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Advanced intrahepatic cholangiocarcinoma (iCCA) treated with arterial-directed therapies (ADT): Outcomes and safety from a multicenter Italian experience

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Background: Most of iCCA patients die because of hepatic progression, even in metastatic stage. Chemotherapy leads to modest increase in life expectancy; arterial-directed therapies (ADT), such as chemoembolization (TACE) or radioembolization (TARE), have been proposed to obtain local disease control, eventually leading to a survival benefit.

**Methods:** We conducted a multicenter retrospective study involving 8 Italian Cancer Centers to evaluate efficacy outcomes and safety of ADT in advanced iCCA. Primary endpoint was overall survival (OS) from the first ADT.

Results: 99 patients received at least one ADT from 2007 to 2017. TACE was performed in 74 patients, TARE in 25 patients. Median time from diagnosis of advanced disease to first ADT was 7.0 months. Median OS from first ADT was 11.9 months (95% CI 9.9-16.1); progression-free survival was 3.4 months (95% CI 3.2-4.0) with a disease control rate of 64% and an objective response rate of 20%. Adverse events (AE) after procedure were reported in 37 patients, more commonly low grade (G1-G2) abdominal pain (19%) and fever (18%); G3-G4 AE were reported in 11% of patients, while one fatal (G5) AE occurred due to brain hemorrhage one week after the procedure. No survival differences were observed in patients receiving more than one ADT (n.47) compared to those receiving only one procedure (n.52). OS according to procedure (TARE or TACE) was 19.1 and 10.5 months respectively (HR 0.53; 95% CI 0.32-0.88; p.031). Extrahepatic disease and Ca19.9 levels > 100 kU/L were significantly associated with worse OS at univariate analysis (HR 1.77 and 2.73, respectively).

Conclusions: Patients receiving ADT had good survival outcomes when compared with historical data of systemic chemotherapy, although authors acknowledge these data could also be driven by a selection bias. Procedures were feasible and tolerable, with limited serious AEs. Notably, patients receiving more than one procedure did not gain an OS benefit compared to those receiving only one ADT. According to these retrospective data, performing ADT in presence of extrahepatic disease may be questionable. Specific prospective studies should be designed in order to confirm ADT role in in ICCA.

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