

Adjuvant Camrelizumab combined with apatinib treatment after resection of hepatocellular carcinoma in CNLC II and III stage: A single-center prospective phase II trial

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Camrelizumab combined with apatinib treatment after resection of HCC in CNLC II and III stage

- Hepatocellular carcinoma (HCC) is a common cancer worldwide and a leading cause of cancer-related death.
- The recurrence of HCC after hepatic resection remains a major obstacle, with recurrence rates as high as 70% at 5 years.
- An urgent need exists for an effective adjuvant therapy to improve outcomes after resection for patients in CNLC II and III stage.

Camrelizumab combined with apatinib treatment after resection of HCC in CNLC II and III stage

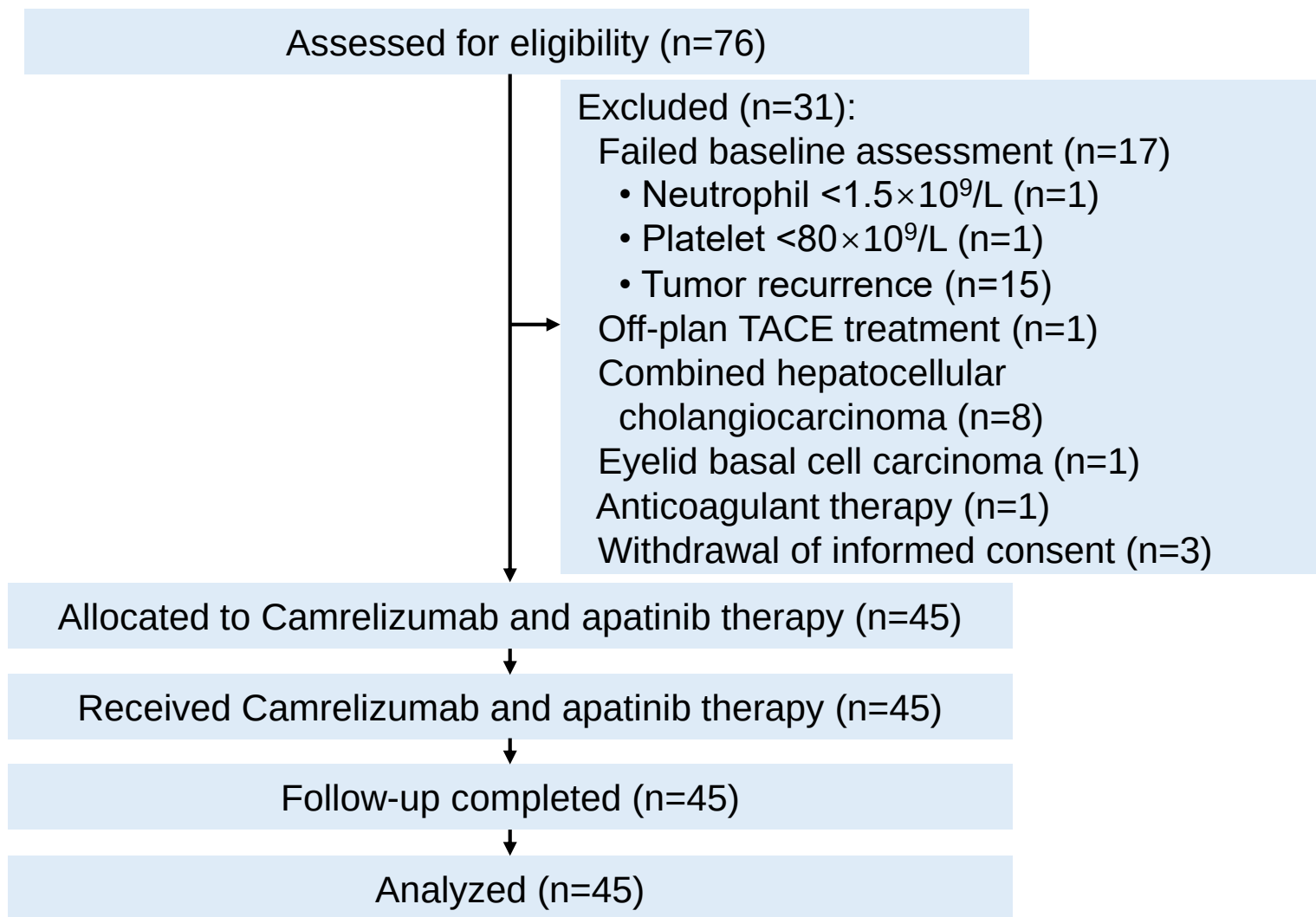
- Camrelizumab is currently available as the second-line treatment for sorafenib-treated HCC.
- Apatinib is currently available as the second-line treatment for sorafenib-treated HCC.
- **Camrelizumab combined with apatinib** has showed promising efficacy and manageable safety in patients with advanced HCC.

