

· 研究原著 ·

文章编号 1000-2790(2005)01-0045-05

## 肝外胆管癌术前影像学检查及 CA19-9 测定的诊断价值

秦兴雷<sup>1</sup>, 王作仁<sup>1</sup>, 强永乾<sup>2</sup>, 韦晓峰<sup>3</sup>, 张毅力<sup>2</sup>, 张云锋<sup>1</sup>, 马 炜<sup>1</sup>(西安交通大学第一医院:<sup>1</sup>肝胆外科,<sup>2</sup>影像中心,陕西 西安 710061,<sup>3</sup>洛阳市中心医院影像中心,河南 洛阳 471009)

## Preoperative diagnosis of extrahepatic cholangiocarcinoma: Application of CA19-9 and imaging

QIN Xing-Lei<sup>1</sup>, WANG Zuo-Ren<sup>1</sup>, QIANG Yong-Qian<sup>2</sup>, WEI Xiao-Feng<sup>3</sup>, ZHANG Yi-Li<sup>2</sup>, ZHANG Yun-Feng<sup>1</sup>, MA Wei<sup>1</sup><sup>1</sup>Department of Hepatobiliary Surgery, <sup>2</sup>Center of Imaging, First Hospital, Xi'an Jiaotong University, Xi'an 710061, China, <sup>3</sup>Center of Imaging, Luoyang Center Hospital, Luoyang 471009, China

**【Abstract】** AIM: To explore the preoperative diagnostic value of different imaging methods, CA19-9 determination and CEA determination in diagnosing extrahepatic cholangiocarcinoma (EHCC). **METHODS:** The diagnostic efficacy of various imaging methods was analyzed retrospectively in 107 patients with EHCC. We measured CA19-9 and CEA concentrations of serum and bile in patients with EHCC ( $n=51$ ) and benign biliary diseases ( $n=42$ ). A receiver operation characteristic (ROC) curve was used to define a new strategy for interpreting CA19-9 and CEA in EHCC. **RESULTS:** The preoperative diagnostic accuracy rates of tumor visualization of ultrasonography (US), computed tomography (CT) and magnetic resonance imaging cholangiopancreatography (MRCP) in diagnosing EHCC were 70.8%, 60.2% and 69.0%, respectively. The diagnostic accuracy rates of tumor location of US, CT, MRCP, endoscopic retrograde cholangiopancreatography (ERCP) and percutaneous transhepatic cholangiography (PTC) in diagnosing EHCC were 72.9%, 75.9%, 100%, 71.4% and 76.9%, and the diagnostic accuracy rates for tumor quality were 70.8%, 73.5%, 86.2%, 61.9% and 58.3%, respectively. The serum CA19-9 and serum CEA concentrations significantly elevated ( $P < 0.01$  and  $P < 0.05$ ) in patients with EHCC compared with those in patients with benign biliary diseases. The ROC curves analysis showed that the area under the ROC curve (AUC) of serum CA19-9, serum CEA, and bile CA19-9 were 0.942 ( $P < 0.001$ ), 0.516 ( $P >$

0.05) and 0.746 ( $P < 0.01$ ), respectively. The outcome showed that the serum and bile CA19-9 were of better diagnostic value than serum CEA. The sensitivity of serum CA19-9, serum CEA, bile CA19-9 and bile CEA in diagnosing EHCC were respectively 86%, 26%, 50% and 32%, and the corresponding specificity when compared with those of the benign biliary disease group were 88%, 95%, 94% and 61%, respectively. **CONCLUSION:** MRCP is superior to US, CT, ERCP and PTC in locating the position and the nature of the tumor. The determination of serum CA19-9 is a reliable test for the differential diagnosis of EHCC. The preoperative diagnosis of EHCC can be performed by two steps: The first is to screen out all patients by US, and the second is to locate the tumor by serum CA19-9 determination and MRCP or CT.

