Intraoperative ketorolac in high-risk breast cancer patients with and without inflammation. A prospective, randomized, placebo-controlled clinical trial.

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Introduction

Perioperative events may affect the risk of breast cancer recurrence

Ketorolac, a non-steroidal anti-inflammatory drug has been associated with better breast cancer outcome in retrospective studies.

Patients and methods

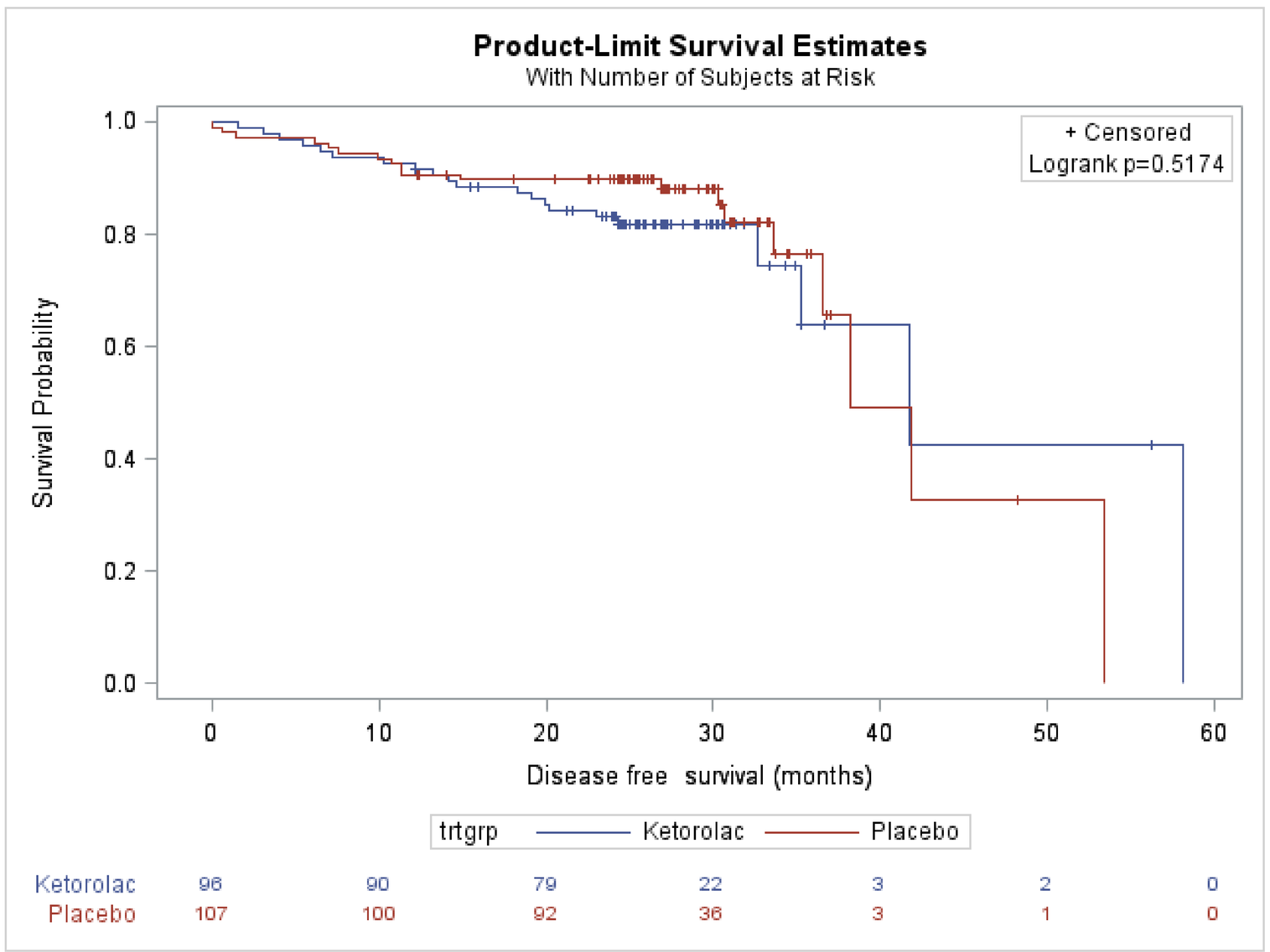
The **KBCt trial** (NCT01806259) is a national, multicenter, double-blind, randomized phase III trial in high risk breast cancer patients.

Ketorolac tromethamine 30 mg (Taradyl®, N.V. Roche S.A., Belgium) ***vs.*** **placebo** before surgery.

Eligible patients:
- invasive ductal/lobular carcinoma
- curative surgery

and with a:
- neutrophil-to-lymphocyte ratio≥4 or
- node-positive disease (cN1-N3) or
- triple-negative histology.

Primary endpoint : Disease-Free Survival (DFS).
Secondary endpoints: Safety, pain assessment and overall survival.



Kaplan-Meier estimates of Disease-Free Survival (DFS) in the overall study population.

Results

203 patients :
- Mean age: 55.7 (SD 14) years
- **No difference for DFS** (p=0.52) nor for OS (p=0.88)
- No difference for intra- and post-operative blood losses and pain.

Conclusion

A single administration of **30 mg of ketorolac tromethamine** before surgery **does not increase DFS** in high risk breast cancer patients.

Overall survival is also comparable.

No safety concerns were observed.

Reference

Forget P, Berlière M, Maanen AV, Duhoux FP, Machiels JP, Coulie PG, Bouche G, De Kock M; KBCtrial group. Med Hypotheses. 2013;81(4):707-12.

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