P24;P72;P73

Journal of Hepatology, 37: 78-86 (2002)

Improved prognosis of postoperative hepatocellular carcinoma patients when treated with functional foods: a prospective cohort study

Yoichi Matsui, Junya Uhara, Sohei Satoi, Masaki Kaibori, Hitoshi Yamada, Hiroaki Kitade, Atsushi Imamura, Soichiro Takai, Yusai Kawaguchi, A-Hon Kwon, Yasuo Kamiyama

Kansai Medical University, Japan

Background

The incidence of hepatocellular carcinoma (HCC) is distributed widely over different geographical areas. The prevention and treatment of the recurrence of HCC following hepatic resection has been studied extensively. However, the prognosis for HCC remains unsatisfactory, with the 5-year survival rate after primary surgical treatment at approximately 40% in Japan. In addition to the treatments mentioned above, there have been many attempts to treat the cancer by stimulating with biological response modifiers (BRMs), but the clinical efficacy of these substances has not been clearly confirmed. AHCC may be considered a potent BRM in the treatment of cancer patients and therefore the effecton HCC is being investigated.

Study design

Prospective Cohort Study (Human intervention trial): Performed from February 1, 1992 to December 31, 2001, consecutive patients with histologically confirme HCC were studied. The enrolled patients were addressed to each arm of the study based on their choice of the therapeutic options, and were trusted with the self-administration of AHCC. Time to treatment failure (disease recurrence or death) and ten parameters related to liver function after surgery were examined.

Subjects

269 consecutive patients with histologically confirmed HCC.(AHCC: 113 and non-AHCC: 156)

Dosage and period

3 g AHCC/day.Period varied on patients.

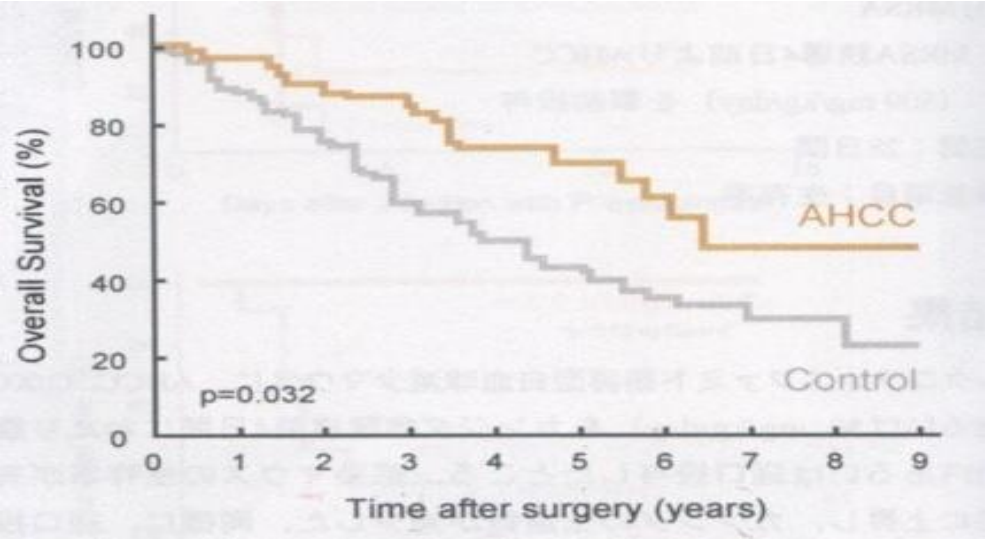
Results

The AHCC group had a significantlylonger no recurrence period and an increased overall survival rate when compared to the control group by Cox's multivariate analysis. AHCC intake seemed to improve the hepatitis disease state, as suggested by improvements in the postoperative levels of AST and GGT.

Conclusion

AHCC intake resulted in improved liver function, the prevention of recurrence of HCC after resection, and the prolonged survival of postoperative HCC patients without any adverse effects.AHCC treatment is a valuable adjuvant therapy as a BRM in these patients.

Figure



Journal of Hepatology, 37: 78-86 (2002)

功能性食品改善肝癌术后患者的一项前瞻性研究

Yoichi Matsui, Junya Uhara, Sohei Satoi, Masaki Kaibori, Hitoshi Yamada, Hiroaki Kitade, Atsushi Imamura, Soichiro Takai, Yusai Kawaguchi, A-Hon Kwon, Yasuo Kamiyama

关西医科大学 （日本）

肝细胞癌（HCC）患者广泛分布在世界不同的区域。预防和治疗肝癌的复发，肝切除术已被广泛的研究。然而，肝癌的预后仍不能令人满意，大多数手术治疗后 5 年存活率约 40%；在日本；除上述治疗，已经有许多尝试通过刺激与生物反应调节剂（BRMS）治疗癌症，但这些物质的临床疗效尚未得到明确的确认。AHCC 可能会被认为是在治疗癌症患者的一个强有力的 BRM（生物学反应调节疗法），AHCC 对 HCC 患者使用效果正在验证。

（人类干预试验）：设计一项前瞻性研究

从 1992 年 2 月 1 日到 2001 年 12 月 31 日期间进行，选择经病理诊断证实患肝癌的患者；选择自愿使用 AHCC；设立非使用人群的对照组。对患者死亡率、生存率、及术后肝功能相关的十项指标进行观察。

269 病例术后肝细胞癌患者（HCC）。

（AHCC 使用群：113 名。AHCC 非使用群：156 名）

使用量及时间

3g　AHCC　/天。使用时间因患者而异。

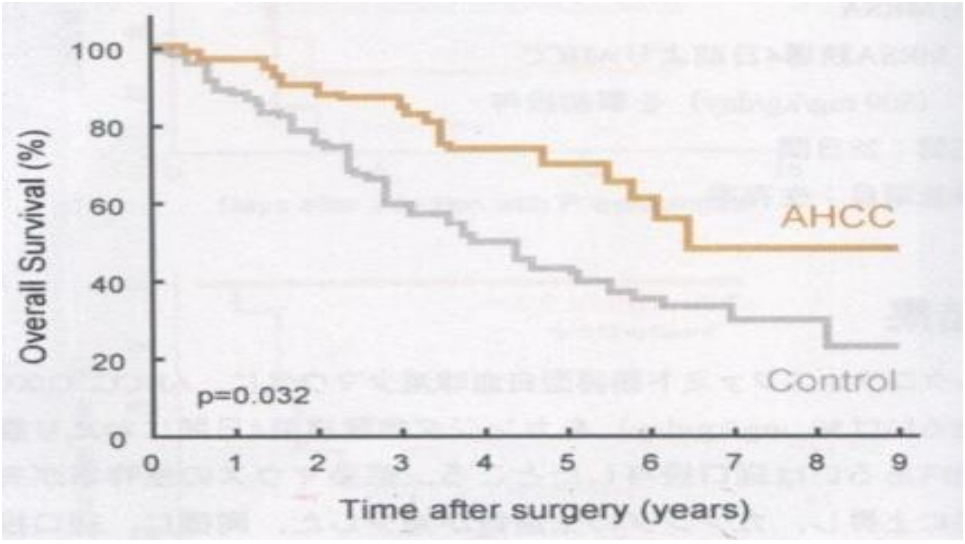
结果

通过 Cox 分析;与对照组相比 AHCC 组有明显延长的无复发期和增加整体的存活率；AHCC 明显改善肝功能相关指标：如 AST、GGT。

结论

AHCC 可改善肝功能，预防术后复发，且无任何不良反应。AHCC 对原发性肝癌术后患者的治疗及生存期的延长是一种有价值的辅助治疗。

图示



P74;P75
Biotherapy, 17(5): 463-465 (2003)

AHCC Provides Survival Advantage for Advanced Cancer Patients

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Background
Systematic chemotherapy is the main method of managing advanced cancer. There have been many attempts to improve effectiveness of anticancer drugs through schedules and biochemical modulation. However, survival benefit sill remains very low. The possible effect of AHCC in cancer therapy are improvement of general condition and enhanced survival rate, which most likely modulate the cancer growth.
Study design
Human intervention trial: Advanced solid cancer patients were divided into an AHCC group and a non-AHCC group. Survival period of these two groups were compared.
Subjects
20 advanced cancer patients(stomach cancer, HCC, lung cancer,choloangiocarcinomas, colorectal cancer, or pancreas cancer)
Dosage and period
3.0-6.0 g AHCC/day combined with other BMRs.Period varied in patients.
Results
The average survival period in the AHCC group was 107 days, and 75 days in the non-AHCC group.
Conclusion
There was no significancefrom statistical data. However, AHCC may have an immunomodulatory role and be helpful for the prolongation of survival period in the treatment of advanced cancer patients.

		AHCC group	Non-AHCC group
No. of patients		10	10
Age	≤49	1	4
	50 - 59	3	2
	60≤	6	4
Sex	male	8	7
	female	2	3
Type of cancer	stomach	3	4

图表

生物治疗，17(5)：463-465 (2003)

AHCC 对晚期癌症患者提高生存质量的研究

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背景

全身化疗是晚期癌症管理的主要方法。已经有许多尝试，以通过提高抗癌药物的有效性和生化调节效果。然而，获得生存率仍然很低。 AHCC 在癌症治疗中的作用是对癌症治疗可能产生的影响是改善全身状况，提高成活率，其中最有可能的控制肿瘤生长。

研究设计

人体干预试验：晚期实体肿瘤患者分为 AHCC 组和非 AHCC 组。这两个群体的生存期进行比较。

受试者

晚期癌症患者（胃癌，肝癌，肺癌，choloangiocarcinomas，结肠直肠癌，胰脏癌）20 例。

剂量和期限

3.0-6.0 克 AHCC/天，结合其他 BRMS

结果

在 AHCC 组中的平均生存期为 107 天，而在非 AHCC 组生物治疗生存期为 75 天。

结论

没有统计学的数据。然而，AHCC 有免疫调节作用，有利于配合药物治疗中晚期癌症患者，延长生存期。

图表

		AHCC group	Non-AHCC group
No. of patients		10	10
Age	≤49	1	4
	50 - 59	3	2
	60≤	6	4
Sex	male	8	7
	female	2	3
Type of cancer	stomach	3	4
	HCC	1	5
	lung	2	-
	cholangiocarcinoma	2	-

Townsend Letter for Doctors and Patients, Feb-March: 88-92 (2005)

An In-Office Evaluation of Four Dietary Supplements on Natural Killer Cell Activity

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Lexington Natural Health Center, USA

Background
Despite recent advances in oncology, a substantial amount of people with cancer are dying in less than fie years. It may be possible to improve a cancer patient's prognosis by maintaining a high NK cell activity level. Several studies have demonstrated improved survival rates after activated killer cells are transferred into cancer patients. The purpose of this in-office study was to determine if nutritional supplements such as AHCC consistently and significantly affected NK cell activity in cancer patients as advertised.
Study design
Nonrandomized, open-label trial (human clinical intervention trial): 34 patients were divided into 4 groups and administrated with 4 different nutritional supplements. NK cell activities were assessed before treatment and after an average of 16 weeks of therapy.

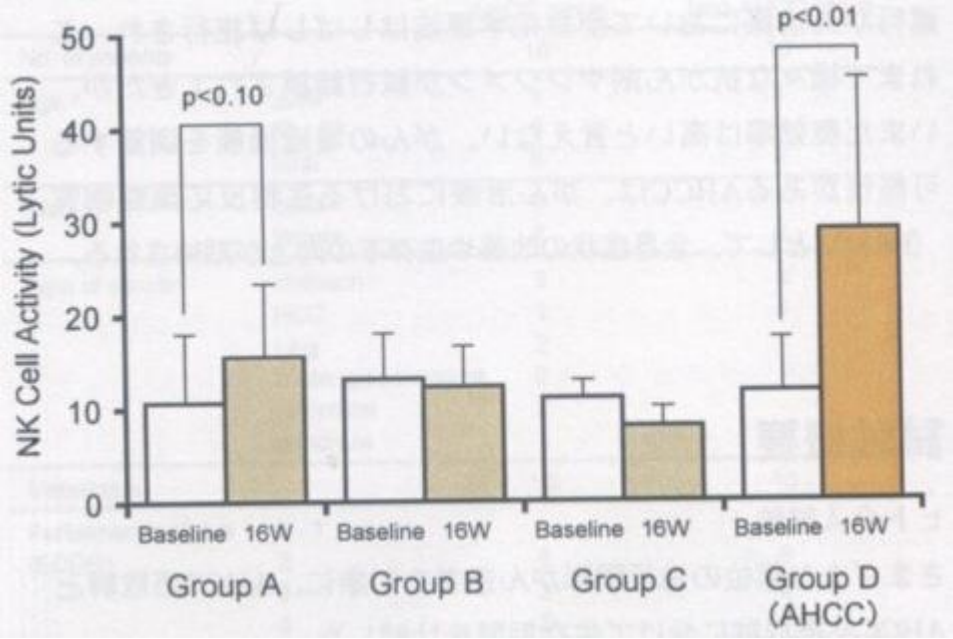
Subjects
34 cancer patients.

Dosage and period

Average 16 weeks.
Group A (n=15): 1-3 g of modified arabinoxylane per day.
Group B (n=8): 6000 mg of coriolus mushroom per day.
Group C (n=3): 4 g of antigen-infused dialyzable bovine colostrum/whey extract per day.
Group D (n=8): 3-6 g of AHCC per day.

Results and conclusion
AHCC was the only supplement that consistently and statistically increased NK cell activity. The average increase was 249%. Modified arabinoxylane statistically increased NK cell activity, but did not consistently help every patient. No side effects were encountered during the study period in any of the four groups.

Figure



Townsend Letter for Doctors and Patients, Feb-March: 88-92 (2005)

四个膳食补充剂对天然杀伤细胞活性的作用

詹姆斯·贝朗格
Lexington Natural Health Center, USA

背景

尽管在肿瘤学领域的最新进展，大量的癌症患者在不足 5 年内死亡。但我们可通过提高患者 NK 细胞活性的水平，以改善癌症患者的预后。许多研究证明激活杀伤细胞可改善已转移癌症患者的存活率。我们这项研究的目的是确定在癌症患者中 AHCC 能否显著影响 NK 细胞的活性。

研究设计

（非随机人体临床干预试验）：34 例患者随机分为 4 组，分别用 4 种不同的营养补充剂。 NK 细胞活性的治疗前和平均 16 周的治疗后进行了评估。

主题 受试者

34 癌症患者。

剂量和期限

平均 16 周。

A 组（N=15）：，每天 arabinoxylane1-3 克。

B 组（N=8）：每天云芝 6000 毫克。

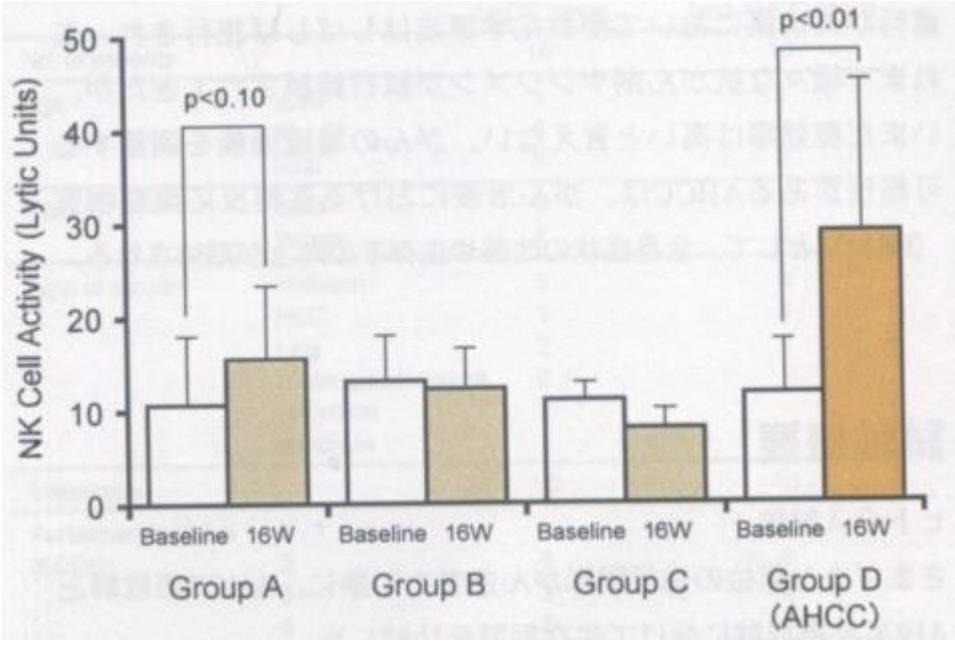
C 组（N=3）：每天牛初乳 4 克。

D 组（N=8）：每天 AHCC3-6 克。

结果与结论

AHCC 增加 NK 细胞活性；平均涨幅为 249％。有统计学意义；arabinoxylane 增加 NK 细胞的活性，但并非每一位病人都有效。在四组研究期间均无副作用。

图示



P32;P78;P79

Asian Pacific Journal of Allery and Immunology, 24: 33-45 (2006)

Prognostic improvement of patients with advanced liver cancer after active hexose correlated compound (AHCC) treatment

Suwanna Cowawintaweewat 1, Suphon Manoromana 2, Hutcha Sriplung 3, Thiravud Khuhaprema 2, Pongsri Tongtawe 1, Pramuan Tapchaisri 1, Wanpen Chaicumpa 1

1 Thammasat University, Thailand

2 Ministry of Public Health, Thailand

3 Prince of Songkha University, Thailand

Background

Most patients with liver cancer are diagnosed when they are not suitable for resection. Although some palliative approaches can be applied to these patients, the overall survival rate remains unsatisfactory. Active hexose correlated compound (AHCC), a newly developed functional food, has been shown to act as a potent biological response modifier in in vitro experiments. Recently, AHCC was found to improve the prognosis of hepatocellular carcinoma patients following surgical treatment. We investigated whether AHCC could prolong survival and improve the prognosis of patients with advanced liver cancer.

