INTISARI

Latar Belakang: Karsinoma hepatoselular (KHS) merupakan keganasan hati primer dengan prevalensi yang tinggi, berhubungan terutama dengan HBV. Di Asia Tenggara insidens KHS, sekitar 18.35 per 100 ribu penduduk pada laki-laki dan 5.70 per 100 ribu penduduk pada wanita. Di Indonesia insidens kanker diperkirakan 100 penderita baru per 100 ribu penduduk. Dengan penduduk sekitar 237 juta, insidens kasus baru 237 ribu per-tahun. Sebanyak 5,7% kematian semua umur karena kanker yang merupakan penyebab kematian no.7. Angka ketahanan hidup KHS antara 2-6 bulan tanpa pengobatan akurat. Terapi umumnya tidak efektif, pasien sudah pada stadium lanjut. *Transarterial Chemoembolization* (TACE) merupakan terapi yang menjanjikan, obat diberikan langsung melalui arteri pemasok terdekat tumornya. Obat *β-Glucan* mampu mengaktivasi sel-sel imun yang berfungsi membunuh sel-sel kanker. Terapi kombinasi TACE dan *β-Glucan* diharapkan lebih berdayaguna mengobati KHS.

Tujuan: Melakukan evaluasi TACE pada KHS yang dikombinasi dengan obat *β-Glucan* yang diberikan secara oral terhadap respon terapi.

Bahan dan Cara: Penelitian dilakukan di RSUP Dr. Sardjito Yogyakarta pada 63 pasien KHS yang masih terbatas didalam hati. Metode uji klinik secara acak. Pasien dibagi 2 kelompok. Kelompok pertama 32 pasien dengan TACE ditambah obat *β-Glucan* peroral. Kelompok kedua 31 pasien dengan TACE ditambah plasebo. Penelitian telah mendapat *Ethical Clearance.* Pasien diberikan *Informed Consent.* Pasien diikuti dan diperiksa laboratorium darah dan CT abdomen. Respon terapi dicatat, dalam respon komplet, parsial, tidak ada respon , memburuk dan respon imun. Dilakukan análisis statistik X^2, *t-test, relative risk* dan *survival.* Tingkat kemaknaan 0.05, tingkat kepercayaan 95%, *power* 80%.

Hasil: Pada kelompok *β-Glucan* didapatkan respon komplet 4(12.50%), parsial 16 (50%), respon tidak ada 3(9.38%) dan memburuk 9 (28.12%). Kelompok plasebo respon komplet 0(0%), parsial 11 (35,48%), respon tidak ada 2(6.45%) dan memburuk 18 (58.07%). Angka ketahanan hidup kelompok *β-Glucan* lebih lama (*median* 39 minggu) dari pada kelompok plasebo (*median* 26 minggu), CER=64.5%, EER=37.5%, RR=0,58, RRR=42%, ARR=27% dan NNT=4. Terdapat peningkatan CD4, CD8 dan IL-2 pada post TACE secara signifikan ($p<0.05$). Kelompok plasebo mempunyai *hazard risk* 4.143 kali dari pada kelompok *β-Glucan* secara signifikan ($p<0.05$).

Kesimpulan: **T**erapi KHS dengan kombinasi TACE dan *β-Glucan* bermanfaat meningkatkan respon terapi, imunitas dan ketahanan hidup secara signifikan.

Kata kunci: KHS-TACE+Glucan-Respon terapi-Imunitas-Ketahanan hidup.

ABSTRACT

Background: Hepatocellular carcinoma (HCC) is a primary liver malignancy with high prevalence rate, associated primarily with HBV. The incidence of HCC in South East Asia is approximately 18.35 per 100.000 male population and 5.70 per 100.000 female population. Cancer incidence in Indonesia is estimated at 100 new cases per 100.000 inhabitants. With a population of around 237 million, the incidence of new cases is 237.000 annually. A total of 5.7% of deaths of all ages are caused by cancer, which is the 7th leading cause of death. HCC survival rate is about 2-6 months without accurate treatment. Treatment is generally ineffective as patients are already at an advanced stage. Transarterial Chemoembolization (TACE) is a promising therapy where the drug is administered directly through the nearest arteries supplying the tumor. β-Glucan drug is able to activate the immune cells that function to kill cancer cells. TACE and β-Glucan combined therapy is expected to treat HCC more efficiently.

Objective: To evaluate the treatment response of TACE in HCC combined with β-Glucan drug administered orally.

Materials and Methods: The study was conducted at Dr. Sardjito Hospital in 63 HCC patients which are still limited in the liver. The study is a randomized clinical trials. Patients were divided into 2 groups. The first group of 32 patients with TACE plus β-Glucan drug orally. The second group of 31 patients with TACE plus placebo. The study has ethical clearance approved. Patients were given informed consent. Patients were followed and examined for blood results and abdominal CT. Treatment response was recorded, as complete response, partial response, no response, deteriorating imunologic response. X^2, t-test, relative risk and survival statistical analysis test were performed. Significance level is 0.05, confidence level is 95%, and power is 80%.

Results: In β-Glucan grup, patients with complete response were 4 (12.50%), partial were 16 (50%), no response were 3 (9.38%) and deteriorated response were 9 (28.12%). In the placebo group, patients with complete response were 0 patients (0%), partial were 11 (35.48%), no response were 2 (6.45%) and deteriorated response were 18 (58.07%). Survival rate of β-Glucan group was longer (median 39 weeks) than in the placebo group (median 26 weeks), CER = 64.5%, EER = 37.5%, RR = 0.58, RRR = 42%, ARR = 27% and NNT = 4. There is an increase in CD4, CD8 and IL-2 post-TACE significantly ($p<0.05$). The placebo group had hazard risk 4.143 times of the β-Glucan group, significantly ($p<0.05$).

Conclusion: HCC therapy with a combination of TACE and β-Glucan is beneficial to increase the therapeutic response, immunity and survival rate significantly.

Keywords: HCC-TACE+Glucan-Therapy response-Immunity-Survival