Tailoring the Diagnostic Pathway in Patients with Gastric Cancer (GC) Using the Innovative inPROBE® Technology Platform to Assess HER2 Expression in Peritoneal Lavage: A Pilot Study

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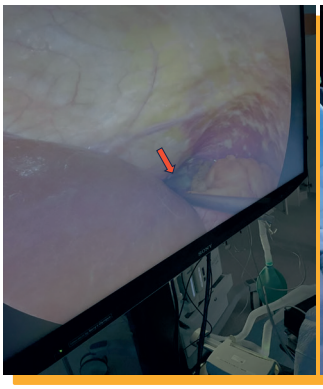
Background

- HER2 expression is an established predictive and prognostic biomarker in gastric cancer (GC) patients, assessed by immunohistochemistry (IHC) in tumor cells.
- Currently, there is no data regarding the measurement of HER2 expression in peritoneal lavage and its usefulness in the diagnosis of GC.

- InPROBE® is an innovative platform merging photonic technology with molecular biology to quantify HER2 expression in vivo in real time.

Material and methods



We performed a peritoneal lavage (PL) during staging laparoscopy using 100 ml of saline in 14 consecutive patients (7 male and 7 female) at the mean age of 65 years (34 – 78) with advanced GC (adenocarcinoma, G1-G3, 4 patients with 1 metastatic site) (red arrows in pictures). The most common location of primary tumor was gastric body (n=7), followed by cardia (n=3), gastroesophageal junction (n=2) and pylorus (n=2). The baseline IHC/FISH showed different expression of HER2 ranging from high expression (+3) and some with low HER2 expression (+1 or 0). Patient's blood in addition to peritoneal lavage samples were collected during staging laparoscopy and preserved for determination of the soluble HER2 protein. Measurements in PL and serum (S) was performed employing the in-house ELISA [1] or using the inPROBE sensor designed specifically for HER2 detection [2].

Results

The HER2 concentration in peritoneal lavage and serum measured by ELISA was variable among patients from different IHC status groups (Tab. 1). In all tested PL samples there was detectable soluble HER2 ranging from 0.48 – 5.98 ng/ml. In comparison, patients' blood serum contained significantly higher level of soluble HER2, ranging from 7.57 – 82.49 ng/ml. Interestingly, also inPROBE recorded a positive signal for HER2 in the tested PL sample.

HER2 status	PL	S
0	1.19 – 5.98 ng/mL	7.57 – 57.47 ng/mL
1	5.43 ng/mL	34.69 – 82.49 ng/mL
3	0.48 – 1.67 ng/mL	35.75 – 38.6 ng/mL
ND	2.73 – 4.22 ng/mL	35.08 – 39.82 ng/mL

Concentration ranges of soluble HER determined by ELISA in peritoneal lavage (PL) and serum (S) samples from GC patients with tumor HER2 IHC status 0, 1+, 3+ or not determined (ND).

Conclusions

- Assessment of HER2 expression in peritoneal lavage in GC patients is feasible and could be an effective method of increasing the identification rate for potential targeted therapy among selected patients.
- The use of inPROBE® technology presents an opportunity for HER2 determination during diagnostic laparoscopy providing numerical and objective results.
- Further studies are needed to establish the correlations between HER2 in PL and serum assessment as well as with the results of standard IHC/FISH methods.

[1] Antos A, Topolska-Woś A, Woś M, Mitura A, Sarzyńska P, Lipiński T, Kurylcio A, Ziółkowski P, Świtalska M, Tkaczuk-Włach J, Gamian A, Polkowski WP, Staniszewska M, The unique monoclonal antibodies and immunochemical assay for comprehensive determination of the cell-bound and soluble HER2 in different biological samples. Sci Rep. 2024 Feb 17;14(1):3978

[2] Staniszewska M, Kurylcio A, Sędłak K, Polkowski WP, Smietana M, Staniszewski M, Novel in vivo photonics-immunoassay system, inPROBE, for the rapid detection of HER2 in breast cancer, European Society of Molecular Oncology (ESMO) Congress, 20-24 October 2023, Madrid, Spain, Publ.: Annals of Oncology, Vol. 34, Supplement S718, October, 2023