**【Keywords】** bile duct neoplasms; bile ducts, extrahepatic; diagnostic imaging; tumor markers, carbohydrate antigen 19-9; diagnosis

**【摘要】**目的 探讨影像学检查和糖链抗原(CA19-9)、癌胚抗原(CEA)测定对肝外胆管癌(extrahepatic cholangiocarcinoma, EHCC)的诊断价值。方法 回顾性分析107例肝外胆管癌超声(US)、CT、磁共振胆胰管造影(MRCP)、内镜逆行胆胰管造影(ERCP)和经皮经肝胆道造影术(PTC)诊断结果,并与手术及病理结果对照。其中51例进行了血清CA19-9、CEA测定,22例进行了胆汁CA19-9、CEA的测定,并分别与胆道良性病变进行对照。通过ROC曲线界定CA19-9、CEA对EHCC的诊断价值。结果 肿块显示率US、CT、ERCP分别为70.8%、60.2%和69.0%;定位诊断准确率US、CT、MRCP、ERCP和PTC分别为72.9%、75.9%、100%、71.4%和76.9%;定性诊断准确率US、CT、MRCP、ERCP、PTC分别为70.8%、73.5%、86.2%、61.9%和58.3%。EHCC组与胆道良性病变组相比较,血清CA19-9、CEA浓度明显升高( $P < 0.01$ ,  $P < 0.05$ )。接收者工作特征(ROC)曲线显示,血清CA19-9、CEA和胆汁CA19-9的ROC曲线下面积(the area under the ROC curve, AUC)分别为0.942( $P < 0.001$ )、0.516( $P > 0.05$ )和0.746( $P < 0.01$ );结果显示血清CA19-9和胆汁CA19-9对EHCC有较好的诊断价值。血清CA19-9、CEA和胆汁CA19-9、CEA的敏感性分别为86%、26%、50%和32%,其特异性分别为88%、95%、94%和61%。结论 MRCP对EHCC定位和定性诊断优于US、CT、ERCP及PTC,血清CA19-9的测定是EHCC术前可靠的定性诊断手段。EHCC的诊断步骤可归结为US结合临床资料进行初步筛选,US阳性者进行血清CA19-9测定,然后采用MRCP或CT进行定位诊断。

收稿日期 2004-07-06; 修回日期 2004-09-27

作者简介 秦兴雷(1968-)男(汉族)河南省商丘市人。博士,副主任医师。Tel.(029)85274739 Email. xinglei@163.com

【关键词】胆管肿瘤;肝外胆管;诊断显像;肿瘤标记物;糖链抗原 19-9;诊断

【中图分类号】R657.4 【文献标识码】A

## 0 引言

肝外胆管癌(extrahepatic cholangiocarcinoma, EHCC)是相对少见的恶性肿瘤,约占肝外胆道肿瘤的1/3<sup>[1-3]</sup>。各种影像学诊断技术有它的局限性,单靠某一项诊断技术对肝外胆管癌确诊有时十分困难。为了提高术前确诊率,我们回顾性总结了1995-01/2003-12间收治的107例经手术或(和)病理证实的EHCC临床影像及手术病理资料,分析糖链抗原(CA19-9)、癌胚抗原(CEA)的测定结果,并与胆道良性病变患者进行对照研究。

## 1 对象和方法

1.1 对象 EHCC患者107例(男62,女45)例,男女比例1.38:1。平均年龄55.8(27~82)岁。临床表现多无特异性,病程3d至7a不等。首发症状以黄疸最多见,占74.8%(80/107),上腹部不适38.3%(41/107),右上腹痛26.2%(28/107),腹胀23.4%(25/107),腹部肿块10.3%(11/107),体质量减轻16.8%(18/107),发热7.5%(8/107)。I,II期患者常以上腹部不适、右上腹痛为首发症状,III,IV期患者以黄疸、腹部肿块多见。既往有胆道手术史者27例(25.2%),其中入院前1a内6例(5.6%)患者曾进行过单纯胆囊切除术,12例(11.2%)进行过胆囊切除、胆总管探查手术。此外,既往有肝炎、肝硬化者5例(4.7%),急性胰腺炎4例(3.7%)。同时伴有肝内外结石及胆囊结石者18例。

