文档翻译结果

# 第1页 - 段落1

## 原文:

肝癌系统治疗的设计和终点   
   
肝癌系统治疗的医疗标准   
   
目前，大约50%的肝癌患者将在其生命周期内接受有效的全身治疗 。   
   
一些试验试图证明全身药物对晚期疾病的生存益处 （ 表2、4），这是一个传统的挑战性环境 ，  
因为传统全身化疗的疗效有限且毒性高 。抗雌激素治疗的随机研究也未能证明任何临床疗  
效。   
   
2008年，具有里程碑意义的 SHARP试验评估了多酪氨酸激酶抑制剂 ——索拉非尼为第一个  
显著提高生存率且不良事件可控的药物 。之后，五种治疗方法成功 ，而其他几种药物失败 。  
一线治疗中 ，阿特利珠单抗 （ 抗PD-L1抑制剂）联合贝伐珠单抗 （ VEGFA抑制剂）在最近报  
道的一项随机对照试验中显示优于索拉非尼 。   
   
在第一次中期分析时 ，总生存（ OS）期的风险比 （ HR）为0.58（ 联合用药组的中位未达到 ，  
索拉非尼组为 13.2个月），无进展生存 （ PFS)期的HR为0.59（ 联合用药组的中位 PFS期为  
6.8个月，索拉非尼组为 4.3个月），目前该研究已经停止 。   
   
这些结果将使这种联合治疗成为晚期肝癌的一线治疗标准 。   
   
第二，在非劣效性反映研究的阳性结果 （ HR为0.92）后，仑伐替尼 （[多激酶抑制剂 （ VEGFRs、  
FGFRs、RET、KIT和PDGFRA）已成为等同于索拉非尼的选择 ；95%可信区间 (CI)0.79~1.06] 。   
   
由于本试验排除了门静脉主干侵犯 、肿瘤累及 >50%肝脏和胆管侵犯的患者 ，因此,仑伐替尼  
与索拉非尼对这些患者的相对益处仍不确定 。   
   
在二线治疗中 ，与安慰剂相比 ，瑞戈非尼 （ VEGFRs、PDGFRs、KIT和Tie2）的Ⅲ期试验在进  
展期和对索拉非尼耐受的患者中改善了 OS期，从7.8个月提高到 10.6个月 HR为0.63）。

## 译文:

Design and endpoints of liver cancer system therapy Medical standards for liver Cancer System therapy Currently, about 50 per cent of cancer patients will receive effective systemic therapy during their life cycle. Some trials attempt to demonstrate the survival benefits of systemic drugs for late-onset diseases (Table 2, 4), which is a traditionally challenging environment because traditional systemic chemotherapy has limited and high toxicity. Random studies for estrogen-resistant therapy have also failed to prove any clinical efficacy. In 2008, a milestone SHARP trial assessed a doxorubian kinase inhibitor – a drug that was the first to significantly increase survival rates and control adverse events. After five treatment methods succeeded, several other drugs failed. In the first-line therapy, the anti-PD-L1 inhibitor and the combined anti-VEGFA inhibitor showed superiority over Sorafin in a recently reported randomized control trial. During the first mid-term analysis, the overall survival (OS) period risk ratio (HR) was 0.58 (unreaching intermediate level in the co-treatment group, Sora Fini was 13.2 months), the non-progressive survival (PFS) period HR was 0.59 (unachieved intermediate PFS period was 6.8 months and Sora fini was 4.3 months), and the study has now been discontinued. These results will make such a combination of therapy a standard for the first line therapy for late cancer. Secondly, after the positive results of the study reflecting non-deficiency (HR was 0.92), Lonvafin ([Doxorubians inhibitors (VEGFRs, FGFRs), RET, KIT and PDGFRA) have become the same as the choice of Soraffin; 95% confidence interval (CI) 0.79–1.06]. Since this trial eliminated arterial arterial invasion, tumor build-up and >50 per cent hepatic and biliary invasion patients, therefore the relative benefits of Lonvanvafin and SorAfin for these patients remain uncertain. In a two-line treatment, compared to a placebo, the trials of Reigo Fini (VegFRs、PDGFRs، KIT, andTie2) have improved both in the advanced stages and for patients resistant to Sora Finni, increasing OS from 7.8 months to 10.6 months HR to 0.63.

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# 第1页 - 段落2

## 原文:

展期和对索拉非尼耐受的患者中改善了 OS期，从7.8个月提高到 10.6个月 HR为0.63）。  
索拉非尼 -瑞戈非尼序贯治疗导致中位 OS期为26个月，而索拉非尼 -安慰剂组为 19个月。  
这些结果需要谨慎对待 ，因为它们并不适用于所有接受索拉非尼治疗的患者 ，而只适用于那  
些能够接受序贯治疗的患者 。   
   
CELESTIAL 研究显示 ，卡博坦尼组 VEGFRs、MET和AXL）的中位OS期为10.2个月，安慰  
剂组为8个月（ HR为0.76）；REACH-2研究中，雷莫芦单抗 （ VEGFR2单克隆抗体 ）对AFP>400（  
ng/ml的患者提供的中位 OS期为8.5个月，而安慰剂组为 7.3个月 HR为0.71）。众所周  
知，AFP在HCC中具有独立的预后能力 。因此，REACH-2是第一个也是唯一一个在生物标记  
物驱动的 HCC患者群体中进行的阳性 Ⅲ期试验（ 图2B）。相反，与索拉非尼相比 ，单独治疗  
[SARAH和SIRveNIB] 或联合应用 Y-90和索拉非尼的 3个Ⅲ期试验均未达到改善 OS期的主  
要研究终点 （ 图2A）。因此，EASL指南不鼓励 Y-90用于晚期 HCC的治疗（ 图1）。尽管纳武  
利尤单抗和帕博利珠单抗的 ORR分别为15%和18%，但将前者与索拉非尼进行一线比较和将  
后者与安慰剂进行二线比较的 Ⅲ期试验结果均为阴性 。特别是，后一项试验显示 HR为0.78，  
上边界95CI低于1，但未达到预先规定的 P值 P<0.0178 ）。

## 译文:

These results require careful treatment, as they do not apply to all patients receiving the treatment, but only to those who are able to receive the treatment consistently. CELESTIAL studies show that the intermediate OS of the carbotenyl group VEGFRs, MET and AXL is 10.2 months, the placebo group is 8 months (HR is 0.76); in REACH-2 studies, the remoacetic monoclonal antibody (VEGFR2) provides a medium OS of 8.5 months for AFP>400 ( ng/ml patients and 7.3 months for placebo groups with 0.71). It is well known that AFP has an independent predictive capacity in HCC. Therefore, REach-2 is the first and only positive III trial in a group of HCC patients driven by biological markers (Figure 2B). Conversely, compared to the treatment alone of [SARAH and SIRveNIB] or the combined use of Y-90 and the three III trials of the patient did not reach the main study endpoint for improving the OS (Fig. 2A). Therefore, the EASL Guide does not encourage the treatment of the late HCC with Y-90 ( Fig. 1). Although the ORR of the Nabu Liyu monoantibody and the Pabloli pearl mono antibody are 15% and 18% respectively, the results of the III trial with the former and the latter in a linear comparison with the stimulant are negative. In particular, the second trial showed that HR was 0.78, the upper limit 95CI was lower than 1, but did not achieve the prescribed P value P<0.0178.

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