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ESMO OPEN SCIENCE FOR OPTIMAL CANCER CARE

CORRIGENDUM

Corrigendum to "Pan-Asian adapted ESMO Clinical Practice Guidelines for the diagnosis, treatment and follow-up of patients with biliary tract cancer"

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The authors report that in the original publication the ESMO-MCBS v1.1 scores for durvalumab-cisplatin-gemcitabine and pembrolizumab-cisplatin-gemcitabine are 4 and 1, respectively. The higher ESMO-MCBS v1.1 score for cisplatin-gemcitabine-durvalumab is due to the high 2-year OS gain observed with this regimen (14.2%). This was, however, based on only 9 patients (2.6% of the durvalumab-treated patients) who were still alive at that time. Thus, it should be noted that it does not currently provide evidence that durvalumab is vastly superior to pembrolizumab in combination with cisplatin-gemcitabine as both drugs incur similar clinical benefit with a HR OS of 0.75 and 0.83 and absolute median OS benefit of 1.6 and 1.8 months, respectively. Future updates to the ESMO-MCBS methodology will account for the proportion of study patients included in tail of the curve survival analyses, resulting in a lower MCBS score for durvalumab-cisplatin-gemcitabine.

Recommendation 4a should read as follows:

"Recommendation 4a. The combination of cisplatin-gemcitabine with durvalumab or pembrolizumab should be considered as standard of care in first-line BTC [I, A; ESMO-Magnitude of Clinical Benefit (MCBS) v1.1 score for durvalumab: 4; ESMO-MCBS v1.1 score for pembrolizumab: 1]. Cisplatin-gemcitabine-S1 is an alternative therapeutic option for fit patients [II, B]."

The revised Figure 1 Algorithm for the treatment of biliary tract cancer is given below.

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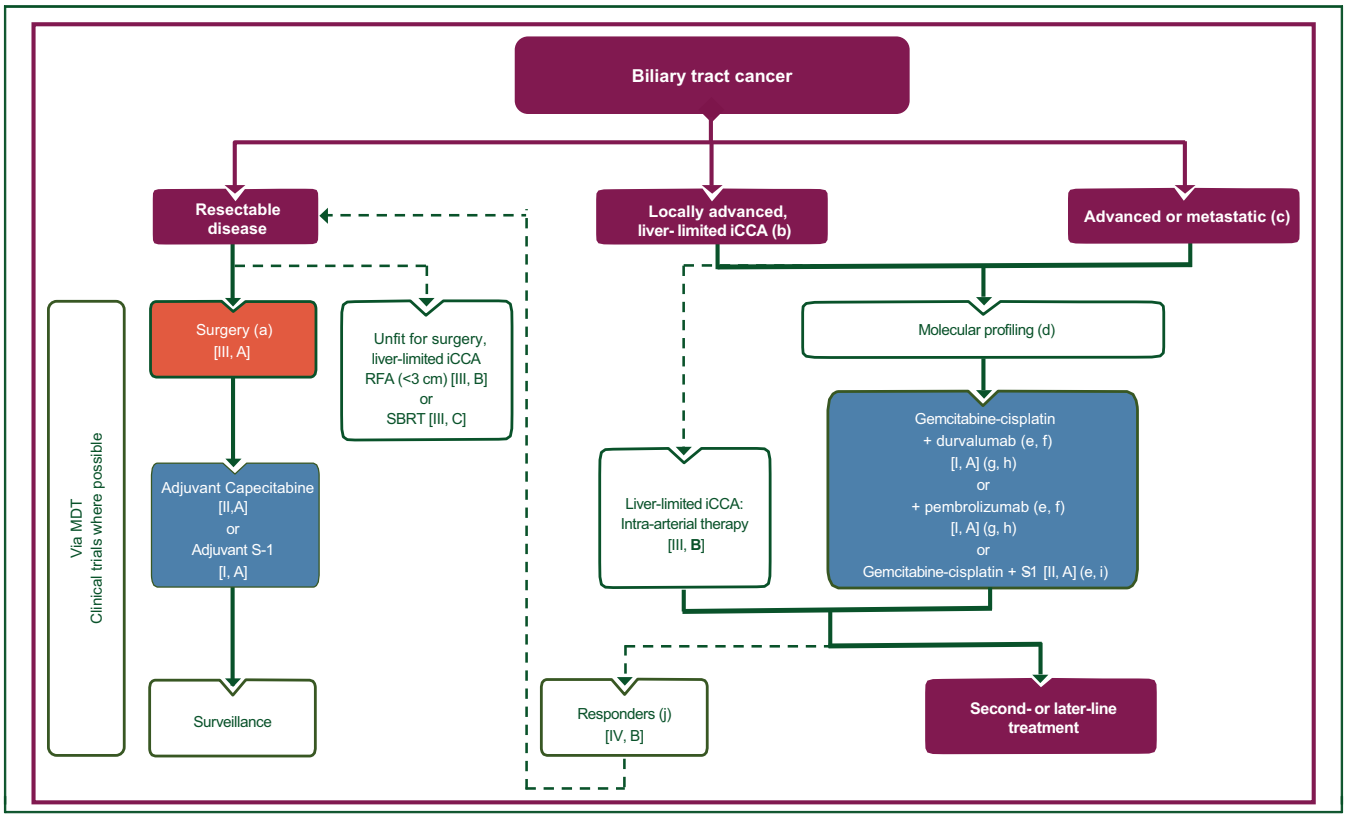