Study design

Randomized prospective, placebo controlled trial (human clinical intervention trial): A prospective cohort study was performed with 44 patients with histologically confirmedliver cancer. Survival time, quality of life, clinical and immunological parameters related to liver function, cellular immunity, and patient status were determined.

Subjects

44 liver cancer patients undergoing supportive care.(AHCC group: 34 and placebo: 10)

Dosage and period

6 g of AHCC per day.Period varied in patients.

Results

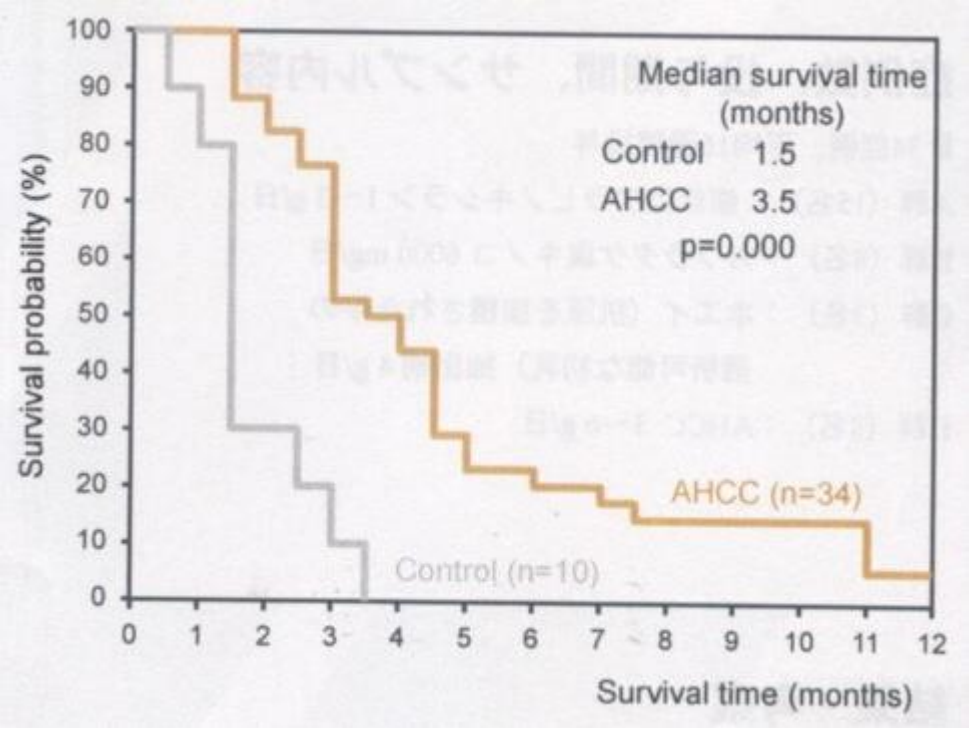
Patients in the AHCC treated-group had a significantly prolonged survival when compared to the control group. Quality of life in terms of mental stability, general physical health status, and ability to have normal activities were significantly improed after 3 months of AHCC treatment.

The apparent different clinical parameters between the two groups were the levels of albumin and percentage of lymphocytes with p-values of 0.000 and 0.026 at 1 and 2 months after treatment, respectively. Unlike the control patients, AHCC treated-patients with longer survival time had the tendency of better outcomes since the levels of AST and ALT had not increased rapidly from their baselines at followup. In addition, the levels of total IL-12 and neopterin were slightly increased in AHCC treated-patients.

Conclusion

This study suggests that AHCC intake could prolong the survival and improve the prognosis of patients with advanced liver cancer and delay the gradual decline of their physiological status.

Figure



AHCC 改善晚期肝癌患者预后的研究

Suwanna Cowawintaweewat 1, Suphon Manoromana 2, Hutcha Sriplung 3, Thiravud Khuhaprema 2, Pongsri Tongtawe 1, Pramuan Tapchaisri 1, Wanpen Chaicumpa 1

1 Thammasat University, Thailand

2 Ministry of Public Health, Thailand

3 Prince of Songkha University, Thailand

背景

大多数肝癌患者被诊断时，他们是不适合手术切除。虽然这些患者可应用一些姑息性治疗方法，但总体生存率仍不能令人满意。AHCC 已被证明作为一种有效的生物反应调节剂在体外实验。最近，AHCC 被发现改善肝癌患者手术治疗后的预后。我们这项研究是证明 AHCC 是否可改善晚期肝癌患者的预后并延长生存期。

研究设计

（人体临床干预试验）：食用 AHCC 患者和食用安慰剂患者随机分组；44 例经病理确诊的肝癌病人。观察患者的生存时间，生活质量，相关的肝功能，细胞免疫水平等免疫学参数。

主题　试验者

44 肝癌患者中：（AHCC 组：34 例和安慰剂组：10 例）。

剂量和期限

每天 6 克。

结果

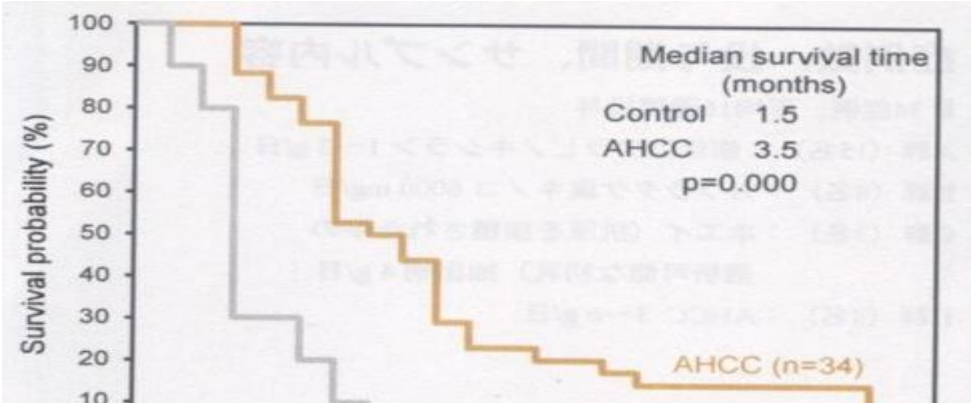
在 AHCC 组患者有显着的生存时间延长，与对照组相比。心理稳定的生活质量方面，一般的身体健康状况，并有明显改善正常的活动能力，3 个月后 AHCC 组显著改善。

服用 1 到 2 个月后；两组之间的明显不同的临床参数为血清蛋白的水平和淋巴细胞的数量；p 值为 0.000 到 0.026；有统计学的意义。AHCC 治疗的患者生存时间更长，有更好的结果，血清 AST 和 ALT 水平没有迅速增加。此外，总的 IL-12 和 neopterin 水平在 AHCC 治疗的患者略有增加。

结论

这项研究表明，AHCC 的摄入可以延长生存期，改善晚期肝癌患者的预后和延缓他们逐渐下降的生理状态。

图示



P43

Journal of Society Integratigve Oncology,6(3),105-109(2008)

AHCC 肝代谢及与化疗药物相互作用潜力的评价

Claire M.March ,Judith Smith,et al.
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从担子菌提取的活性己糖相关化合物（AHCC）是一种能被广泛接纳、无副作用的营养补充剂。已显示它具有潜在的抗肿瘤活性和免疫调节活性。但是，目前还没有任何有关 AHCC 自身代谢及其联合与化疗药物之间相互作用可能性的报道。本研究的目的是探讨 AHCC 在肝脏的代谢，特别是与化疗药物之间相互作用的情况。采用高通量细胞色素 P450（CYP450）代谢抑制试验，在体外评价细胞色素 P450 3A4、2C8、2C9 以及 2D6，随后把 AHCC 作为这些同功酶的底物进行试验。　采用冻存人肝细胞的体外模型，评价 AHCC　对细胞色素 P450 代谢酶（P450 3A4、2C8、2C9、2D6）的诱导性能。结果没有观察到 AHCC 对 CYP450 活性有抑制作用；AHCC 却成为了 CYP 2D6 的底物。CYP450 诱导代谢试验表明，AHCC 是 CYP450 2D6 的诱导因子。AHCC 可能具有对诸如阿霉素和奥坦西隆这类含有 CYP450 2D6 的药物产生相互作用的潜力。不过，综合数据显示，AHCC 与几乎所有不经过 CYP450 2D6 通路代谢的化疗药物一齐使用都是安全的。

P84;P85

Nutrition & Cancer, 60(5), 643-651 (2008)

Immunological Effect of Active Hexose Correlated Compound (AHCC) in Healthy Volunteers:a Double-Blind, Placebo-Controlled Trial.

Naoyoshi Terakawa, Yoichi Matsui, Sohei Satoi, Hiroaki Yanagimoto, Kanji Takahashi, Tomohisa Yamamoto, Jun Yamao, Soichiro Takai, A-Hon Kwon, Yasuo Kamiyama

Kansai Medical University, Japan

Background

Recently, the incidence of malignant tumor has been increasing consistently in Japan. The development of imaging modalities has enabled the diagnosis of malignant tumor at an early stage with relative ease. However, it is still difficult to control disease progression of advanced cancer. We have shown clinically that AHCC intake resulted in improved liver function, prevented the recurrence of hepatocellular carcinoma (HCC) after resection, and prolonged survival of postoperative HCC patients without any adverse effects. Herein, we report the results of a randomized controlled trial to evaluate the effects of AHCC intake on immune responses by investigating the number and function of circulating DCs in healthy volunteers.

Study design

Double-blinded Randomized Placebo Controlled (Human clinical intervention trial): The number of circulating CD11c+ DCs (myeloid DC population; DC1), CD11c- DCs (lymphoid DC population; DC2), natural killer (NK) cells, and CD4+/CD8+ T lymphocytes were measured in each sample by flow cytometric analysis. To assess immune function, the allogeneic (allo-) mixed-leukocyte reaction (MLR; allo-MLR) was determined. NK cell activity and the proliferative response of T lymphocytes toward

mitogen (phytohemagglutinin [PHA]) were measured. We also measured serum hormone levels (thyroid-stimulating hormone, 3,5,3'-triiodothyronine, thyroxine, and estradiol) and cytokine concentrations(IL-2, IL-4, IL-6, IL-10, IFN-γ tumor necrosis factor [TNF]-a).

Subjects

21 healthy volunteers, divided into
AHCC (n = 10) and placebo (n = 11) groups.

Dosage and period

3.0 g AHCC/day (n = 10) for 4 months.

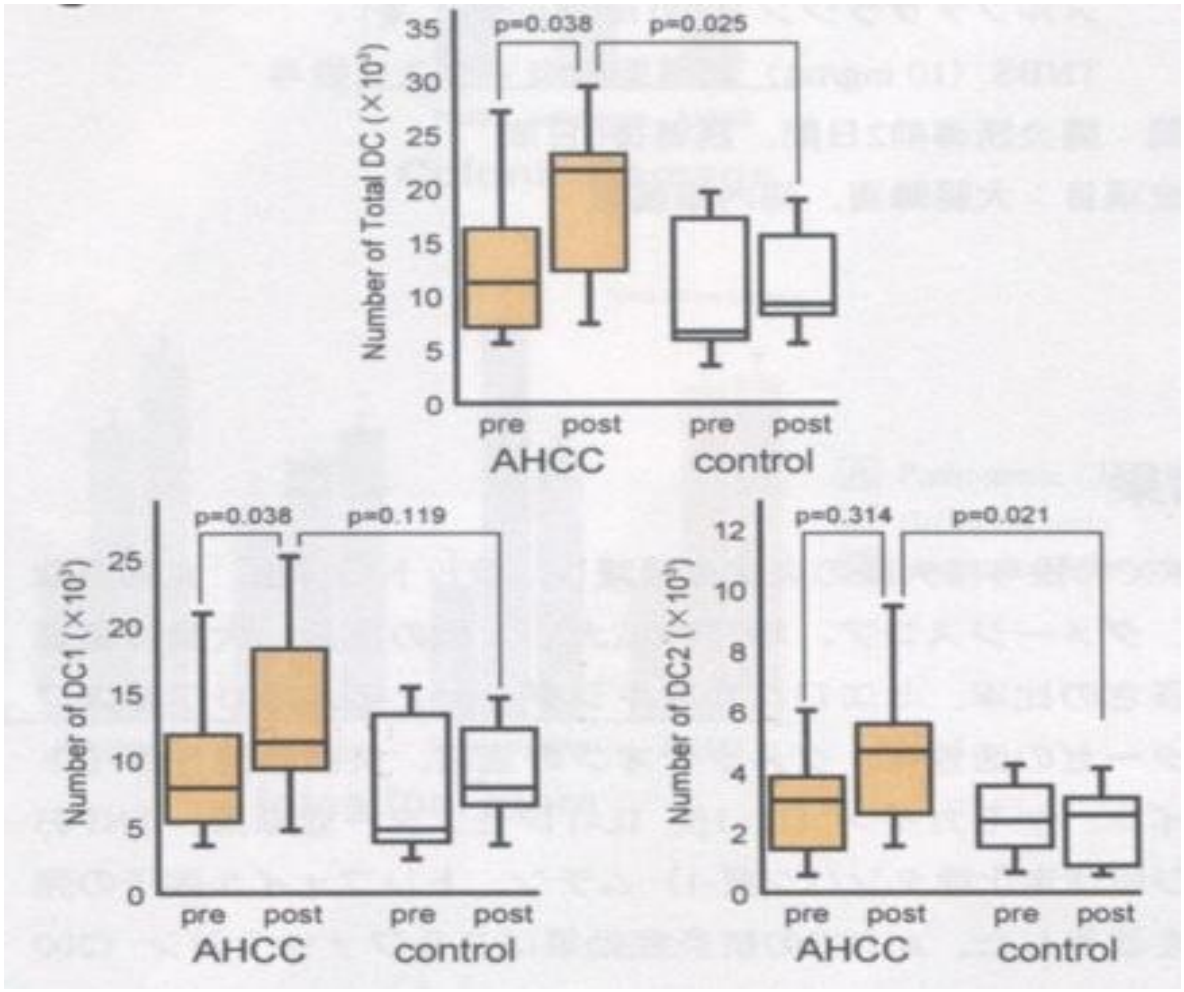
Results

- Greater number of total DCs than at baseline and compared to control
- The number of DC1 cells was greater after AHCC intake than at baseline and the AHCC group had a tendency to have higher DC1s than control
- DC2s were significantly increased after 4 weeks compared to control
- The allo-stimulatory activity of DC1s was also increased after intake compared with control as measured by the mixed lymphocyte reaction (MLR)
- No significant differences in PHA and NK cell activity were found between the AHCC group and controls

Conclusion

AHCC intake for 4 weeks in healthy volunteers resulted in the improved number of DCs and function of DC1s, which is a part of specific immunity.

Figures



Nutrition & Cancer, 60(5), 643-651 (2008)

一项双盲试验：在志愿者中使用 AHCC 免疫效果观察。

Naoyoshi Terakawa, Yoichi Matsui, Sohei Satoi, Hiroaki Yanagimoto, Kanji Takahashi, Tomohisa Yamamoto, Jun Yamao, Soichiro Takai, A-Hon Kwon, Yasuo Kamiyama

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背景

近年来，恶性肿瘤的发病率一直在日本的持续增长。影像技术的发展使早期恶性肿瘤的诊断在一个相对容易。然而，晚期癌症仍然是难以控制的。我们已经证明，AHCC 可改善肝功能，

阻止肝细胞癌（HCC）术后复发，延长术后肝癌患者的生存时间，无任何不良影响。在此，我们报告了一项随机对照试验的结果，调查在健康志愿者中 DCs 的数量和的功能，以评估摄取 AHCC 对免疫反应的影响。

研究设计

双盲随机，安慰剂对照（人体临床干预试验）：循环的数目的 CD11c + DCS（髓系 DC 人口；DC1），表面 CD11c DCs（淋巴 DC 人口；DC2），自然杀伤（NK）细胞，和 CD4 + / CD8 +每个样品中的流式细胞仪检测 T 淋巴细胞。评估免疫功能，同种（异体）混合白细胞反应（MLR；异体 MLR）的测定。NK 细胞活性和 T 淋巴细胞对丝裂原（PHA 的增殖反应，植物血凝素[ ]）的测定。我们还测量了血清激素（促甲状腺激素，3,5,3’-三碘甲状腺原氨酸，甲状腺素，和雌二醇）和细胞因子（IL-2，IL-4，IL-6，IL-10，TNF-α，IFN-γ 和肿瘤坏死因子）

主题（受试者）

21 名健康志愿者，分为

AHCC 组（n = 10）和安慰剂组（n = 11）。

剂量和期限

3.0 克 AHCC/天（n= 10）4 周。

结果

- 与对照组相比 DCs 的数目的数量是增加的。
- AHCC 组 DC1 细胞的数大于对照组，具有更高 DC1s。
- 4 周后 DC2s 与对照组相比显着增加

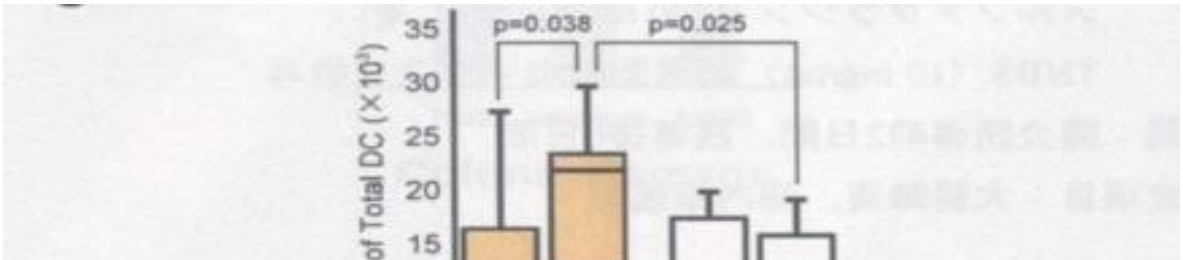
-通过测量混合淋巴细胞反应（MLR）；AHCC 组 DC1s 的主动活性也增强.

