Immunoscore feasibility study in routine postsurgical pathologic review for early-stage colon cancer (CC) cases risk-assessment

Background
Immunoscore® Colon is an in vitro diagnostic test predicting the risk of relapse in early-stage CC patients, by measuring the host immune response at the tumor site.

Method
Risk of relapse assessment and survival prediction
In the international validation (Pagès et al. The Lancet 2018), of all clinical parameters, the relative contribution to the risk of relapse showed that Immunoscore® (47%) was better than TNM staging (28%), grade of differentiation (15%), VELIPI (8%), sex (<3%), mucinous, and MSI-status.

Immunoscore® was stronger than all these clinical parameters, showing the highest contribution (30%) to the risk of recurrence regardless of the MSI-status.

Conclusion
The observed distribution between IS 0 to 4, and clinical groups: Immunoscore High (IS 3‐4) for highly infiltrated tumors, Immunoscore Intermediate (IS 2) and Immunoscore Low (IS 0, 1, low infiltration, eligibility) criteria; surgical samples from primary tumors containing both CT and IM, with sufficient tissue area (minimum 3mm²).

Patients with stage II and III CC were recruited from 13 centers in Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, India, Israel, Spain, UK. For each center, 20% to 40% of all consecutive patients with CC were included.

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Immunoscore® can be performed on most of the surgical specimens and can be included in the pathological report in a timely manner, compatible with post-surgery treatment decisions.

Results
265 individual patient samples were received and 253 were eligible. A valid Immunoscore result was obtained in 97% of cases (n=245). Reasons for failures were immunostaining background, torn tissues, insufficient tumor content or absence of IM.

Immunoscore® was reported in categorical scores IS 0 to 4, and clinical groups: Immunoscore High (IS 3-4) for highly infiltrated tumors, Immunoscore Intermediate (IS 2) and Immunoscore Low (IS 0, 1, low infiltration, eligibility) criteria; surgical samples from primary tumors containing both CT and IM, with sufficient tissue area (minimum 3mm²).

Immunoscore distribution was 4%, 16%, 46%, 30%, and 2% for IS 0, IS 1, IS 2, IS 3 and IS 4 respectively.

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