Patients and Methods

➤ Inclusion criteria

- HCC confirmed by pathological examination;
- AFP levels below 20 $\mu\text{g/L}$ or confirmed no tumor by MRI at 3-4 weeks after surgery ;
- no history of other tumor types;
- no evidence of extrahepatic metastasis;
- CNLC II and III stage;
- no perioperative mortality.

Flow chart of patient selection



Characteristics of the participants

Characteristics	Values (n=45)
Age, median [range], years	54 [30-77]
Sex (male/female)	42/3
HBsAg (positive/negative)	40/5
α -fetoprotein, median (IQR), ng/mL	121.9 (11.3-3745.0)
Total bilirubin, mean $\pm$ SD, μ mol/L	14.5 $\pm$ 5.8
Alanine transaminase, mean $\pm$ SD, U/L	42.8 $\pm$ 40.3
Aspartate aminotransferase, mean $\pm$ SD, U/L	38.2 $\pm$ 18.8
Albumin, mean $\pm$ SD, g/L	43.0 $\pm$ 3.9
γ -glutamyl transferase, mean $\pm$ SD, U/L	115.8 $\pm$ 112.0
International normalized ratio, mean $\pm$ SD	1.0 $\pm$ 0.1
Hemoglobin, mean $\pm$ SD, g/L	148.6 $\pm$ 18.4
Platelets, mean $\pm$ SD, $\times 10^9$ /L	173.2 $\pm$ 58.3
Leukocytes, mean $\pm$ SD, $\times 10^9$ /L	5.6 $\pm$ 2.0
Portal vein invasion (yes/no)	19/26
Tumor number, median (IQR)	2.0 (1.0-4.0)
Tumor size, mean $\pm$ SD, cm	6.7 $\pm$ 3.0
Tumor encapsulation (yes/no)	13/32
Tumor differentiation (III-IV/I-II)	34/11
CNLC stage (III/II/I)	20/25/0