- 在 AHCC 组和对照组之间发现了 PHA 和 NK 细胞活性无显著差异

结论

在健康志愿者中摄取 AHCC 4 周后；DCs 的数目和功能 DC1s 是增强的，它是特异性免疫的一部分。

图示



Natural Medicine Journal, 1(1) (2009)

Improved Survival of Patients with Gastric Cancer or Colon Cancer when treated with Active Hexose Correlated Compound (AHCC): Effect of AHCC on Digestive System Cancer

Yusai Kawaguchi
Kansai Medical University, Japan

Background

Gastric cancer is the second most common cause of cancer death world-wide (700,000 deaths in 2002) and colorectal cancer is the third most commonly diagnosed cancer worldwide (1 million diagnosed in 2002). Decreasing incidence and mortality for both gastric cancer and colon cancer have been achieved with earlier detection of disease, improved surgical techniques and advances in novel chemotherapeutics. However, gastric cancer and colon cancer continue to incur significant morbidity and mortality in patients despite these advances. AHCC is a potent biological response modifier capable of increasing innate and adaptive immune activity in vivo and in humans. Studies show thatAHCC may stimulate an anti-tumor immune response in humans that could improve cancer treatment outcomes. The purpose of this study was to evaluate the potential for AHCC to improve overall survival in postoperative gastric and colon carcinoma patients receiving standard chemotherapy.

Study design

Prospective cohort study (Human intervention trial): Patients with a histopathological diagnosis of gastric or colon cancer were recruited to receive oral AHCC as a postoperative adjunctive therapy in conjunction with standard chemotherapy. The cumulative survival rates for gastric and colon cancer patients were analyzed by Kaplan-Meier method from April 1995 to April 2002.

Subjects

132 gastric cancer patients and 113 colon cancer patients.

Dosage and period

3.0 g AHCC/day for stage I, II or III patients.

6.0 g AHCC/day for stage IV patients.
Period varied depending on patients.
Results
AHCC as a functional food improved the cumulative fiveyear survival rates of Stage IA to Stage IIIA gastric cancer (n = 83) and Stage II to Stage III colon cancer (n = 52) patients compared to other institutions.
Conclusion
AHCC is a potent biological response modifier that warrants further investigation as an adjunctive immunotherapeutic in gastric and colon cancer treatment.

Tables

Cumulative 5 Year Survival Rate for Gastric Cancer by Institution

	AHCC Study	Japanese Gastric Cancer Association	Other Japanese Institutions	
Stage I A	100%	93.4%	91.5-93.4%	
Stage I B	100%	87.0%	85.5-88.7%	
Stage II	92.3%	68.3%	74.9-75.9%	
Stage III A	82.8%	50.1%	53.6-61.7%	
Stage III B	35.7%	30.8%	40.4-42.4%	
Stage IV	14.3%	16.6%	Stage IVA Stage IVB	14.3-19.7% 4%

Cumulative 5 Year Survival Rates for Colon Cancer by Institution

	AHCC Study	Other Japanese Institutions
Stage 0	100%	100%
Stage I	100%	93-100%
Stage II	100%	81-88%
Stage III A	95.2%	73-76%
Stage III B	73.3%	63-78%
Stage IV	7.1%	0- 17%

Natural Medicine Journal, 1(1) (2009)

AHCC 改善胃癌或结肠癌的生存率观察：AHCC 对消化系统癌症有效作用

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关西医科大学，日本

背景

胃癌是最常见的癌症死亡原因（2002 全球 700000 人死亡）和大肠癌是全球第三大最常见的癌症诊断（2002 例 1000000）。降低发病率和死亡率胃癌和结肠癌已经与疾病的早期检测的中可实现，得益于手术技术的改进和新型化疗药物的研究进展。然而，胃癌和结肠癌继续产生明显发病率和死亡率的患者。以下是一种能够提高先天免疫和适应性免疫活性在人体内的生物反应调节剂。研究表明， ahcc 可以刺激人体的生物反应调节剂能够增加固有免疫和适应性免疫活性活细胞，可以提高癌症治疗效果的抗肿瘤免疫反应。本研究的目的是评估潜在的 AHCC 改善在接受标准化学治疗术后胃癌和结肠癌患者的整体存活率。

研究设计

前瞻性研究（人类干预试验）：胃癌或结肠癌患者接受口服 AHCC 作为术后辅助治疗与标准化疗联合使用。累积生存率为胃癌和结肠癌患者采用卡普兰迈耶法，从 1995 年 4 月分析，至 2002 年 4 月积累生存率例数。

主题　受试者

132 例胃癌患者和 113 结肠癌患者。

剂量和期限

3.0 克 AHCC/天 I 期，II 期或 III 期患者。

6.0 克 AHCC/天，Ⅳ期患者。

服用期内根据患者不同情况调整。

结果

AHCC 作为功能性食品改善 IA 期的累积 5 年生存率为 IIIA 期胃癌组（n =83）和第二阶段到第三阶段结肠癌组（n =52）的患者相比其他机构。

结论

AHCC 是一种有效的生物反应调节剂，值得进一步研究在胃癌和结肠癌治疗的辅助免疫治疗。

图表

Cumulative 5 Year Survival Rate for Gastric Cancer by Institution

	AHCC Study	Japanese Gastric Cancer Association	Other Japanese Institutions	
Stage I A	100%	93.4%	91.5-93.4%	
Stage I B	100%	87.0%	85.5-88.7%	
Stage II	92.3%	68.3%	74.9-75.9%	
Stage III A	82.8%	50.1%	53.6-61.7%	
Stage III B	35.7%	30.8%	40.4-42.4%	
Stage IV	14.3%	16.6%	Stage IVA Stage IVB	14.3-19.7% 4%

Cumulative 5 Year Survival Rates for Colon Cancer by Institution

	AHCC Study	Other Japanese Institutions
Stage 0	100%	100%
Stage I	100%	93-100%
Stage II	100%	81-88%
Stage III A	95.2%	73-76%
Stage III B	73.3%	63-78%
Stage IV	7.1%	0- 17%

P51；P94；P95
International Journal of Integrative Oncology, 3(2): 12-16 (2009)

Retrospective Study in Breast Cancer Patients Supplemented with AHCC

Yoichi Matsui, Yasuo Kamiyama
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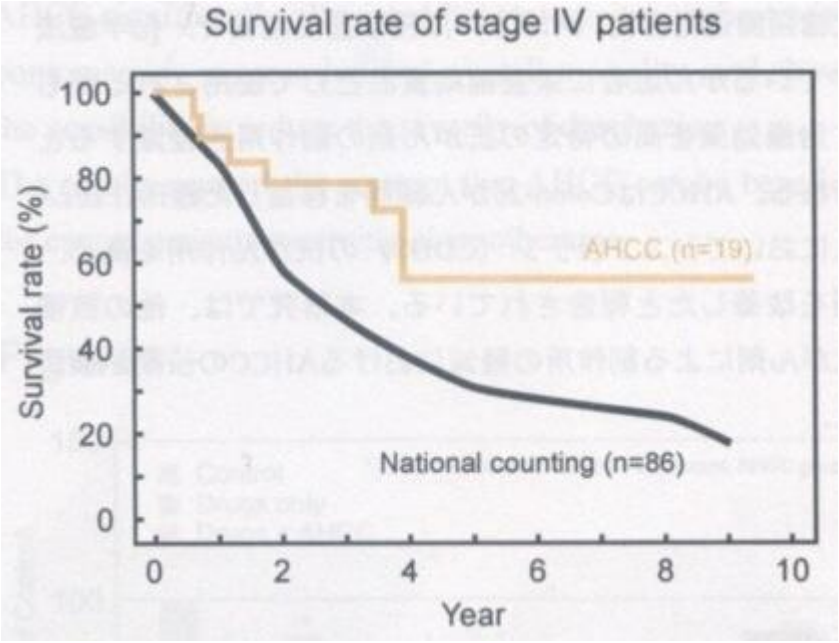
Background
Breast cancer is ranked in third place after gastric and lung cancers in the cause of cancer death of Japanese women. This retrospective study was conducted in terms of the prognosis of advanced breast cancer patients supplemented with AHCC.
Study design
Retrospective cohort study: The study period was six years from May of 1996 to 2002, and the subjects were breast cancer patients who started AHCC administration in our department. The subjects at the age of 28 to 85 years received operative treatment of breast cancer during thirteen years from October, 1987 to September, 2000.
Subjects
47 breast cancer patients
(stage I = 5, II = 13, III = 10, and IV = 19)
Dosage and period
3-6gAHCC/day.period varied on patients.
Results
AHCC supplementation improved the prognosis in Stage IV as compared to the national counting.
Conclusion
The retrospective study in breast cancer patients with AHCC suggested that AHCC might contribute to improving the prognosis in Stage IV although the improvement remains to be elucidated in Stage I, II and III. Therefore, it is considered that a randomized controlled trial of AHCC in breast cancer patients is worthy enough to perform in the future.

Figure



International Journal of Integrative Oncology, 3(2): 12-16 (2009)

乳腺癌患者服用 AHCC 的回顾性研究

Yoichi Matsui, Yasuo Kamiyama
Kansai Medical University, Japan

背景

乳腺癌是排在第三位后的日本女性癌症死亡原因，仅次于胃癌和肺癌。 这项回顾性研究 AHCC 对中晚期乳腺癌患者的预后进行调查。

研究设计

研究期间从 1996 年 5 月到 2002 年的六年期间；,乳腺癌患者开始服用 AHCC。受试者是 1987 年 10 月到 2000 年底十三年间；接受手术治疗的年龄在 28 岁到 85 周岁的乳腺癌患者。

受试者

47 名乳腺癌患者

（I 期= 5，II =13，III= 10，IV =19）

使用剂量和时间

3-6gAHCC/天.病人使用剂量因人而异。

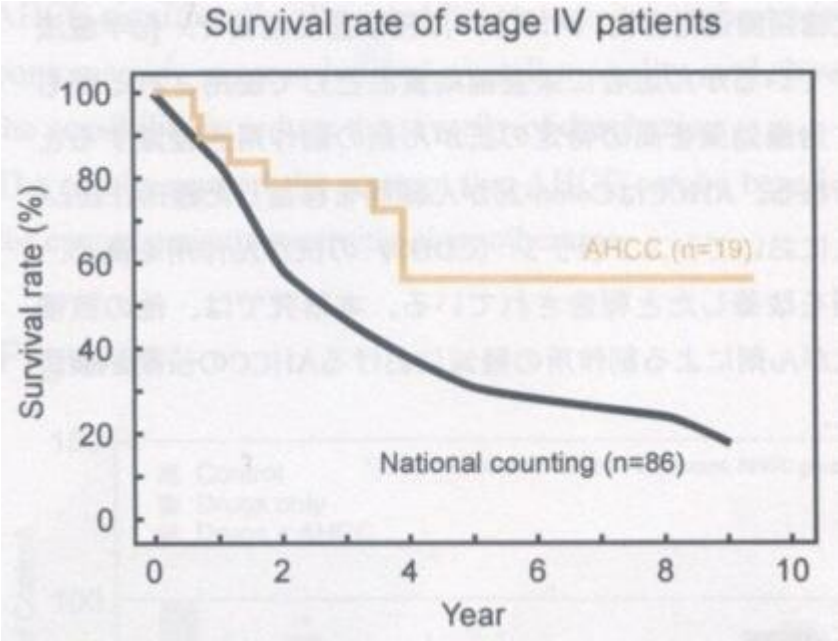
结果

据统计 AHCC 提高Ⅳ期预后。

结论

使用 AHCC 乳腺癌患者的回顾性研究表明,AHCC 对 IV 期乳腺癌患者的预后有改善作用；当然在 I 期 II 期 III 期的乳腺癌患者也支持这个结论。因此该试验表明 AHCC 对乳腺癌患者的未来值得期待。

图示



P52; P96; P97
Anti-Cancer Drugs, 20: 215-216 (2009)

Dramatic Prostate-Specific Antigen Response with activated hemicellulose compound in metastatic castration-resistant prostate cancer

Jeffrey Turner, Uzair Chaudhary
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Background

Castration-resistant prostate cancer (CRPC) is an incurable disease with limited treatment options. Herbal supplements are unconventional treatments for a variety of diseases. Active hemicellulose compound (AHCC) is a Japanese supplement discovered by hybridizing several mushrooms used in traditional healing for the purpose of maintaining 'super immunity'. We report on a 66-year-old gentleman withCRPC with an excellent serologic response to AHCC. This case hypothesizes that AHCC may have potential activity against CRPC.

Study design

Case Study (Human clinical intervention trial).

Subjects

1 Caucasian male (66 years old) with CRPC.

Dosage and period

For 6 months. Dosage is not reported.

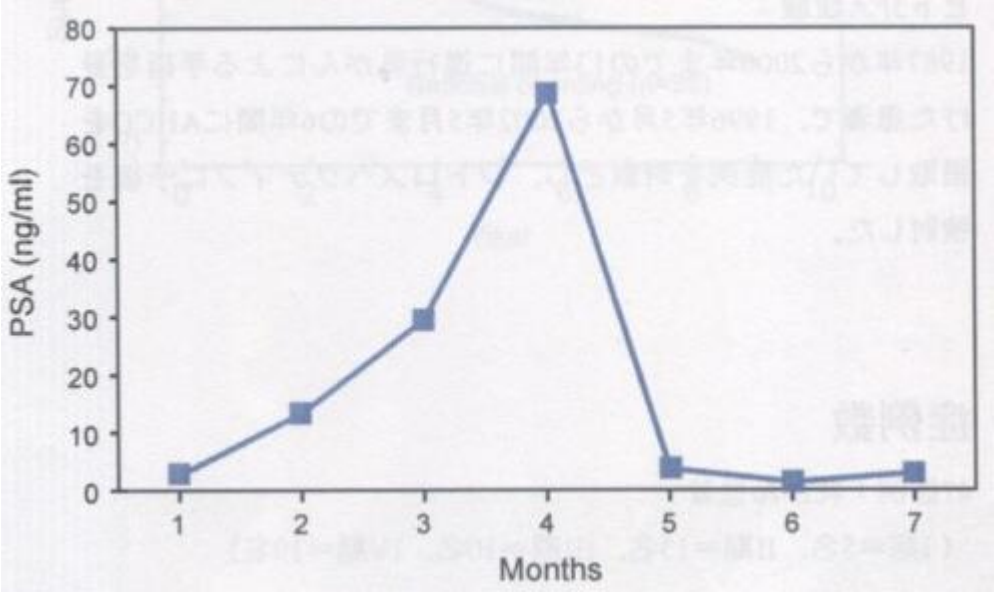
Results

Caucasian gentleman with CRPC with high-risk features who benefited less than 6 months from initial complete androgen blockade. The self-administration of AHCC resulted in a dramatic PSA decrease within 1 month, which continued to control his disease for over 6 months from initial supplementation with AHCC.

Conclusion

Based on limited studies to date, it seems that AHCC may have a role in the management of prostate cancer patients especially those who have failed hormonal therapy.

Figure



Anti-Cancer Drugs, 20: 215-216 (2009)

前列腺癌患者 PSA 的指标观察

Jeffrey Turner, Uzair Chaudhary
Medical University of South Carolina, USA

背景

阉割性前列腺癌（CRPC）是一种很难治愈的疾病。草本植物是多种疾病的非传统的治疗方法。在日本通过杂交几种蘑菇中发现的 AHCC 具有“超级免疫”的功能。我们报告一位 66 岁的老先生的血清学反应。我们推测，AHCC 可能具有潜在的抗 CRPC 活性。

研究设计

案例研究（人体临床干预试验）。

主题　受试者

1 名白人男性（66 岁）与 CRPC。

剂量和期限

6 个月。剂量不具体说明。

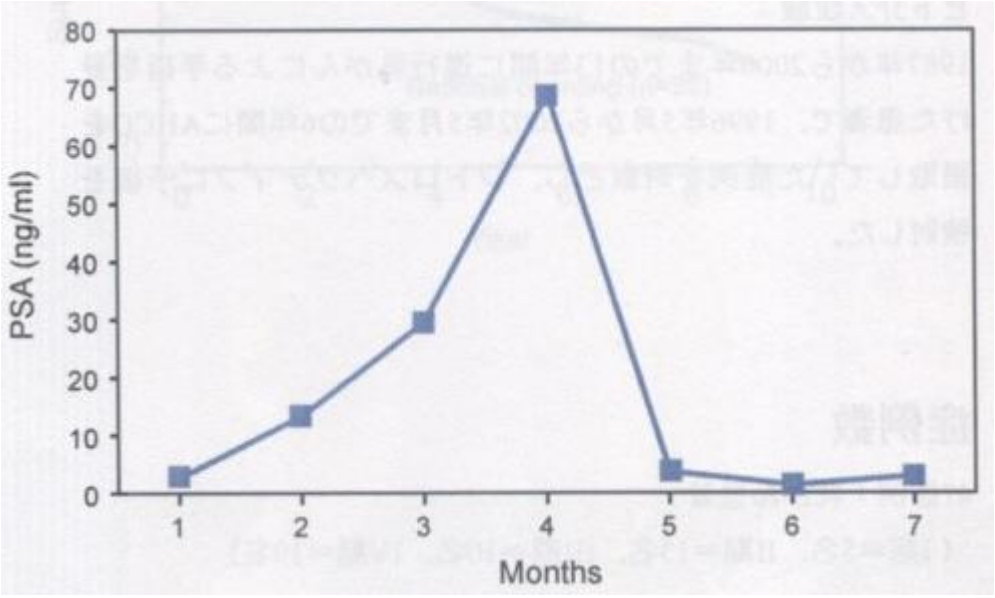
结果

该患者少于 6 个月的高风险特征。 AHCC 使其 1 个月内大幅下降的 PSA，继续控制自己的疾病超过 6 个月不恶化。

结论

到目前为止基于有限的研究，AHCC 可能在前列腺癌病人，特别是那些激素治疗失败的患者有很好的作用。

图示



P98; P99
International Journal of Integrative Medicine, 2(1): 98-111 (2010)

Review of Cancer Therapy with AHCC(R) and GCP(R); The Long-Term Follow-Up over 12 Years for Stage IV (M1) Cancer of the Lung and the Breast

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1 Tajima Clinic, Japan
2 Amino Up Chemical Co., Ltd., Japan

Background

According to the domestic statistics on cancer death in 2007, lung cancer stands the wotst mortality in Japan, and breast cancer stands on the 4th mortality of female cancer. New anti-cancer drugs have been developed in current cancer therapy, and the standard Evidence Based Medicine (EBM) on cancer chemotherapy has been recommended. However, cancer death has not reduced despite of recently advanced chemotherapy. Repeat trials have brought therapeutic gaps between the standard EBM and survival with good QOL. For the patients who are wishing extended survival, individual EBM should be considered. In the view of complementary/integrative medicine, AHCC and GCP have been used as immune support under individual EBM.

