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MULTIMODAL INTEGRATION OF LIQUID BIOPSY AND RADIOLOGY FOR NONINVASIVE DIAGNOSIS OF GALLBLADDER CANCER AND BENIGN DISORDERS: A MULTI-CENTER, PROSPECTIVE STUDY

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Background : Gallbladder cancer (GBC) often resembles gallbladder benign lesions (GBBLs) on radiological imaging findings, which results in a preoperative misdiagnosis for patients with GBC.

Methods : We established a prospective, multicentre clinical trial (ChicCTR2100049249 and NCT04183712) and proposed a multimodal integrated non-invasive diagnostic model for differentiating patients with GBC from those with GBBLs. A total of 301 patients diagnosed with gallbladder-occupying lesions (GBOLs) (203 GBC and 98 GBBLs) from 11 medical centres across 7 provinces in China were enrolled and divided into a discovery cohort (n=203) and an independent external validation cohort (n=98). Plasma samples were collected from all participants preoperatively to extract circulating cell-free DNA (cfDNA), which was subsequently subjected to targeted exon sequencing.

Results : We revealed the cfDNA mutation landscapes of GBC and GBBL patients and developed a predictive model, CBM, leveraging these genomic alterations for detecting GBC. We also developed a modified radiomic

model, RM, via automated segmentation and classification and combined it with the CBM into GBCseeker. GBCseeker displayed strong performance in accurately differentiating GBC and GBBL patients in the discovery cohort (accuracy: 93.3%; 41 GBC and 19 GBBLs) and the external validation cohort (accuracy: 87.7%; 62 GBC and 36 GBBLs). The model also reduced surgeons' diagnostic errors by 56% and reclassified GBOL patients into three categories to assist surgical option.

Conclusions : This multi-analytical method, which relies on personalized, targeted NGS and automatically extracted image features, holds great potential in clinical practice for the adjuvant diagnosis of GBC and subsequently optimizing surgical strategy.

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