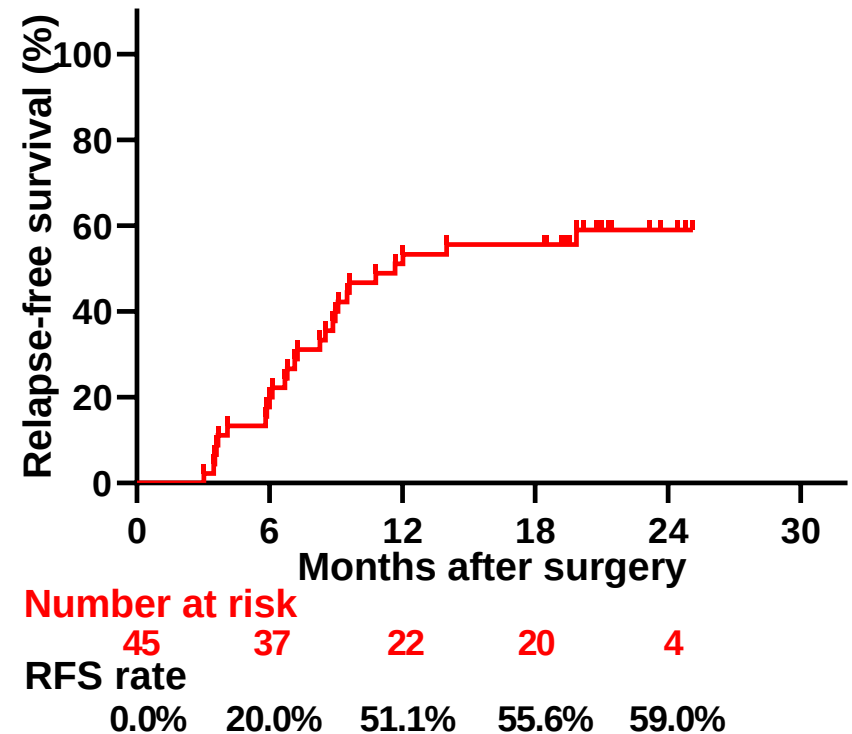
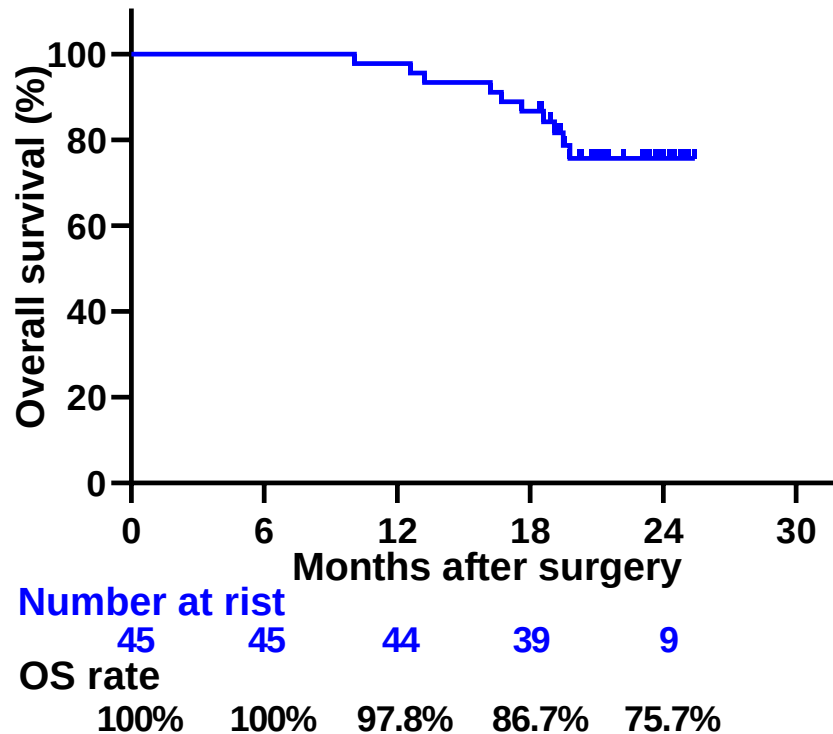
Abbreviations: HBsAg, hepatitis B surface antigen; IQR, interquartile range; SD, standard deviation; CNLC, China liver cancer.

Efficacy evaluation

Variables	Values
Median follow-up (months) median (IQR)	21.5 (19.6–24.0)
Median RFS (months) (95% CI)	11.7 (5.8–17.6)
Median OS (months)	Not reached
1-year RFS rate (%)	48.9
1-year OS rate (%)	97.8

Abbreviations: IQR, interquartile range;
RFS, relapse-free survival; OS, overall survival.

Kaplan-Meier analysis for OS and RFS



Safety of Camrelizumab combined with apatinib in CNLC II and III stage HCC

- The treatment-related adverse events (TRAE) occurred in some patients (18/45, 40.0%) received Camrelizumab plus apatinib treatment.
- Grade ≥ 3 TRAEs occurred in two (4.44%) patients.
- No patient withdrew Camrelizumab plus apatinib due to unbearable adverse events, all patients could tolerate adverse events after dealing with symptoms.
- No treatment-related deaths occurred.

Treatment-related adverse events of Camrelizumab combined with apatinib in CNLC II and III stage HCC

Adverse events	Any grade, n (%)	Grade 3/4, n (%)
Hematological		
Thrombocytopenia	2 (4.4)	1 (2.2)
Leukopenia	1 (2.2)	1 (2.2)
Non-hematological		
Liver dysfunction	11 (24.4)	0 (0.0)
Hypothyroidism	1 (2.2)	0 (0.0)
Infectious pneumonia	1 (2.2)	0 (0.0)
Skin lesion	1 (2.2)	0 (0.0)
Lacunar infarction	1 (2.2)	0 (0.0)

Discussion

- **Camrelizumab combined with apatinib was well tolerated in patients after resection in CNLC II and III stage HCC patients after resection.**
- **Camrelizumab plus apatinib could prolong the 1-year OS rate for HCC patients in CNLC II and III stage compared previously reported.**
- **A prospective, randomized clinical trial with a larger sample size is required to confirm the efficacy and safety of Camrelizumab combined with apatinib in CNLC II and III stage HCC after resection.**



Thank you for your attention!