Study design

Human intervention trial: Under individual EBM, AHCC and GCP have been used for stage IV cancer of the lung and the breast. Longterm follow-up over 12 years since 1996 has been studied.

Subjects

36 stage IV lung cancer patients and34 stage IV breast cancer patients.

Dosage and period

3.0-6.0 g AHCC/day and 1.92-2.56 g GCP/day.Period varied on patients.

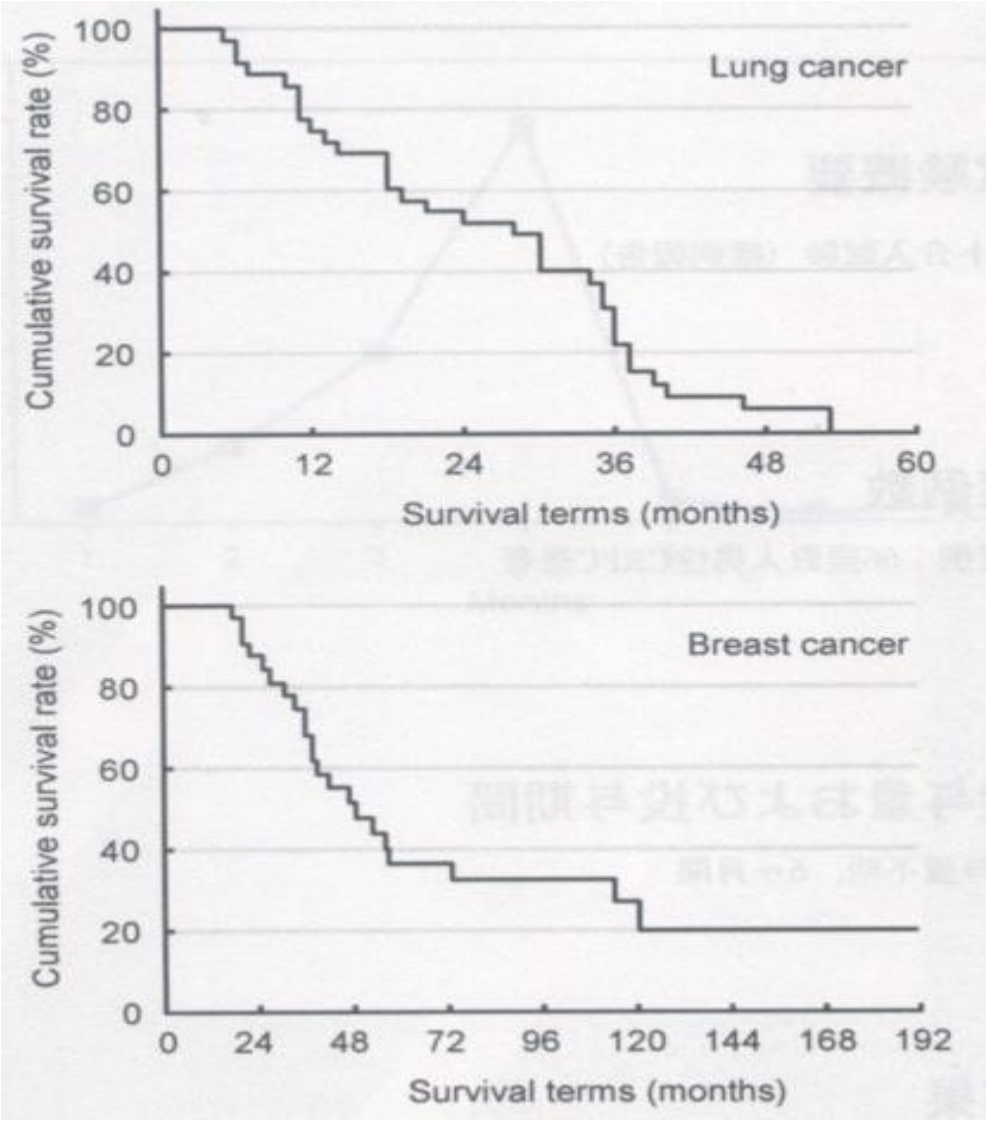
Results

- Lung cancer: Cumulative survival rate of 1-year, 2-year, 3-year, and 4-year are 75.0%, 52.1%, 21.8%, and 6.2%, respectively. Median survival terms (MST) are 26.90 months. On QOL study, 41.7% had better QOL in class A and B.
- Breast cancer: Cumulative survival rate of 1-year, 2-year, 3-year, 4- year, and 5-year are 100.0%, 84.4%, 68.3%, 47.9%, and 36.8%, respectively. MSTs are 47.86 months. On QOL study, 67.7% had better QOL in class A and B.

Conclusion

Based on these results in comparing with the current cancer therapy, extension of survival terms with better QOL for stage IV cancer patients could be suggested by combination of AHCC and GCP in cancer therapy under individual EBM.

Figures



International Journal of Integrative Medicine, 2(1): 98-111 (2010)

“第 4 期肺癌、乳癌的生命延长和生活质量的改善：个性化 EBM(Evidence Based Medicine)与 AHCC 和 GCP 的长期使用(12 年)”

Reiki Ishizuka1, Hajime Fujii2, Takehito Miura2, Yukiko Fukuchi2, Kuniyoshi Tajima 1

1 Tajima Clinic, Japan

2 Amino Up Chemical Co., Ltd., Japan

背景

根据 2007 的癌症死亡的国内统计，肺癌的死亡率在日本最高，乳腺癌在女性癌症死亡中排第四位。经过标准的循证医学（EBM）推荐应用在肿瘤化疗上新的抗癌药物越来越多。然而，癌症死亡率并没有减少。在循证医学治疗领域改善患者生存质量的产品一直是空白。对于那些希望延长生存期的患者，应考虑个人的需求。从中西医结合的角度，AHCC 和 GCP 已被广泛用于患者的免疫支持。

研究设计

人类干预试验：自 1996 年以来； AHCC 和 GCP 用于肺和乳腺 IV 期癌症患者。长期随访超过 12 年，

主题 受试者

36 IV 期肺癌患者和 34 IV 期乳腺癌患者。

剂量和期限

3.0-6.0 克 AHCC/天 1.92-2.56 克 GCP/ 天。病人因人而异。

结果

- 肺癌：1 年，2 年，3 年，4 年累积生存率分别为 75.0%，52.1%，21.8%和 6.2%。平均生存时间（MST）为 26.90 个月的条款。对生活质量的研究，41.7%的 A 类和 B 有较好的生活质量

- 乳腺癌：1 年，2 年，3 年，4 年和 5 年生存率累积分别为 100.0%，84.4%，68.3%，47.9%和 36.8%。47.86 个月后（MSTS）。对生活质量的研究，67.7%的 A 类和 B 较好的生活质量。

结论

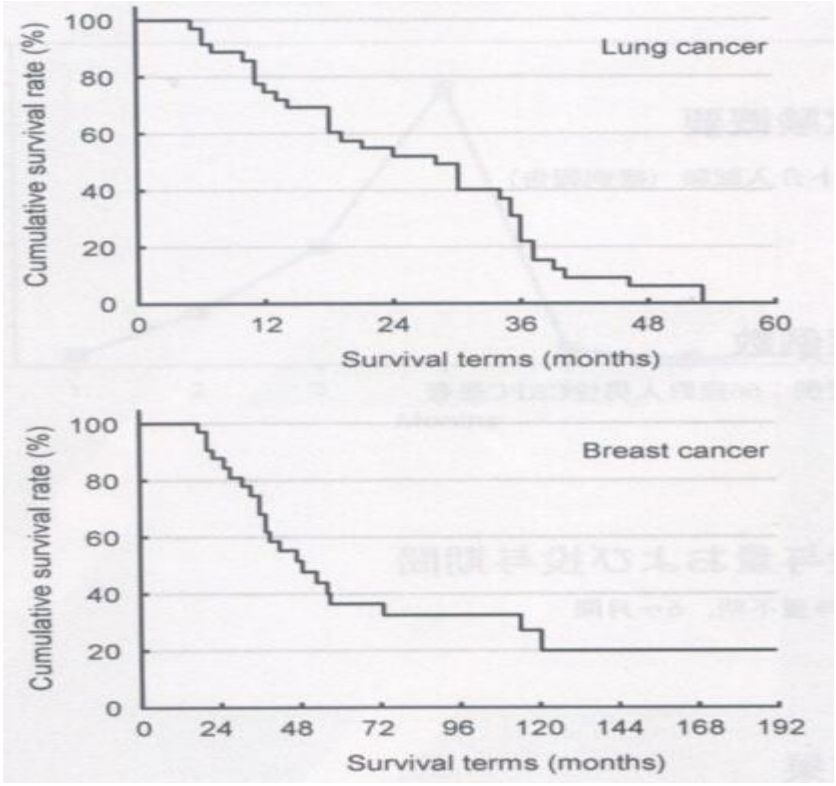
基于这些结果与当前的癌症治疗相比，可以建议 AHCC 和 GCP 组合使用可改善 IV 期癌症患者的生活质量延长生存期。

（很有意思研究过程摘要）

对肺癌及乳癌的第 4 期患者使用 AHCC 和 GCP，11 年观察延长生命及改善 QOL(生

活质量）的状况。（肺癌）：40 病例中，除了第 1A 期的 5 例(CR，都在生存)以外，对 35 病例，即；第 1B 期（CR）1 例、第 3A 期(SD）1 例、第 4 期(M1)33 例进行观察。现在，35 病例的生存率为 8.6%(3/35)。第 4 期患者的 4 年生存率为 3.0%(1/33)，表明晚期复发癌的生存率相当低，但看 1 年、2 年、3 年的生存率，分别为 77.1%、54.3%、31.4%，平均生存时间为 24.8 个月，与其他报告相比 1-3 年的生存率较高。35 病例中，有 77.2%的患者表示 A(最好)到 C 级的 QOL，AHCC/GCP 服用明显提高 QOL 并减少末期的住院日数。（乳癌）：34 病例中，除了 2 例（切除两侧乳房，没有复发，CR）以外，对 32 病例（第 4 期，M1）进行观察。复发后生存率为 50%，其中 3 年以上 62.5%，4 年以上 50.5%，5 年以上 31.3%。复发后平均生存时间为 5 年 10.4 个月，从初发诊断起为 8 年 8.6 个月。复发后 1 年内没有死亡例。关于 QOL，100%生存患者表示 A-B 级，没有 C 级以下的。

图示



P53；P100；P101

Japanese Journal of Clinical Oncology, 40(10), 967-972 (2010)

Dietary Administration of Mushroom Mycelium Extracts in Patients with Early Stage Prostate Cancers Managed

Expectantly: A Phase II Study

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Background

Recently, most prostate cancers are discoverable at an extremely early stage using PSA screening. An alternative to active treatment, watchful waiting has been adopted as a treatment for early stage prostate cancer to avoid complications and cancer progression. In this study, significance and safety of AHCC as complementary and alternative medicine of early stage prostate patients are investigated.

Study design

Open label trial (Human intervention trial): Rate of patients whose level of prostate-specificantigen decreased 50% or more was mainly evaluated. Also, adverse event, change in prostate-specificantigen, and quality of life (QOL) were evaluated.

Subjects

74 early stage prostate patients, average 73.5 years of age.

Dosage and period

4.5 g AHCC/day for 6-12 months.

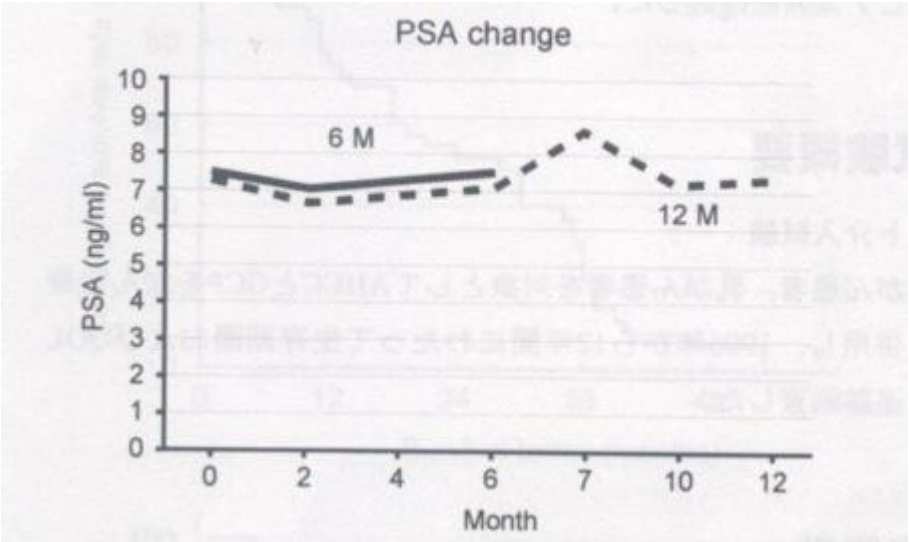
Results

Only one of 74 patients (1.4%), the prostate specific antigen value decreased more than 50%. Grade 2 diarrhea and grade 1 itching were observed in one patient, and patient ingestion compliance was maintained near 100%. The alternation of prostate specific antigen values was stable before and after treatment. In subjects with strong anxiety prior to supplement ingestion, these feelings were significantly alleviated (state anxiety, $P = 0.0018$; trait anxiety, $P = 0.0099$).

Conclusion

Only 1.4% of patients displayed PSA levels that were decreased by 50% or more after AHCC treatment. Changes in PSA levels before and after treatment were substantially stable.

Table and Figure



State-trait anxiety inventory at baseline and 6 months

Anxiety	No. pts.	Baseline	6 M	*P*
State	19	51±9	44±8	0.0018
Trait	15	53±8	45±10	0.0099

Japanese Journal of Clinical Oncology ;40(10);967-972(2010)

蘑菇菌丝体提取物与早期前列腺癌患者膳食管理：II 期研究

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背景

近年来；早期的 PSA 筛查是发现大部分前列腺癌的一个非常确切的手段。辅助替代治疗，已被作为一种早期前列腺癌的治疗手段，避免肿瘤恶化及并发症的发生。在这项研究中， AHCC 的意义是给早期前列腺癌患者在辅助替代医学方面有了更加安全的选择。

研究设计

人体干预试验：患者的前列腺特异性抗原水平率下降的超过 50%。此外，评估指标包括：不良反应，PSA 的变化，生活质量（QOL）。

主题 受试者

74 例早期前列腺癌患者，平均年龄为 73.5 岁

剂量和期限

4.5 克 AHCC/天，6-12 个月。

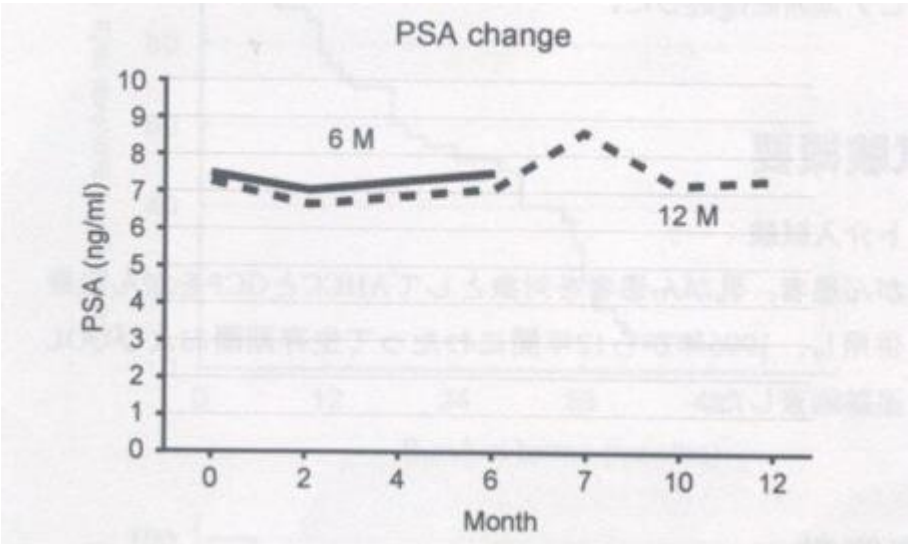
结果

只有 74 例（1.4%），前列腺特异性抗原值降低 50%以上。一个病人中观察到了 2 级腹泻和 1 级的瘙痒，患者摄入依从性保持在 100%。治疗前和治疗后前列腺特异性抗原值的变化是稳定的。焦虑和不安感觉明显减轻（P = 0.0018；状态焦虑，特质焦虑，P = 0.0099）。

结论

患者显示 PSA 水平只有 1.4%治疗后下降 50%或更多。PSA 水平于治疗前和治疗后基本稳定。

图表



State-trait anxiety inventory at baseline and 6 months

Anxiety	No. pts.	Baseline	6 M	*P*
State	19	51±9	44±8	0.0018
Trait	15	53±8	45±10	0.0099

P54；P102；P103

Human Immunology, 71, 1187-1190 (2010)

Effects of active hexose correlated compound（AHCC） on the frequency of CD4+ and CD8+ T cells producing IFN-γ and/or TNF -α in healthy adults

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1 Yale School of Medicine, USA; 2 Amino Up Chemical Co., Ltd., Japan; 3 Harvard Medical School, USA

Background

AHCC has been shown to have an enhancing effect on immune function of humans and rodents including an increase of NK cell activity, IL-12 production and resistance to bacterial infection. Of interest, it has been found that the effects of AHCC are more evident in hosts with the impaired immune function. In fact, we have demonstrated that AHCC can enhance interferon (IFN)-γ production by CD8+T cells and the numbers of NK and γδT cells. However, it is largely unknown whether AHCC could enhance immune parameters such as IFN-γ and tumor necrosis factor (TNF)-α production by CD4+ and CD8+T cells in humans, in particular, elderly adults with increased risk of infection and malignancy.