### 1.2 方法

1.2.1 影像学检查 96例行B型超声(US)检查,83例行CT检查,29例行MRI及磁共振胆胰管造影(MRCP)检查,21例行逆行胰胆管造影(ERCP)检查,13例行经皮肝穿胆道造影(PTC)检查。

1.2.2 CA19-9,CEA测定 51例患者进行了血清CA19-9,CEA的测定;其中22例术中取胆管胆汁进行CA19-9,CEA测定。同时,选择同期无感染的胆道良性病变患者42例作为对照研究;其中,血清CA19-9,CEA测定42例,术中取胆管胆汁进行CA19-9,CEA测定33例。胆管癌组与对照组在性别、年龄上无统计学差异。在血清中采用所公认的CA19-9,CEA正常值范围分别为CA19-9 $\leq 37$  ku/L,CEA $\leq 22$   $\mu\text{g/L}$ 。胆汁CEA的分界值采用对照组的95%参考值范围上限 $\bar{x} + 1.645s$ 为分界值,大于 $\bar{x} + 1.645s$ 作为

阳性标准,其正常值范围为 $\leq 61$   $\mu\text{g/L}$ ;胆汁CA19-9的分界值采用对照组的P95,大于P95作为阳性标准,其正常值范围为 $\leq 1.02 \times 10^5$  ku/L。

1.3 诊断情况 就诊前有52例(48.6%)曾被误诊,其中误诊为肝炎23例(21.5%),胆石症17例(15.9%),胆囊切除或胆道手术后综合征7例(6.5%),慢性胃炎2例,消化性溃疡、原发性肝癌、风湿病各1例。手术前明确诊断肝外胆管癌76例(71.0%);同时伴有肝转移16例(15.0%)或(和)伴有腹膜转移11例(10.3%)。上段胆管癌(肝门部胆管癌)71例(66.4%),中段胆管癌13例(12.1%),下段胆管癌23例(21.5%)。在71例上段胆管癌中,根据Bismuth-Corletter法进行临床分型,I型7例(9.9%),II型11例(15.5%),IIIa 10例(14.1%),IIIb 15例(21.1%),IV型17例(23.9%),其余11例(15.5%)因病变范围不清难以分型。肝内型(周围型)胆管癌置研究范围之外。

1.4 病理诊断 98例经病理检查证实,包括乳头状腺癌3例,高分化腺癌16例,中分化腺癌47例,低分化腺癌21例,未分化腺癌8例,黏液腺癌2例,腺鳞癌1例。

统计学处理:采用SPSS 11.0统计软件,根据数据类型不同分别进行 $t$ 检验、方差分析、 $\chi^2$ 检验及确切概率法;采用Bayes公式和接收者工作特征(ROC)曲线进行诊断试验的评价。

## 2 结果

2.1 影像学检查 行US检查96例,均提示肝弥漫性肿大,肝内或(和)外胆管扩张,胆囊及胆总管萎缩或胆囊肿大,其中68例显示肝外胆管实质性回声或弱回声(Fig 1)。83例行CT检查,提示肝内或(和)肝外胆管扩张,胆囊萎缩或胆囊肿大,其中50例显示肝外胆管低密度团块影(Fig 2)。29例行MRI及MRCP检查,有25例显示肝内或(和)肝外胆管扩张、肝外胆管截断或狭窄、肿瘤部位及大小(Fig 3~5)。21例行ERCP检查,诊断符合率为62.0%(13/21),13例行PTC检查,诊断符合率为53.8%(7/13),显示肝外胆管梗阻部位,呈鸟嘴状或截断改变。定位准确率以MRCP最好,为100%,显著高于其他检查( $\chi^2 = 2.340$ ,  $P = 0.039 < 0.05$ )。软组织肿块诊断率US最高(70.8%),定性准确率MRCP最好(86.2%),但均无统计学意义(Tab 1)。US,CT和MRCP检查无并发症发生。ERCP检查后并发症急性胆管炎3例(14.3%),急性胰腺炎2例(9.5%),其中1例因急性重症胆管炎并急性胰腺炎死亡。PTC

