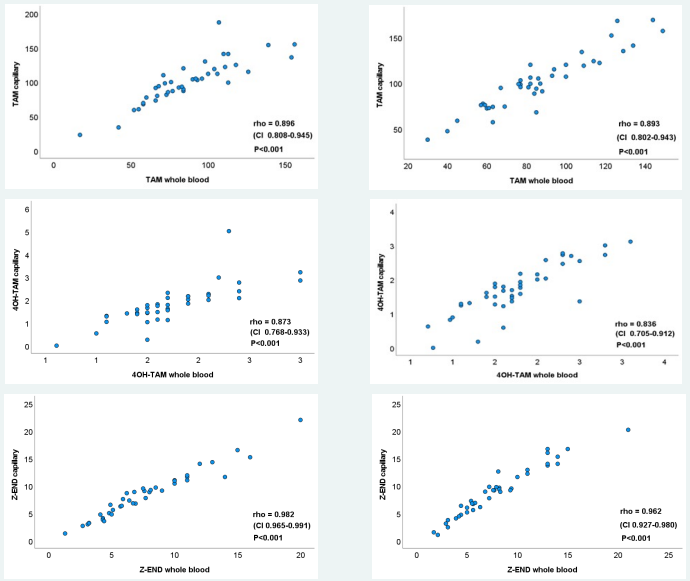

Figure 1. Correlations between capillary and venous blood sampling of TAM, 4HT, and Z-END at baseline and control after 3 weeks.

Results

A capillary sampling kit was used for 40 participants. Mean TAM, 4HT and Z-END concentrations did not differ significantly in the 3 types of samples (Figure 1). In addition, mean capillary TAM, 4HT and Z-END concentrations did not differ significantly between nurse and patient (Figure 2).

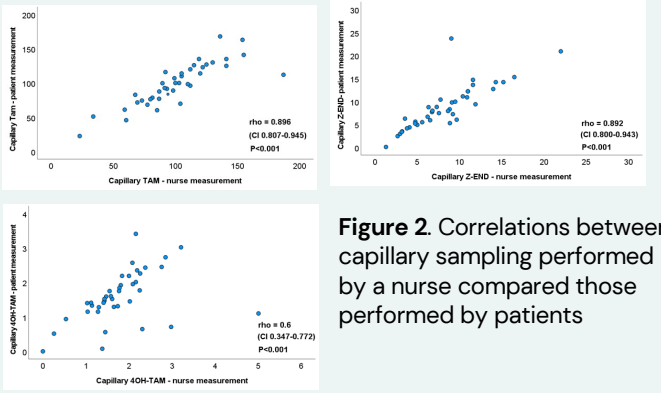

Figure 2. Correlations between capillary sampling performed by a nurse compared those performed by patients

Conclusions

Using capillary blood sampling for TAM and Z-END yielded similar results to venous blood sampling. Capillary samplings by the nurse and patient were comparable, demonstrating that capillary sampling constitutes a reliable option to measure the concentration of TAM and Z-END.

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