Study design

Open-label trial (Human clinical intervention trial): Subjects were treated with AHCC for 60 days. Peripheral blood was collected at baseline, 30 and 60 days during supplementation, and another 30 days after supplementation had been discontinued. The production of interferon IFN-γ and TNF-α by CD4+ and CD8+T cells was measured by flow ctometry.

Subjects

30 healthy adults over the age of 50.

Dosage and period

3 g AHCC/day (3-500 mg capsules twice daily) for 60 days.

Results

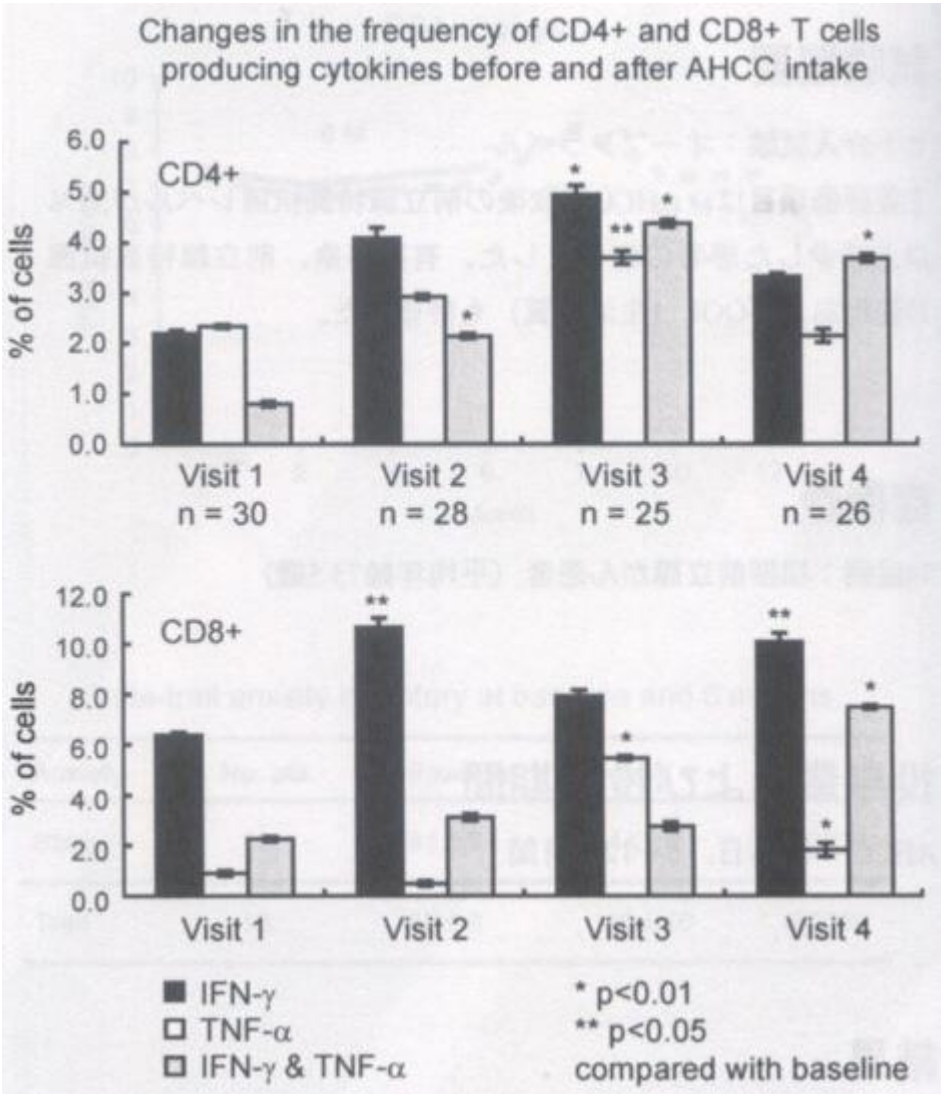
The frequency of CD4+ and CD8+T cells producing IFN-γ alone, TNF-α or

both increased during AHCC intake compared with baseline values. Furthermore, the frequency of such cells remained high even 30 days after discontinuing AHCC.

Conclusion

Our results suggest that AHCC can enhance CD4+ and CD8+T cell immune responses in healthy persons via increasing production of cytokines IFN-γ and TNF-α from T cells. AHCC may improve immune response against pathogens through this mechanism.

Figures



Human Immunology, 71, 1187-1190 (2010)

“对健康老年人 AHCC 使用前后评估产生 IFN-γ(干扰素)及 TNF-α （肿瘤坏死因子）的 CD4+、CD8+T 细胞数”（第 16 届 AHCC/GCP 国际研究会，2008）

Zhinan Yin1, Hajime Fujii2, Thomas Walshe3

1 Yale School of Medicine, USA; 2 Amino Up Chemical Co., Ltd., Japan; 3 Harvard Medical School, USA

背景

AHCC 已被证明对人类和啮齿类动物增加 NK 细胞活性、生成 IL-12、抗细菌感染等免疫增强作用。有趣的是，已经发现，AHCC 在与免疫功能受损主动修复更加明显。事实上，我们已经证明，AHCC 可以通过增加 CD8 + T 细胞和 NK 细胞的数目及 γδT 细胞的数从而增强干扰素（IFN）-γ 产生。然而 AHCC 是如何增强免疫功能，在人类中特别是老年人感染和患恶性肿瘤的风险增加；CD4+和 CD8 + T 细胞生产干扰素 IFN-γ 和肿瘤坏死因子（TNF-α ）尤其重要。

研究设计

人体临床干预试验：受试者在 60 天以内收集外周血，30 和 60 天为一个周期；测定 CD4 +和 CD8 + T 细胞的数量和干扰素 IFN-γ 和肿瘤坏死因子 TNF-α 的产生。

主题 受试者

30 名 50 岁以上健康成年人。

剂量和期限

3 克 AHCC/天（3-500 毫克胶囊，每天两次）60 天。

结果

AHCC 摄入后增加了 CD4 +和 CD8+ T 细胞数量；即使 30 天停止使用 AHCC 后；产生 IFN-γ， TNF-α 频率仍然很高，。

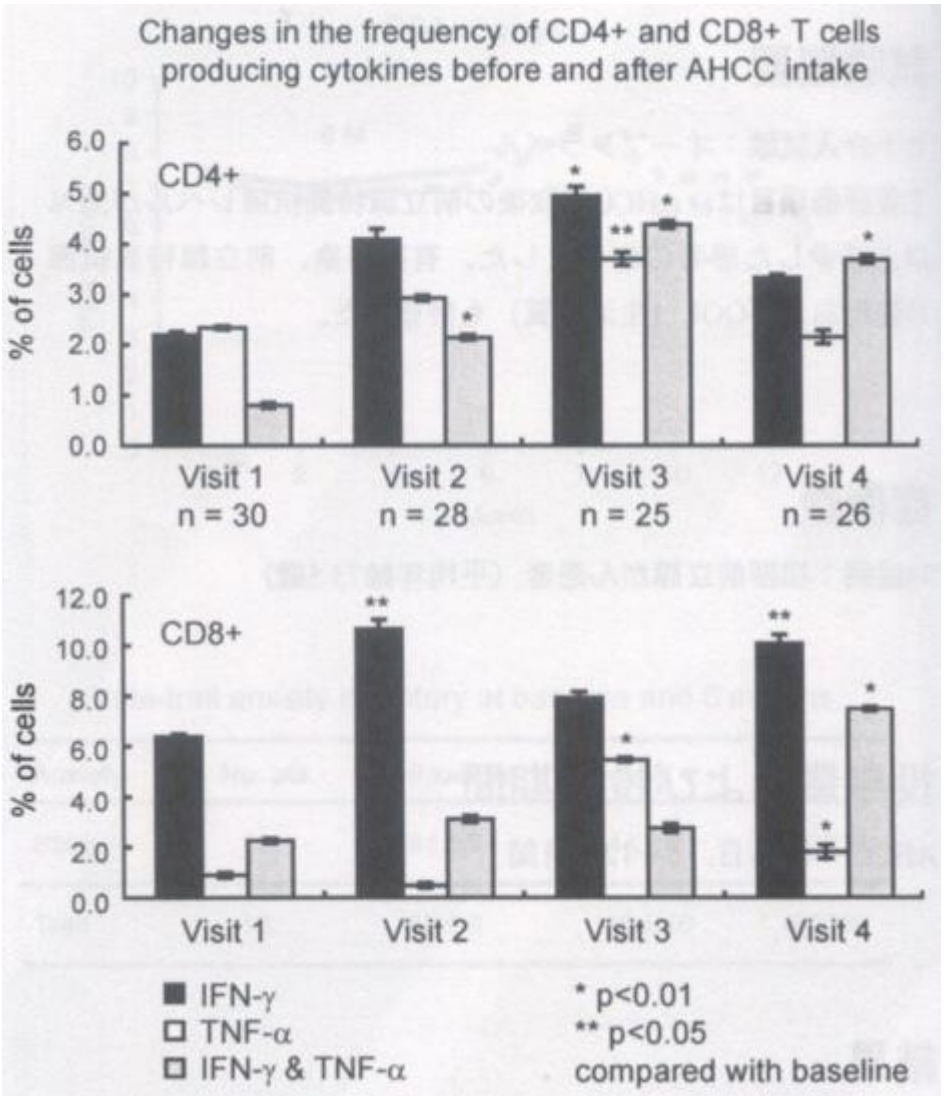
结论

研究结果表明，AHCC 可以通过增加细胞因子 IFN-γ 和 TNF-α，提高人体 CD4 +和 CD8 + T 细胞的免疫反应。AHCC 可以通过这个机制提高对病原体的免疫反应。（很有意思研究过程摘要）

对健康老年人使用 AHCC，观察 CD4+和 CD8+ T 细胞的 IFN-γ （干扰素γ）及

TNF-α（肿瘤坏死因子α）产生。在 AHCC 服用第 0 天(第一观察日)、30 天（第二观察日)、60 天（第三观察日)、服用结束后 30 天（第四观察日）分别进行观察，测定产生 IFN-γ 单独、TNF-α 单独、IFN-γ 和 TNF-α 组合的 CD4+和 CD8+ T 细胞。与第一观察日相比，第二观察日和第三观察日的 CD4+ T 细胞明显增加,但在第四观察日已经开始减少，因此表明 AHCC 服用对 CD4+ T 细胞的增强作用很明显。有意思的是产生 IFN-γ 和 TNF-α 组合的 CD4+ T 细胞在第四观察日还是较多，表明 AHCC 服用结束后 30 天还在起作用。单独产生 IFN-γ 的、单独产生 TNF-α 的 CD8+ T 细胞都在第二、三观察日比第一观察日增加，并在第四观察日还在保持高水平。产生 IFN-γ 和 TNF-α 组合的在第四观察日才明显增加。这些结果表示，AHCC 服用增强老年人的 CD4+、CD8+ T 细胞的免疫反应，并结束服用后至少 30 天还保持其作用。

图示



P60；P106；P107
The Medical News (Thailand), 325, 13-16 (2010)

A study of the efficacy of Active Hexose Correlated Compound (AHCC) in the treatment of chronic Hepatitis C patients at Phramongkutklao Hospital

Sayam Thaiudom, Wanich Piyaniran, Anuchit Chutaputthi

Phramongkutklao Hospital, Thailand

Background

Hepatitis C virus (HCV) infection is one of the major causes of chronic liver disease, cirrhosis and hepatocellular carcinoma. Current treatment with pegylated interferon and ribavirin can achieve 54 to 61% sustained virological response, and significant number of patients does not respond to the treatment. AHCC biological effects in terms of immuno-modulator, anti-tumor properties, and viral suppress in chronic hepatitis C patient. In this study, we investigated the effects of AHCC in chronic hepatitis C patients.

Study design

Prospective, randomized, double-blinded placebo-control trial (Human intervention trial): chronic hepatitis C patients received AHCC or placebo. All patients received HCV RNA levels and liver function tests monitoring.

Subjects

39 chronic hepatitis C patients, 15 years of age or older, were divided into AHCC (n=19) and placebo (n=20) groups.

Dosage and period

6 g AHCC/day for 6 months.

Results

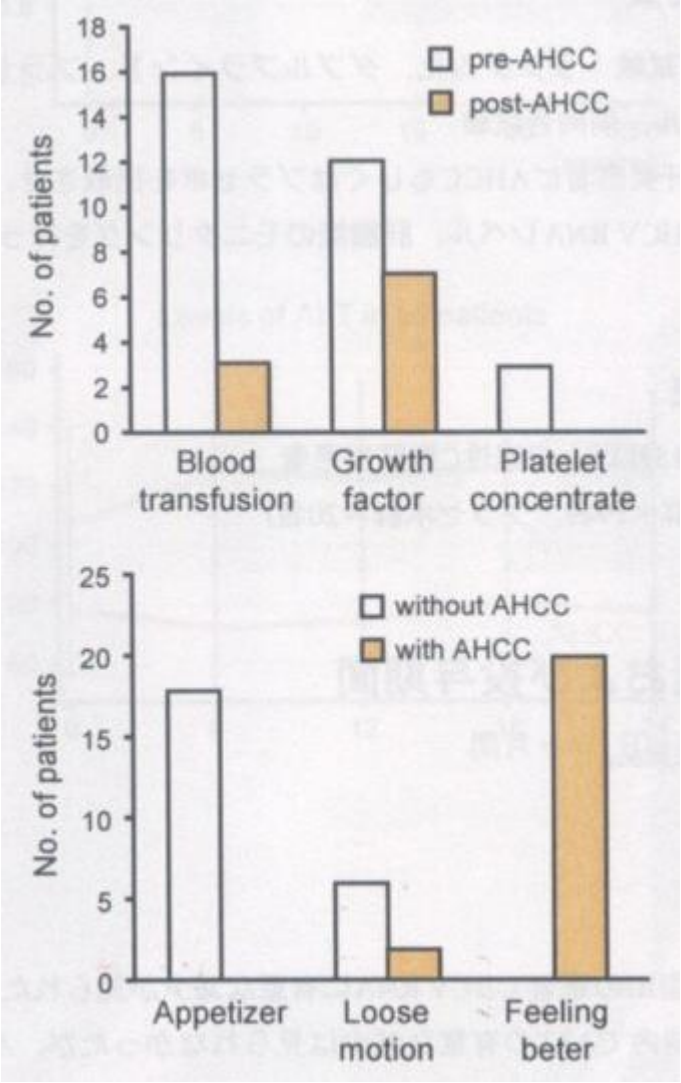
Significant HCV RNA decline was noted in subgroup analysis of genotype-3 patients. Although the reduction of ALT levels within AHCC group was not

significant, the significantdifferencewas found between AHCC and placebo groups. AHCC tended to stabilize HCV RNA levels ingenotype-3 chronic hepatitis C patients comparing AHCC to placebo group. Efficacy was shown in control ALT levels in all chronic hepatitis C patients. No serious side effects were found from the treatment.

Conclusion

AHCC showed significant HCV RNA reduction in genotype-3 patients, and ALT levels were stabilized. The results indicate that AHCC could be used for complementally and alternative medicine in HCV patients.