Algorithm for the treatment of biliary tract cancer.
Purple boxes: general categories or stratification; red boxes: surgery; white boxes: other aspects of management; blue boxes: systemic anticancer therapy; dashed lines: optional recommendation.

BTC, biliary tract cancer; ChT, chemotherapy; dCCA, distal cholangiocarcinoma; dMMR, mismatch repair deficiency; EMA, European Medicines Agency; ESCAT, ESMO Scale for Clinical Actionability of Molecular Targets; FDA, US Food and Drug Administration; FGFR2, fibroblast growth factor receptor 2; FOLFOX, 5-fluorouracil, leucovorin and oxaliplatin; GBC, gallbladder cancer; HER2, human epidermal growth factor receptor 2; iCCA, intrahepatic cholangiocarcinoma; IDH1, isocitrate dehydrogenase 1; MCBS, ESMO-Magnitude of Clinical Benefit Scale; MDT, multidisciplinary team; MSI-H, microsatellite instability-high; NTRK, neurotrophic tyrosine receptor kinase; pCCA, perihilar cholangiocarcinoma; PD-1, programmed cell death protein 1; PS, performance status; RFA, radiofrequency ablation; S-1, tegafur, gimeracil and oteracil; SBRT, stereotactic body RT; RET, rearranged during transfection; TMB-H, tumour mutational burden-high.

(a) Special considerations: (i) consider the need for preoperative drainage; (ii) avoid percutaneous biopsy in resectable d/pCCA; (iii) assess future liver remnant; (iv) neoadjuvant approach (selected cases); (v) completion surgery for incidental GBC stage _T1b.

(b) Salvage surgery or local therapies should be considered in responding patients with initially inoperable disease.

(c) Clinical trial recommended when available.

(d) Molecular profiling should be carried out before/during first-line therapy. Gene panel should include *FGFR2*, *IDH1*, *HER2*/neu and *BRAF* to test for hotspot mutations, but may also include genes such as *NTRK* and *c-MET*. The rapidly evolving landscape of drug targets and predictive biomarkers may necessitate larger panels in the future.

(e) Cisplatin-gemcitabine-durvalumab [I, A], cisplatin-gemcitabine-pembrolizumab [I,A], and cisplatin-gemcitabine-S-1 [II, A] are recommended for first-line treatment. Consider gemcitabine monotherapy in patients with a compromised PS or significant debility who are at risk of toxicity from platinum-containing ChT regimens; oxaliplatin or carboplatin can replace cisplatin in the presence of renal insufficiency or ototoxicity; gemcitabine plus S-1 can be considered for patients with or susceptible to peripheral sensory neuropathy.

(f) EMA and FDA approved.

(g) ESMO-MCBS v1.1[36] was used to calculate scores for therapies/indications approved by the EMA or FDA. The scores have been calculated by the ESMO-MCBS Working Group and validated by the ESMO Guidelines Committee (https://www.esmo.org/guidelines/esmo-mcbs/esmo-mcbs-evaluation-forms).

(h) *"The ESMO-MCBS v1.1 scores for durvalumab-cisplatin-gemcitabine and pembrolizumab-cisplatin-gemcitabine are 4 and 1, respectively. The higher ESMO-MCBS v1.1 score for cisplatin-gemcitabine-durvalumab is due to the high 2-year OS gain observed with this regimen (14.2%). This was, however, based on only 9 patients (2.6% of the durvalumab-treated patients) who were still alive at that time. Thus, it should be noted that it does not currently provide evidence that durvalumab is in some way better than pembrolizumab in combination with cisplatin-gemcitabine as both drugs incur the same benefit with an HR OS of 0.7 and absolute benefit of 1.5 months. Future updates to the ESMO-MCBS methodology will account for the proportion of study patients included in survival analyses, resulting in a lower MCBS score for durvalumab-cisplatin-gemcitabine."*

(i) Not FDA or EMA approved.

(j) Reconsider surgery in the event of adequate response to treatment.

[36]Cherny NI, Dafni U, Bogaerts J et al. ESMO-Magnitude of Clinical Benefit Scale version 1.1. Ann Oncol 2017; 28(10): 2340-2366.

The authors would like to apologise for any inconvenience caused.