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Randomised controlled trial to evaluate a new sealant to prevent biliary fistula in liver surgery: Should we reconsider bile leak classification?

Matteo Maria CIMINO*, Fabio PROCOPIO, Simone FAMULARO, Jacopo GALVANIN, Simone GIUDICI, Valentina TAGLIAFERRI, Matteo DONADON, Luca VIGANO', Daniele DEL FABBRO, Guido TORZILLI

General and Hepatobiliary Surgery, Humanitas Clinical and Research Center - IRCCS, Rozzano Milan - Italy, Italy

Introduction: Biliary fistula (BF) is the most common post hepatectomy complication. Different definitions have been proposed. The International Study Group of Liver Surgery (ISGLS) definition is the most used. The definition adopted in Humanitas Research Hospital (HRH) defines BF as bilirubin concentration in the drain fluid greater than 10 mg/dL on or after POD 3. Various topical haemostatic agents have been developed, their usefulness in preventing BF remains unclear and needs to be assessed.

Methods: First endpoint: assess the clinical benefit of using Hemopatch to prevent post-operative BF. Secondary endpoint: evaluate the clinical impact of the two definitions. We designed a randomized controlled study on 220 patients: 110 Hemopatch group (group-A) and 110 standard group (group-B), who underwent hepatic resection from 2018 to 2020. All patients were drained. Drains were removed with drain bilirubin concentration less than 10 mg/dL on POD 7.

Results: BF (ISGLS definition) occurred in 139 (63.5%) patients, 67 (60.9%) in group-B and 72 (66.1%) in group-A ($p = 0.515$). One-hundred-twenty fistulas (54.5%) were grade A, 18 (9%) grade B, 1 (0.5%) grade C. Considering HRH definition, BF occurred in 19 (8.7%) patients, 6 (5.5%) in group-B and 13 (11.9%) in group-A ($p = 0.144$). Sixteen (84.2%) were treated conservatively, 2 (10.5%) performed ERCP, 1 (5.3%) underwent relaparotomy. At multivariate analysis the only factor associated with BF increased risk was transection of the main portal branch (OR = 54.35; $p = 0.026$).

Conclusions: Hemopatch does not reduce the incidence of BF, considering both the ISGLS and HRH definition. The different rate of BF in the two classification may lead to reconsider its definition.

Corresponding Author: Matteo Maria CIMINO (matteo_maria.cimino@humanitas.it)

Presenter: Matteo Maria CIMINO (matteo_maria.cimino@humanitas.it)



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