Figures



The Medical News (Thailand), 325, 13-16 (2010)

AHCC 在慢性丙型肝炎患者的治疗研究

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Phramongkutklao Hospital, Thailand

背景

丙型肝炎病毒（HCV）感染是慢性肝病，肝硬化和肝细胞癌的主要病因之一。当前治疗与聚乙二醇化干扰素和利巴韦林可以达到 54～61％的持续病毒学应答，但是许多患者对治疗没有反应。AHCC 是一种生物免疫调节剂；具有免疫调节，抗肿瘤特性。在这项研究中，我们调查了 AHCC 对慢性丙型肝炎患者的影响。

研究设计

前瞻性，随机，双盲，安慰剂对照试验（人类干预试验）：慢性丙型肝炎患者接受 AHCC 或安慰剂。所有患者均接受 HCV RNA 水平和肝功能检查。

主题 受试者

39 例慢性丙型肝炎患者，15 岁以上，分为 AHCC 组（n = 19）和安慰剂组（n = 20）。

剂量和期限

6 克 AHCC/天，6 个月。

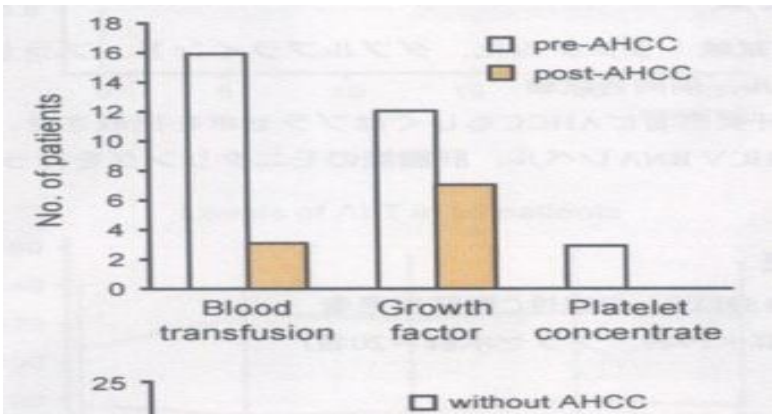
结果

虽然在 AHCC 组 ALT 水平的降低不显著， 但是 AHCC 组基因 3 型患者较安慰剂组 HCV RNA 显著下降。在所有使用 AHCC 的慢性丙型肝炎患者中 ALT 水平稳定。并在治疗中没有严重的副作用。

结论

AHCC 显著减少基因 3 型 HCV RNA；减少和 ALT 水平稳定。在所有使用 AHCC 的慢性丙型肝炎患者中 ALT 水平稳定。结果表明，AHCC 可以用于丙型肝炎 HCV 患者辅助治疗。

图示



P60；P106；P107

International Journal of Clinical Medicine, 2: 588-592 (2011)

Integrating Complimentary and Alternative Medicine in Form of Active Hexose Correlated Compound (AHCC) in the Management of Head & Neck Cancer Patients

Dillip Kumar Parida1, Koji Wakame2, Taisei Nomura3

1 North Eastern Indira Gandhi Regional Institute of Health & Medical Sciences, India
2 Amino Up Chemical Co., Ltd., Japan
3 National Institute of Biomedical Innovation, Japan

Background

In the state of Meghalay, India, the incidence of cancer of head and neck region is highest in males while esophageal cancer is highest in females. Evidences show that majority of the population inhabiting tobacco in some or other form is responsible for initiation of oropharyngeal, lung, and upper aerodigestive tract cancers.

Study design

Open label trial (Human clinical intervention trial): 25 patients were administered AHCC along with conventional palliative chemotherapy regimen out of which 16 patients received paclitaxel, and cisplatinum/carboplatin, 9 patients received combination of cisplatim and 5-Flurouracil.

Subjects

25 patients of advanced state head and neck cancer (T3=13 and T4=12). 13 patients were cancer of Cheek, followed by cancer of tongue (n=4), oropharyngeal cancer (n=6) and cancer of nasopharynx (n=2)

Dosage and period

3 g AHCC/day. Period varied on patients.

Results

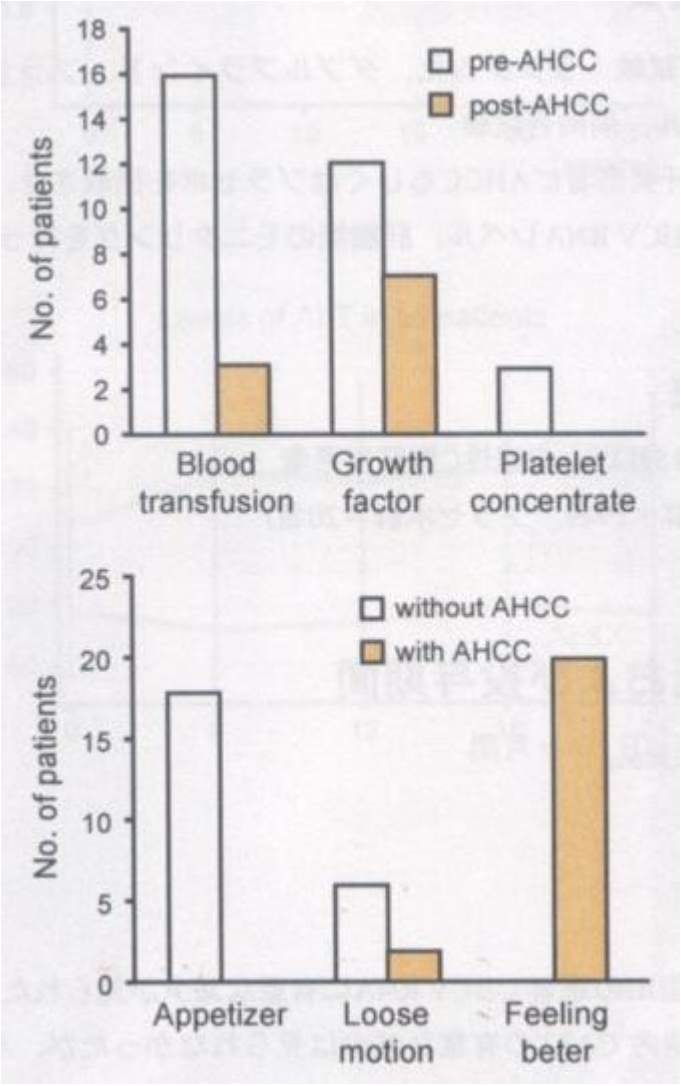
All the patients tolerated AHCC well with no added symptoms. 20 patients re- ported that they are feeling stronger than before at the time of initiation of chemotherapy cycles. Almost all the patients reported to have better appetite after they started taking AHCC. 16 patients who required blood transfusion before chemotherapy cycles, decrease in the rate of fall in hemoglobin was observed in these patients and only 3 patients required blood transfusion before subsequent chemotherapy cycles. In 22 patients definitereduction of chemotherapy side effectslike nausea, vomiting, drop in totalleucocytes count, loose motion/constipation etc. were observed, which reduced the hospital stay of these patients.

Tumor regressed in 11 patients, and 8 patients had stable disease.

Conclusion

AHCC up to 3 g is safe to administer and definitely helps cancer patients in reducing side effects of chemotherapeutic drugs, getting a sense of wellbeing and improved intake maintains general condition as well as prepare them to continue and tolerate further cycles in a better way.

Figures



International Journal of Clinical Medicine, 2: 588-592 (2011)

AHCC 在头颈部癌症患者的作用

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背景

在印度 meghalay 州，头部和颈部癌症的发病率很高的，男性食管癌是高于女性。证据显示，吸烟及空气污染是影响肺和上呼吸和上消化道癌症的主要原因。

研究设计

人体临床干预试验：25 例患者服用 AHCC 与传统的姑息性化疗方案；其中有 16 名患者接受紫杉醇，顺铂和/卡铂，9 例接受 cisplatim 和 5 氟尿嘧啶的组合使用。

受试者

25 名头部和颈部癌症患者（T3= 13 和 T 4= 12）。 13 例患者面颊的癌症，其次是舌头病患（n= 4），口咽癌组（n =6）和鼻咽癌（n = 2）

剂量和期限

3 克 AHCC/天。患者因人而异。

结果

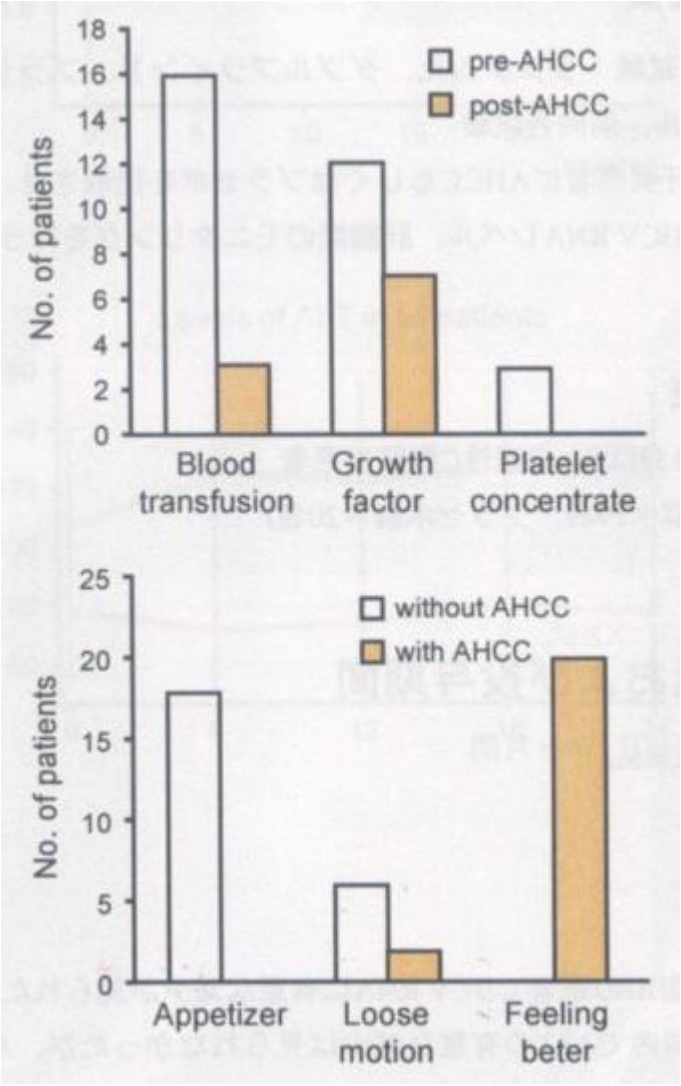
服用 AHCC 所有患者的身体耐性变好，没有副作用。20 例患者，他们感觉比以前的化疗期更强壮。几乎所有的患者食欲好转。16 个病人血红蛋白下降减缓，观察在这些患者中，只有 3 例患者需要输血，在随后的化疗周期。22 例化疗的副作用如：恶心，呕吐，白细胞减少，腹泻及便秘等明显减少；从而降低这些患者的住院时间。

肿瘤消退 11 例，8 例患者病情稳定。

结论

每日 AHCC 3 g 摄入量肯定有助于癌症患者减少化疗药物的副作用，让情绪变好；并改善他们的生活质量及身体的一般状态；入他们更好接受下一周期治疗。

图示



The Journal of Applied Research,4(3);6-14(2011)

Evaluation of Active Hexose Correlated Compound (AHCC) in combination with pegylated liposomal doxorubicin for treatment of ovarian cancer

AHCC 结合聚乙二醇 liposomal 阿霉素用于治疗卵巢癌的评价

美国德州大学和 MD 爱德森癌症中心

（摘要）

AHCC 在抑制卵巢癌的繁殖效果明显；进一步的临床试验正在进行中。

其他临床论文

The Journal of Alternative and Complementary Medicine (2013)

Effect of Active Hexose-Correlated Compound in Women Receiving Adjuvant Chemotherapy for Breast Cancer: A

Retrospective Study

Sho Hangai

Department of Hematology and Oncology, The University of Tokyo Hospital, Tokyo, Japan.

Background

Anthracyclines and taxanes are often used as first-line chemotherapy treatments in patients with breast cancer. There are, however, severe toxicity and side effects associated with these therapies. This study aimed to explore the beneficialeffects of AHCC on adverse events in patients receiving adjuvant chemotherapy for breast cancer.

Methods Study design: 41 women pathologically proven as breast cancer from October 2004 to March 2011 (Age; 20 to 64) were selected. They received doxorubicin and cyclophosphamide, followed by taxane-based regimens.

The subjects ingesting AHCC (1.0 g/day) or those non-ingesting AHCC were assigned to AHCC group (n=18) and control group (n=23), respectively. The occurrence of adverse events in patients who received AHCC was compared with those of control group in accordance with National Cancer Institute Common Terminology Criteria for Adverse Events (NCI-CTCAE). In addition, the use frequency of granulocyte colony-stimulating factor (G-CSF) in adjuvant chemotherapy period was also evaluated in neutropenia.Measurements: Aspartate aminotransferase (AST), alanine aminotransferase (ALT), γ-glutamyl transpeptidase (γ-GTP), triglycerides (TG), total cholesterol (T-Chol), white blood cell (WBC) count, neutrophil count, the average number of G-CSF usage.

Results

The number of patients with high γ-GTP was increased as compared with control group. In contrast, the neutrophil decline and use frequency was significantly suppressed in AHCC group in comparison with control group.

Conclusion

AHCC has the potential to reduce the severity of neutropenia induced by breast cancer chemotherapy and the use of G-CSF during chemotherapy, suggesting that AHCC may reduce the toxicity of chemotherapy and may

then allow for intensification of the chemotherapy dosage.

The Journal of Alternative and Complementary Medicine (2013)

AHCC 在女性乳腺癌接受辅助化疗的一项回顾性研究

Sho Hangai

血液科、肿瘤科，东京大学医院，日本东京

背景

蒽环类药物和紫杉烷类化合物通常被用来作为乳腺癌患者的最常使用的药物化疗的治疗方法。然而，这些治疗方法有严重毒副作用。本研究旨在探讨使用 AHCC 对乳腺癌患者接受化疗时不良反应辅助治疗的效果。

研究方法:

设计：41 女病理证实为乳腺癌，2004 年 10 月至 2011 年 3 月（年龄 20～64 岁）入选。他们使用阿霉素和环磷酰胺，其次是紫杉烷类为基础的方案。

受试者摄取 AHCC（1.0 克/天）AHCC 组（n=18）和对照组（n=23）。分别记录 AHCC 组与对照组不良反应的发生（NCI-CTCAE）；按照美国国家癌症研究所常见术语标准进行比较。包括：G-CSF、中性粒细胞减少量、天门冬氨酸转氨酶（AST），丙氨酸转氨酶（ALT），γ-谷氨酰转（γ-GTP），甘油三酯（TG），总胆固醇（T-CHOL），白细胞（WBC）计数，嗜中性粒细胞计数，G-CSF 使用的平均次数等等。

结果

与对照组相比 AHCC 组患者的γ-GTP 增加，。相反，AHCC 组与对照组比较中性粒细胞减少明显降低。

结论

AHCC 减少乳腺癌的化疗和化疗期间使用 G-CSF 的数量；教育降低中性粒细胞减少的潜力，这表明 AHCC 可以减轻化疗毒副反应，可能会允许的化疗剂量增强。

其他临床论文中文摘要（英文原文已快递过去）

有，英文在电子版中

GCP 美国哥伦比亚大学 Presbyterian 医疗中心泌尿外科 Aaron E. Katz 教授

Regression of Prostate Cancer Following Administration of Genistein Combined Polysaccharide (GCP), a Nutritional Supplement: A Case Report. *The Journal of Alternative and Complementary Medicine* 8(4):493-497, 2002. （GCP 对前列腺癌作用：病例报告）

（摘要）

对前列腺患者在前列腺切除手术前 6 周开始服用 GCP。患者的 PSA 原来有 19.7ng/mL，可 GCP 服用 44 天后下降到 4.2ng/mL，在前列腺切片观察没有发现癌细胞，并没有任何毒副作用。实验结果表示 GCP 对前列腺癌的治疗及预防效果非常明显。

有，在电子版中 2004_Adult Urology,63,259-263.pdf

GCP 美国加州大学 Davis 分校医学部泌尿科/癌症中心 Ralph W. deVere White 教授

Effects of a genistein-rich extract on PSA levels in men with a history of prostate cancer. Urology 63(2):259-263, 2004. （GCP 对有前列腺癌病史患者的 PSA 抑制作用）

（摘要）

52 名前列腺癌患者参加服用 GCP6 个月，其中 8 名患者显著下降 PSA（下降 50%以上 1 名、下降 50%以内 7 名）。这 8 名都是主动监测(watchful waiting，已诊断为前列腺癌但还没达到做手术、放化疗或激素治疗的阶段，只继续观察病情是否发展。)过程中的患者。下一步需要针对主动监测患者作进一步的临床试验

Phase I/II Atudy of AHCC as Adverse Effect Reducer in Advanced Cancer Patients with Chemotherapy(the Second Report) -Usefulness of the Levels of HHV-6 DHA in Saliva as a Surrogate Biomarker for QOL during Chemotherapy-

○Takumi lgura[1], Toru Kitagawa[2],Ryoko Sumi[1],Miki Sakaue[1], Kei Hirai[1.3],Kazuhiro Kondo[4],Toshinori Ito[1]

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[3]Center of the Study for Communication Design,Osaka University, Osaka,Japan

[4]Department of Virology, Jikei University School of Medicine, Osaka,Japan

Purpose:Active Hexose Correlated Compound(AHCC),a culture extract from Basidio-mycetes,is a functional food that has been widely used as a complementary to conventional chemotherapy in Japan. The objective of this study was to evaluate the safety and effectivenss of AHCC on chemotherapy-associated adverse sffects and qualities of life (QOL) in cancer patients with chemotherapy, Recently, we found out that human herpesvirus(HHV)-6 reactivated and was shed in saliva according to the extent of fatigue, We examined whether HHV-6 could be an objective surrogate biomarker for QOL

undergoing chemotherapy.

