“The German- Registry” of incidental gallbladder cancer and the GAIN - phase III trial: Transformation from a registry to treatment platform due to a trial in trial concept

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Background: The biggest biliary platform in Europe - the German- Registry (GR) shows significant survival benefit for radical resection (RR) in gallbladder carcinoma. But nevertheless results for T2-3 are still disappointing even after RR.

Methods: For data analysis the GR was used. Currently more than 1100 cases of incidental gallbladder carcinoma (IGBC) are registered. Based on the GR a new multicenter neoadjuvant trial (GAIN) with the support of the DFG (grant) /AIO/CALGP/ACO has been started in 20 centers in Germany and in addition a trial in trial concept, including GAIN and the GR is planned. GAIN is a randomized multicenter phase III study for T2-3 IGBCs + resectable and borderline resectable biliary tract cancers (BTC), evaluating the role of neoadjuvant CTX with Gem/Cis in a multimodal setting in front of and after surgery vs. upfront surgery alone. If screened pts. is not eligible for curative treatment, pts. will be directly included in another 1st line trial (trial-in-trial concept) under the direction of the GR. All IGBCs in addition will be directly registered in the GR.

Results: In the GR (n > 1100 pts) in T1b- T3 cases there is a significant survival benefit for patients with IRR. Wedge resection of the liver showed good data in T1b and T2. For T3 more radical techniques showed better results. Less than 50% of T2-3 tumors in the GR have had RR.

Conclusions: There is a significant benefit after RR in T1b- T3 IGBC but the results in T3-3 are disappointing like in the whole entity of BTC. Data of current (PRODIGE 15, BILCAP) adjuvant trials are inconsistent. Therefore the multimodal concept based on a biliary network is needed. The GAIN trial is supported by the DFG and is also supported by the German AIO and the German CALGP/ACO. Due to the trial in trial concepts patients screened for GAIN but are candidates for 1st line will be directly included in another 1st line trial without time delay so the project directly closes a healthcare gap. The data of the GR were already able to change the current treatment standards for GBCA in Germany, reflected by the current S3- Guidelines. So GR will now transform to treatment platform and potentially create a new way how to treat biliary pts.

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