Method; Twenty-five patients with advanced cancer (stomach,colorectal,lung,pancreas and ovary: five patients each) will be enrolled in this trial.All patients receive the first cycle of chemotherapy without AHCC and then received second cycle of chemotherapy with AHCC.the dose of AHCC was 3g daily orally in three divided doses,We evaluated chemotherapy-related adverse effects and the QOL by blood test,the EORTC QLQ-C30 questionnaire and the DNA level of HHV-6 in saliva weekly. Reactivation of HHV-6 in saliva was examined for viral DNA by semi-quantitative PCR method.

Result:At this moment, 17 patients(five were lung cancer, six were pancreatic cancer, four were ovarian cancer and two were colorectal cancer) could be evaluated, Administration of AHCC improved hematologic toxicity (mainly neutropenia)and hepatotoxity.Although there was no change in any score of the EORTC QLQ-C30, interestingly the levels of HHV-6 in saliva(1055±338vs. 224.8±54.6 copy/ml, $p < 0.05$)during chemotherapy was improved after administration of AHCC.

Conclusion:These findings suggest that AHCC might be safe and have a beneficial effect on chemotherapy-associated adverse effects and that the level of the HHV-6 DNA in the saliva could be a good indicator of QOL in patients during chemotherapy.

AHCC 日本大阪大学院医学系研究科机体机能辅助医学科 井仓技教授

“关于 AHCC 对化疗毒副作用减轻效果的临床试验”

（摘要）

对 17 名癌症患者(肺癌 5 例、胰脏癌 6 例、卵巢癌 4 例、大肠癌 2 例）并用化疗和 AHCC。第一化疗过程中单独使用抗癌药物并没使用 AHCC，从第二化疗过程开始并用 AHCC。治疗过程中 AHCC 没有引起任何有害作用。进行单独使用抗癌药物的第一次化疗后，1、2 级(CTCAE v3.0)的白血球减少有 10 例，3、4 级的有 3 例，1、2 级的中性粒细胞减少有 5 例，3、4 级的有 4 例，1、2 级的肝脏损害有 4 例。并用 AHCC 的第二次化疗后，1、2 级的白血球减少有 12 例、1、2 级的中性粒细胞减少有 10 例，但没有 3、4 级的毒副作用及肝脏损害。另外，AHCC 并用后唾液中 HHV-6 DNA（疲劳程度的生物指标，化疗过程中的生活质量指标之一）明显减少

Alleviating Function of Health Food (AHCC) for Side Effect

in Chemotherapy Patients

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*Introduction:*Although recent cancer chemotherapy has made a great advance and exhibits prominent efficacy,concern is raised for the impairment of cancer patients' QOL owing to its side effects expressed with a high incidence. We have reported on the immunoenhancement and prognostic improvement of AHCC, a functional food extracted from basidiomycete, in the patients with cancer ,However, up to now ,the alleviating function of AHCC on side effects in chemotherapy patients has not been assessed. Here, we would report the result of study on the alleviating function of AHCC for the side effects caused by chemotherapy in the patients with pancreatic or biliary tract cancer.

Methods: The study was conducted for the patients (50 cases) with pancreatic or biliary tract cancer who underwent chemotherapy with gemcitabine hydrochloride,being divided into two groups which were given AHCC (AHCC group) and not AHCC (control group),The assessment was performed on hematological and non-hematological toxicity over two months during the chemotherapy, and the data shown by range in radian values.

*Results:*AHCC group consisted of 20 cases, aged 64 (48 to 76), and the ratio of male and female was 13 to 7, and control group 30 cases, aged 66 (51 to 82),and the ratio 19 to 11. The ratio of pancreatic and biliary tract cancer ,and unresectable and postoperative adjuvant therapy in each group was as follows: the ratio of the former was 18 to 2, and the ratio of the latter was 10 to 10 in AHCC group ; and the former was 26 to 4, and the latter was 18 to 12 in control group. There was no discontinuation due to the side effect and so on caused by chemotherapy during the period of observation. There were also no difference between the two groups in the background, and no significant difference in the baseline levels of hematological examination. The Hb values in hematological test showed that anemic condition in AHCC group was significantly mitigated compared to control group ,namely the former was 10.4 g/*dl* (9.0 to 12.6) and the latter 9.4 g/*dl* (6.7 to 11.7). In addition ,the CRP value ,an index of inflammatory reaction, was significantly lower in AHCC group than in control group; the former was 0.5 mg/*dl* (0.02-6.1), and the latter 1.93 mg/*dl* (0.24-20.2). No difference was found between the two groups in leukocyte and platelet counts,and hepatic function . AHCC group tended to alleviate taste disturbance,anon-hepatological side effect, caused by chemotherapy.

Conciusion: It is suggested that AHCC might have alleviating function for side effects

caused by chemotherapy and is an efficacious adjuvant to perform chemotherapy safely .Moreover, it is also indicated that AHCC might be useful to maintain the QOL of cancer patients who receive chemotherapy.

AHCC 日本关西医科大学 外科 柳本泰明教授

“AHCC 对化疗过程中的毒副作用减轻效果”

（摘要）

化疗过程中的胰脏癌、胆管癌患者 50 名分两组进行 2 个月的观察。AHCC 组有 20 例，其中胰脏癌 18 例，胆管癌 2 例；不能切除 10 例，手术后辅助 10 例。对照组有 30 例，其中胰脏癌 26 例，胆管癌 4 例；不能切除 18 例，手术后辅助 12 例。开始服用后 2 个月进行血液检查，与对照组相比 AHCC 组的贫血状况和炎症反应明显轻度；Hb（贫血指标）：AHCC 组 10.4g/dl(9.0-12.6),对照组 9.4g/dl(6.7-11.7)；CRP（炎症指标）：AHCC 组 0.5mg/dl(0.02-6.1), 对照组 1.93mg/dl(0.24-20.2)。另外，作为非血液学性毒副作用，AHCC 组对化疗引起的味觉异常有明显的改善作用。

韩文、英文在电子版 PDF 文件中

AHCC+GCP 韩国延世大学 Sun yoon 教授

AHCC+GCP（简称为：GAC）对转移性前列腺癌患者生存质量及生化指标观察。（韩国《泌尿科学》发表，2006 年 5 月）

（摘要）

32 名确诊为转移性前列腺癌患者分为二组，一组 23 人服用 5g/日 GAC，另一组 9 人服用安慰剂，三个月和六个月后，服用 GAC 组较安慰剂组生活质量明显改善，外周血生化指标测定在正常的范畴内。提示，GAC 可明显提高转移性前列腺癌患者的生活质量。

英文电子版 PDF 文件中　2008

AHCC 日本大阪关西医科大学 外科 上山泰男教授

使用双盲法，观察 AHCC 和安慰剂对免疫功能的改善情况。（美国《癌症与营养》发表，2008）

（摘要）

21 名健康志愿者，其中 11 名服用安慰剂，10 名服用 AHCC，四周后取外周血检测，如下表：

表 1

Immunological Parameters[a]

	Baseline			4Wk		
	AHCC	Control	pValue	AHCC	Control	pValue
PBMC(×10^6/ml)	2.35±1.03	2.15±0.71	0.820	2.95±0.81	2.35±0.76	0.184
CD4(%)	32.2±12.2	20.2±12.8	0.137	32.7±6.4	26.2±15.7	0.184
CD8(%)	8.5±4.3	8.3±8.6	0.470	8.9±3.5	8.5±6.4	0.790
CD4:8	4.2±1.1	3.9±2.6	0.271	4.0±1.4	4.2±3.3	0.382
NK(%)	6.9±3.1	9.2±7.4	0.704	7.6±3.9	8.9±5.3	0.514
NK activity(%)	30.8±15.8	35.7±14.8	0.526	31.3±12.5	35.3±13.0	0.704
PHA(cpm)	39,304±16,570	51,221±20,812	0.324	41,768±13,517	56,117±18,783	0.157

表 2

Cytokine Production Stimulated by LPS[a]

	Baseline			4Wk		
	AHCC	Control	pValue	AHCC	Control	pValue
IFN-γ (pg/ml)	774.3±329.7	915.8±299.4	0.205	844.3±395.6	701.5±283.7	0.481
TNF-α (ng/ml)	64.4±44.6	63.4±28.4	0.573	60.8±43.0	61.7±21.8	0.725
IL-10(pg/ml)	281.1±87.9	317.7±252.6	0.944	288.0±142.5	251.0±162.4	0.526
IL-6(ng/ml)	148.1±111.8	140.8±71.2	0.833	142.7±91.8	150.0±75.5	0.778
IL-4(pg/ml)	601.6±246.3	744.1±382.1	0.204	598.6±225.2	455.7±457.5	0.205
IL-2(pg/ml)	290.0±72.7	420.8±197.1	0.058	285.4±94.2	192.2±219.0	0.398

以上数据显示服用 AHCC 组有明显的免疫增强效果。

英文电子版 PDF 文件中 2009

AHCC 日本大阪关西医科大学 外科 上山泰男教授

Improved Survival of Patients with Gastric Cancer or Colon Cancer when treated with Active Hexose Correlated Compound(AHCC):

Effect of AHCC on digestive system cancer.

By Yusai Kawaguchi,MD,phD

Department of Surgery,Kansai Medical University

AHCC 对胃癌及肠癌等消化道肿瘤疗效观察。（《自然医学杂志》发表，2009）

（摘要）

在 245 例病人中（胃癌和肠癌）使用 AHCC，并结合标准的化学治疗，结果显示：AHCC 可显著改善病人免疫监测功能，对 1-3 期的胃癌患者及 2-3 期的肠癌的患者效果明显。

The Effect of AHCC in Non-Viral,Chronic,and Abnormal Liver Function Condition: a Randomized,Double-Blind,Placebo-Control Study

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Objective:Active hexose correlated compound(AHCC),a Basidiomycotina extract,has demonstrated potential antitumor activity and immune modulator activity.The purpose of this study was to examine whether AHCC improves liver function in patients with non-viral,chronic,and abnormal liver function condition.

Methods:We conducted a randomized,double-blind,placebo-control study of 30 male subjects with non-viral,chronic,and abnormal liver function condition who received either AHCC(1g or 3g daily)or placebo for 12 weeks.The inclusion criteria were one or more

abnormal values among three liver function tests,aspartate aminotransferase(AST),alanine aminotransferase(ALT),or γ-glutamyltransferase(γ-GT),at least.Body weight,height,blood pressure(BP),pulse rate(PR)and biochemical tests were measured after 4,8,and 12 weeks.

Results:After 4,8,and 12 weeks,1g AHCC intake group significantly decreased AST,ALT,and γ-GT values.And 3g AHCC intake group also significantly decreased AST,ALT,and γ-GT values,except the 4-week value of γ-GT.

Conclusions:It was shown that the consumption of AHCC possessed beneficial effects on non-viral,chronic,and abnormal liver function condition.

Keywords:AHCC;Clinical trial;Non-viral;Chronic;Abnormal liver function;AST;ALT; γ-GT

AHCC 韩国首尔大学医学部　Chung-Ang 教授

The Effect of AHCC in Non-Viral,Chronic,and Abnormal Liver Function Condition: a Randomized,Double-Blind,Placebo-Control Study。（AHCC 对非病毒性、慢性肝功能异常的效果观察。ISIM 国际统合医学会发表，2010）

（摘要）

双盲法选用30例非病毒性、慢性肝功能异常者，分别给予每日1ｇAHCC和每日3ｇAHCC，12周后测定试验对象的谷草转氨酶、谷丙转氨酶和γ-GT，结果显示，从第四周开始，1ｇ组和3ｇ组三项指标都出现明显降低，以γ-GT降低更为明显，提示AHCC对肝细胞功能状况具有明显的改善作用，对肝癌的预防具有积极的作用。

AHCC Exploratory Clinical Research:Impact of AHCC on the Breast Cancer Patients Treated with LH-RH as Adjuvant Endocrine Therapy

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Adjuvant endocrine therapy,including LH-RH, aromatase inhibitor and antiestrogen drugs, is widely administered following primary surgery for breast cancer. LH-RH,applied to premenopausal women,is often accompanied by its adverse effects of estrogen deprivation, as with menopause. These include hot flashes, sweats, insomnia, depression and malaise. These symptoms severely decline the QOL of LHRH-treated patients. Active Hexose Correlated Compound(AHCC) is known that it increases anticancer effect used with anticancer agents. Moreover it ameliorates the side effects of anticancer agents as bone marrow suppression, hepatic toxicity, renal toxicity and acomia. Recently AHCC is proved to ameliorate endocrine disturbances by several stresses.

Our trial is being planed to reveal the effects of AHCC on menopausal symptoms with the patients treated with LH-RH as breast cancer adjuvant endocrine therapy. AHCC at a dose of 3.0g/day will be orally administrated after every meal. The treatment duration is 180 days. The patients' several parameters are recorded at one day before the first administration, the 30th day, and the 180th day. We put kupperman menopausal index as primary endpoint in this study, and evaluate EORTC QLQ-C30,QLQ-BR23,HADS, haematological value and adverse effects assessed by CTC-AE for secondary endpoint. We are planning to start this study in April,2011. We expect this trial to reveal endocrine adjustment effect of AHCC, and AHCC to be an agent to decrease adverse effects of LH-RH therapy and to improve the QOL of breast cancer patients.

AHCC 东京大学医学部附属医院　岩濑哲教授

AHCC Exploratory Clinical Research:Impact of AHCC on the Breast Cancer Patients Treated with LH-RH as Adjuvant Endocrine Therapy。（AHCC 对乳腺癌术后辅助治疗的观察。ISIM 国际统合医学会发表，2010）

（摘要）

每天 3 g AHCC，患者服用后第 30 天开始观察，提示：AHCC 对减缓更年期症状（如发汗、失眠、抑郁、易疲劳）有明显效果，同时显示 AHCC 对减轻骨髓抑制、脱发及肝、肾功能损害有显著效果，对内分泌紊乱亦具有明显的纠正作用

AHCC Exploratory Clinical Research:Impact of AHCC on the Breast Cancer Patients

Treated with Adjuvant Chemotherapy

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Breast cancer has been the most popular malignant tumor among women in Japan.The number of patients with breast cancer is estimated to be higher than 40,000.About 11,000 people die of breast cancer per year.The death has doubled in the past 20 years in Japan and the treatment of breast cancer is becoming more and more important.

The treatment of early breast cancer consists of surgery, adjuvant or neo-adjuvant chemotherapy,hormone therapy,and molecular target therapy. For advanced or recurrent cancer systemic therapy is performed.

The chemotherapy can prolong the survival of patients with breast cancer.However it has various side effects.Anthracycline and Taxan have been used for first-line chemotherapy for breast cancer.These anticancer drugs have a lot of side effects such as bone marrow suppression,hair loss,digestive symptom,and myocardial damage.These side effects not only disturb the continuation of treatment but also harm quality of life(QOL)of the patients receiving chemotherapy.

Active Hexose Correlated Compound (AHCC)has been shown to reduce side effects of chemotherapy,such as bone marrow suppression.hepatotoxity,nephrotoxity,and hair loss,which has been shown by experiments using rodents.Therefore,AHCC has been expected to improve the QOL of the patients receiving chemotherapy through the reduction of side effects.

We evaluate how AHCC affects the QOL of the patients using EORTC QLQ-C30 and QLQ-BR23,which are widely used scales for evaluation of the QOL of the patients with breast cancer.This study will reveal how QOL of the patients with breast cancer shifts,and will be useful for better understanding of AHCC using for human.

AHCC 东京大学医学部附属医院　岩濑哲教授

AHCC Exploratory Clinical Research:Impact of AHCC on the Breast Cancer Patients Treated with Adjuvant Chemotherapy。（AHCC 对乳癌化疗后副作用改善情况观察。ISIM 国际统合医学会发表，2010）

（摘要）

日本的乳腺癌发病率高居榜首，在乳腺癌的治疗上，化学治疗是常用的，但化疗后病人常出现严重的毒副作用，使用 AHCC，能显著减轻乳癌化疗后出现的骨髓抑制、脱发、消化道溃疡等副作用，对患者的生活质量的提升具有显著效果

AHCC 美国德州大学和爱德森癌症中心

Evaluation of Active Hexose Correlated Compound (AHCC) for the Prevention or Delay of Tumor Growth in Human Cervical Cancer Xenograft Model（AHCC 预防或延迟对人宫颈癌移植瘤模型肿瘤生长的评价;ISIM 国际统合医学会发表，2011）

（摘要）

AHCC 预防或延迟人感染 HPV16/18 具有良好的效果；对宫颈癌移植瘤模型肿瘤生长有很好的抑制作用。进进一步的临床试验正在进行中。

英文在 PDF 电子版文件中　2006 泰国卫生部 癌症中心

AHCC 泰国国家卫生部癌症中心 Suphon Manoromana 教授

Prognostic Improvement of Patients with Advanced Liver Cancer after Active Hexose Correlated Compound (AHCC) Treatment. *Asian Pacific Journal of Allergy and Immunology* 24:33-45, 2006. （AHCC 对进展期肝癌患者的预后状况作用）

（摘要）

对进展期肝癌患者 44 名中，34 名服用 AHCC，10 名使用安慰剂。AHCC 组显著延长生存率，在情绪的稳定性、身体的总健康状态、普通运动能力等生活质量方面 AHCC 服用 3 个月后有明显的改善，在临床指标方面血清中白蛋白及血中淋巴细胞比对照组高，IL-12 等免疫指标也有明显的提高。

Perioperative Application of AHCC in Hepatobiliary Tumor

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Twenty eight cases of hepatobiliary tumor without other disease, treated by liver lobectomy with obstruction of liver blood flow, were divided randomly into two groups: control group and treated group.

The treatment group was given 4 g of AHCC for seven days before operative treatment, and for twenty eight days after operation, three times a day.

There were significant differences in CD3,CD4,CD8,CD16 and CD57 T-lymphocyte subgroups before and after treatment between control group and treated ,indicating that AHCC has the effect in raising the number of lymphocytes and enhancing immunity in patients witn hepatobiliary tumor.

AHCC 福建中医学院 杜建院长

AHCC 在肝胆肿瘤围手术期的应用 （第 15 届 AHCC/GCP 国际研究会, 2007）

（摘要）

病人均为肝胆肿瘤，无其他合并疾病。实施肝脏切除手术，术中均使用肝门阻断。年龄在 30-70 岁之间，随机进行分为实验组与对照组。

28 名肝胆肿瘤患者分两组，14 名为服用 AHCC 组，14 名为对照组。AHCC 组在肝脏切除前 7 天开始服用 AHCC，术后继续服用 4 周。服用前后 AHCC 组 CD3、CD4、CD8、CD16、CD57 均与对照组呈显著差异，提示 AHCC 对恶性肿瘤患者有提升淋巴细胞作用，并有保护和提高机体免疫功能的功效。

GCP 广州珠江医院肿瘤科 汪森明主任医师

GCP 对非小细胞肺癌患者初步临床观察（2005）

（摘要）

30 名非小细胞肺癌 IV 期患者分两组，对照组单用化疗，GCP 组在化疗期间同时服用 GCP，每三周为一周期。两个周期后，对血液系统、消化系统、肾及膀胱、神经系统、生活质量进行评价，GCP 组在各项目有些改善。结果显示 GCP 能减轻肺癌化疗的毒副作用，对患者生活质量有明显改善效果。

三羟基异黄酮灵芝多糖聚合体（GCP）对非小细胞肺癌患者初步临床观察

珠江医院肿瘤科主任医师　　汪森明

化疗是 IV 期非小细胞肺癌治疗重要手段之一，但由于化疗药物对正常组织损伤常导致严重的毒副作用，如何减少化疗药物对非小细胞肺癌患者毒副反应。提高生活质量，是目前临床探讨的重要课题。本研究拟观察三羟基异黄酮灵芝多糖聚合体（GCP）对肺癌化疗患者能否减轻毒副作用，提高治疗效果，提高生活质量，现将结果报告如下：

1、　　临床资料与方法。

1.1　病例资料：30 例非小细胞肺癌，均经病理检查证实，Ⅳ期患者，上述病例随机分为两组：A 组：15 例、男 11 例、女 4 例，年龄 42-58 岁；B 组：15 例、男 10 例、女 5 例，年龄 39-56 岁。以上病例均初治患者，体力状况评分（ECOG）均为 1-2 分。

1.2 治方案：两组病人均选择化疗，化疗方案选择 1000mg/m^2，$d_{1.8}$ 顺铂 70mg/m^2，d_1。每三周为一周期。A 组单用化疗，B 组病人在化疗期间及化疗间歇期均同时口服 GCP 1.8g/日。两个周期治疗后评价疗效。

1.3 观察指标；

疗效：疗效评定按 WHO 制定的肿瘤疗效判断标准。

毒副反应评估：观察治疗中毒副作用。

生活质量（QL）：治疗中及治疗后生活质量比较。

2、　　结果：

2.1 治疗结果：

	A 组	B 组
CR	1	2
PR	6	4
SD	5	5
PD	3	4
有效率（CR+PR）	46.6%	53.3%
临床获益率	80%	73%

2.2　毒副反应：第二周期化疗后十天，按 WHO 标准评价两组病人化疗后急性毒性反应。

2.2.1 血液系统：

A 组病人：　Ⅰ级白细胞下降占 52%，血小板下降占 34%
Ⅱ级白细胞下降占 14%，血小板下降占 9%
Ⅲ级白细胞下降占 5%，血小板下降占 3%
无Ⅳ级骨髓毒性

B 组病人：Ⅰ级白细胞下降占 36%，血小板下降占 29%
Ⅱ级白细胞下降占 9%，血小板下降占 5%
Ⅲ级白细胞下降占 3%，血小板下降占 1%
无Ⅳ级骨髓毒性

2.2.2 消化系统：

A 组：Ⅰ级恶心呕吐占 30%，腹泻占 10%，谷丙酶升高 3%
Ⅱ级恶心呕吐占 1%，腹泻占 8%，谷丙酶升高 2%
Ⅲ级恶心呕吐占 2%，腹泻占 2%，谷丙酶升高 2%

B 组：Ⅰ级恶心呕吐占 23%，腹泻占 6%，谷丙酶升高 1%
Ⅱ级恶心呕吐占 8%，腹泻占 3%，谷丙酶升高 1%
Ⅲ级恶心呕吐占 1%，腹泻占 1%，谷丙酶升高 1%

2.2.3 肾及膀胱：

A 组：Ⅰ级 BUN 升高 3%，肌酐升高 4%
Ⅱ级 BUN 升高 2%，肌酐升高 3%

B 组：Ⅰ级 BUN 升高 1%，肌酐升高 2%
Ⅱ级 BUN 升高 1%，肌酐升高 1%

2.2.4 神经系统：

A 组：Ⅰ级周围神经毒性 10%，便秘 30%
Ⅱ级周围神经毒性 8%，便秘 10%

B 组：Ⅰ级周围神经毒性 6%，便秘 21%
Ⅱ级周围神经毒性 4%，便秘 7%

2.2.3 生活质量（QL）：两周期化疗后半月，评价两组病人生活质量改善情况。

	A 组		B 组	
	有效例数、	有效率	有效例数、	有效率
睡眠改善	8	53.3%	12	8%

食欲改善	6	40%	9	60%
精神改善	7	46.6%	8	53.3%
体重增加	5	33.3%	9	60%

3、结论：从本组资料结果看 GCP 能减轻肺癌化疗病人毒副反应，对病人生活质量有明显改善作用，但因例数较小，能否增加化疗药物反应，提高化疗效果尚难定论，尚需增加临床观察样本量。

Case Report on Co-administration of AHCC for Posttransplantation of Liver

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Although liver transplantation is the most effective therapy, the risk of postoperative complications is high, the postoperative bleeding, blood vessel and bile duct diseases, and allotrio immunological rejection are often observed. Therefore, the prophylaxis and therapy against the complication of the blood vessel and bile duct is one of the problems that must be solved in some way at clinical site. Here, we report that the favorable effects of AHCC administrating through nasogastric tube after a liver transplantation performed in our hospital in September 2005.

[General information] A patient with hepatic cancer is 47-year-old man, whose blood type is B that is compatible to the donor. By the preoperative CDFI no clot formation was found at portal, abdominal cavity, and splenic veins, and no sign of metastasis was shown at peritoneal cavity.

[Therapy] Administration of immunosuppressive agents such as steroids and FK506 to the patient was started just after the operation. From day 4, 12 capsuls of AHCC was divided into three, and administered to the patient three times a day via a nasal duct with the patient's consent.

[Surveillance Indices] Twenty-four hours after the operation, CDFI and PW examination (hepatic artery peak velocity (HAmax), portal vein mean velocity, internal diameter of hepatic artery and blood flow resistant index, and internal diameter of portal and hepatic veins) were performed.

[Results] No abnormal remark was observed at the posttransplant liver in 24 hr and in a week: the location, shape, size, appearance of hepatic body, structure of intrahepatic duct, choledoc, portal vein, hepatic vein, abdominal cavity vein, internal diameter of abdominal cavity vein and hepatic artery at porta hepatica, and blood flow and peripheral part of liver. Postoperative blood flow obstruction is often observed in liver transplanted patients. Although the peak of blood flow volume distinctively tended to be lower than that of healthy individuals,

[Discussion] Liver transplantation is the most effective therapy in terminal stage of liver ailment and widely performed in the world. The survival rate is growing with the advancement of surgical technique, anesthesia treatment, and pre- and post-operative care. However, the incidence rate of the complication remains 14-55%. Postoperative bleeding, inflammation of blood vessel and bile duct, and immunologic rejection are often observed. Therefore, the restoration of hepatic function is a crucial key to the success of operation. Since anoxic injury in the liver cause serious damage to liver function, prevention of oxygen deficit after liver transplantation, treatment for immunological rejection and enhancement of immunity has been a clinical challenge. According to the condition of patients in our

hospital and other clinical reports, the clinical symptom of the complication after the liver transplantation is mainly 毒(DU), 熱(RE), and 湿(SHI). The characteristic of the complication is abrupt onset and rapid progression, with a high possibility to develop systemic dysfunction, and poor prognosis. The condition of the disease is caused by 解毒(JIE DU), with interaction between 湿毒(SHIDU) and 鬱毒(YUDU). 化鬱解毒(HUA YU JIE DU) and 保肝利胆(hepatic protective and choleretic effects) have to be selectively introduced for the therapy of the complication. Our experiences in using AHCC for 12 years demonstrated that AHCC improve 去熱(QURE), 解毒(JIEDU), 消湿(XIAOSHI), and immune function. Thus, it is considered that AHCC may be useful for the recovery of the condition after the liver transplantation, the prevention of the complication, and the improvement of QOL.

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AHCC 在肝移植中应用报告及 12 年临床应用 AHCC 临床总结（第 14 届 AHCC/GCP 国际研究会, 2006）

（摘要）

肝胆移植手术术后经鼻饲灌服 AHCC（12 粒/天），能促进肝移植患者术后恢复，减少并发症发生，提高生活质量。

此外，通过我院 12 年临床运用 AHCC 观察，从中医角度分析，凡患者出现烦躁，夜间睡眠不安，特别容易惊醒，口干或伴有口腔溃疡，容易出汗，胸部有烦热感觉，大便干结，小便颜色多黄色，还有舌苔黄、厚等。应用 AHCC 配合治疗，能明显缓解症状。

中国传统医学对中药的认识，把中药分为:“寒、热、温、凉”四性，凡“寒凉”的药物可治疗“热症”，凡“温热”的药物可治疗“寒症”。因此从临床观察，AHCC 应属于“寒凉”药性，它可用于治疗属于“热症“的患者。

Clinical observation of stage MI malignant tumors treated with the Combination of chemotherapy and AHCC

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Slide 1

Title

Slide 2

The purpose of this study is to observe the changes of immune function in the advanced malignant tumor patients co-administrated with chemotherapy and AHCC .189patients were registered into this study. All the patients must be over 18 years old, and have a diagnosis of malignant tumor. And a Karnofshy score is over 60 points

Furthermore, it is necessary for them to receive over two treatment courses of chemotherapies. The enrolled patients had survival terms more than 3 months. We excluded the patients without the criteria above.

Slide3

All of the 189 patients were divided into Group A and Group B randomly by considering different stages and using crossover. Group A had 90 patients, and Group B had 99 patients.

Slide4

Group A received co-administration of chemotherapy and AHCC in the first treatment term was considered as Group AI and chemotherapy alone in the second treatment term was considered Group A2.

Slide5

Reversely, Group B received chemotherapy alone in the first treatment term as Group B2 and co-administration of chemotherapy and AHCC in the second treatment term as Group BI.

Slide6

All the subjects were taken 3 ML of blood one week before and 3,8,15 days after the chemotherapy for analyzing the subtypes of lymphocytes and the cyto-activities.

Slide7

All the data were represented by means ± SD. The comparison of tumor size used Student's Test and the analysis of immune index used SPSS software.

Slide8

Observed indicators included the changes of tumor size, subtypes of T cell, Natural Killer (NK) Cell and IL-2 Activated Kill(LAK)cell activities between the pre-and post-treatments.

Slide9

As the result, AgNORs level, NK and LAK activities decreased obviously on the 3rd day after chemotherapy.

Slide10

AHCC treated groups increased AgNORs expression and LAK activity significantly ($p < 0.05$) and showed a tendency to enhance NK activity ($p < 0.05$).

Slide11

AHCC can increase the activities of peripheral NK and LAK cells ,up-regulate the activity of DNA transcription of T cells.

Slide12

This slide showed the background of all the patients . All the patients received the treatments over the whole study period . There was no difference in gender and age Also there was no difference in cancer types: gastric, colon, esophagus, nasal, breast and pulmonary.

Slide13

It is AgNORs level change of the patients who continued to take AHCC after this therapy. The data was compared with no treatment group. Intake of AHCC increased the AgNORs level.

Slide14

This slide showed the changes of the activity index of LAK cells at 0, 2, 4 and 8 weeks after the therapy. Also the activity of LAK cells was increased by taking AHCC .

Slide15

This slide showed the changes of the activity of NK cells . Intake of AHCC results in enhancing the activity of NK cells .

In our previous studies, we found that some patients have good responses in the inhibition of side-effects of chemotherapy or radiotherapy while combined with AHCC and the improvement QOL but others do not .Thus, the patients who took in AHCC were analyzed. As a result , we found that AHCC is effective in the patients with following symptoms.

1. Unquiet mind
2. Sleep disorders(unable to sleep well)
3. Easy to sweat
4. Heartburn
5. Tend to be constipated and have deep urinary colors.

On the other hand, the patients who do not have good responses to AHCC have a tendency of depression and cold-constitution. Especially for the patient with cold-constitution, the effect of AHCC is low. Those patients cause abnormalities by taking in cool-food and cold water. These patients are diarrhea tendencies. Moreover, AHCC cannot be easily effective against patients who have fur coating of tongue. Especially those patients tend to exaggerate the gastrointestine. It is difficult to use AHCC for them.

We classified AHCC as a “cold” or “cool” type of substance based on Chinese traditional medicine. According to the medicine, AHCC should be well effective to the people with “hot” or “warm” constitution. On the other, I do not know if AHCC shows the effect well in the patients who are “cold” constitution. It is a theme for the future research.

スライド 1

Clinical observation of stage M1 malignant tumors treated with the combination of chemotherapy and AHCC

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スライド 2

Purpose:To study the changes of immune function in the advanced malignant tumor patients co-administered with chemotherapy and AHCC

スライド 3

Method:189 patients were divided randomly into Group A and Group B by considering different stages and using

スライド 4

Group A received co-administration of chemotherapy and AHCC in the first treatment term as Group A1 and chemo-therapy

スライド 5

Reversely: Group B received chemotherapy alone in the first treatment term as Group B2 and co-administration of chemotherapy and AHCC in

スライド 6

All the subjects were taken 3ml of blood one week before and 3,8,15days after the chemotherapy for analyzing the subtypes of lymphocytes

スライド 7

All the data were represented by means ±SD. The statistical analysis used student’s test, and the data analysis used SPSS software

スライド 8

Observed indicators included the changes of tumor size, subtypes of T cell, Natural Killer Cell (NK)and IL-2 Activated Kill Cell (LAK)

スライド 9

Result :AgNORs level, NK and LAK activities decreased obviously on the 3rd day after chemotherapy.

スライド 10

AHCC-treated groups increased AgNORs expression and LAK activity significantly ($p < 0.05$) and showed a tendency to enhance NK activity($p < 0.05$).

スライド 11

Conclusion: AHCC can increase the activities of peripheral NK and LAK cells, upregulate the activity of DNA

AHCC 福建中医学院 杜建院长

在恶性肿瘤化疗中与 AHCC 并用的临床观察。

（摘要）

189 例确诊为恶性肿瘤的患者随机分为 A、B 组，其中 A 组 90 例，B 组 99 例，所有受试者在实验一周前及化疗 3，8，15 天之后，抽取 3ml 血液作分析，观察指标包括肿瘤大小，T 淋巴细胞亚群，NK 细胞，IL-2 和 LAK 细胞的活性，实验结果表明 AHCC 能增加外周血 NK 细胞和 LAK 细胞的活性，T 淋巴细胞亚群明显升高，统计学统计差异有明显性（P<0.05）。

The Therapeutic Effects of AHCC on Perioperative Patients With Tumor of Digestive System

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Objective : This study was to investigate the effect of AHCC on immunity, cytokine and VEGF (vascular endothelial growth factor) of perioperative patients with tumor of digestive system.

Methods : Forty eight perioperative patients with tumor of digestive system (gastric cancer, colon cancer)were divided randomly into control and treatment groups. The patients of treatment group were given AHCC 3.6 g (12 capsules/day, 4 capsules/time) form the seventh days before operation. The blood samples were taken at the seventh day before operation, as well as the first and seventh days after operation. The following indexes of blood were examined:①immune function: including T –lymphocyte subgroups and NK cells,②VEGF,③cytokine: including IL-2,IL-4,IL-6 and IL-10,④INF-γ,⑤colony stimulating factor: including G-CSF and GM-CSF.

Results: There were significant increase in the level of CD_3,CD_4,NK cells,IL-2,INF-γ and GM-CSF expression($P < 0.05$ or $P < 0.01$),and significant decrease in the level of VEGF,IL-4, IL-6, IL-10 and G-CSF($P < 0.05$) at the first and seventh days after operation compared with the seventh day before operation in the blood of control and treatment groups ($P < 0.05$).These results suggest that AHCC was effective in enhancing the immune function of perioperative patients with tumor of digestive system.

AHCC **中国福建中医学院 杜建院长**

"AHCC 在围手术期消化器官肿瘤患者的治疗效果"

（摘要）

对围手术期消化器官癌症患者(胃癌、大肠癌）48 名随机分两组，即 AHCC 组和对照组。AHCC 组在手术前 7 天开始服用 AHCC(12 粒/天，分三次)，手术前第 7 天、手术后第 1 天、手术后第 7 天进行观察。与手术前相比，AHCC 组在手术后第 1 天、第 7 天明显提高 CD3、CD4、NK 细胞、IL-2、IFN-gamma、GM-CSF，明显下降 VEGF、IL-4、IL-6、IL-10、G-CSF，

并与对照组相比差异有统计学意义。试验结果表明 AHCC 具有增加淋巴细胞、增强免疫系统作用。