检查后并发急性胆管炎 2 例 (15.4%),胆漏 1 例和膈下感染各 1 例 (7.7%)。

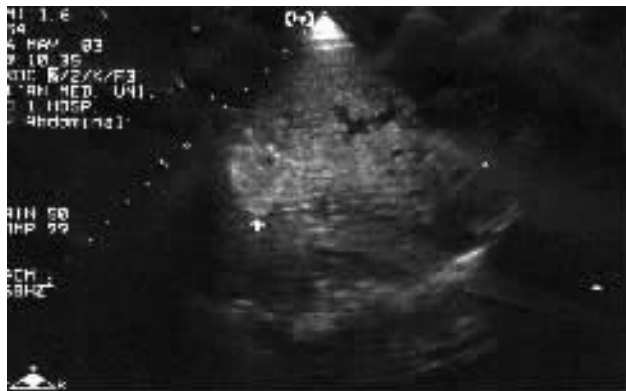


Fig 1 Ultrasound shows a 33 mm x 16 mm signal intensity lumen of identical echo in the confluence of the right and left hepatic ducts in continuity proximal common bile duct, with dilatation of both intrahepatic bile ducts

图 1 US 见肝内胆管扩张,于左、右肝管汇合部胆管内见 33 mm x 16 mm 等回声光团充填,延续至胆总管上段



Fig 2 CT scan shows an irregular, hypoattenuating mass at the hepatic hilar area and dilatation of both intrahepatic bile ducts

图 2 CT 平扫见肝门区见形态不规则肿块影,肝内胆管扩张

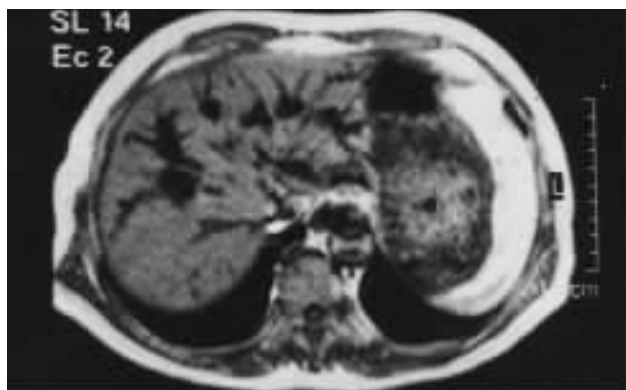


Fig 3 MR (T<sub>1</sub> WI) image shows ill-defined, water-like signal intensity in the hepatic hilar level and marked dilatation of the intrahepatic bile ducts

图 3 MRI T<sub>1</sub> WI 见肝门层面,肝内胆管明显扩张,呈水样信号影,肝门结构紊乱,显示不清

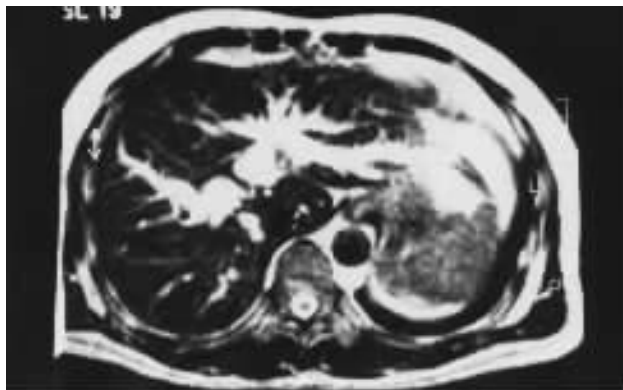


Fig 4 MR (T<sub>2</sub> WI) image shows marked dilatation of the intrahepatic bile ducts with flexible rattan sign

图 4 MRI T<sub>2</sub> WI 见肝内胆管明显扩张,呈软藤征



Fig 5 MRCP image shows a stricture and filling defect at the distal common bile duct, with extrahepatic and intrahepatic ductal dilatation and irregularity, and a stasis gallbladder

图 5 MRCP 见胆总管中下段充盈缺损,胆管连续性中断,同时显示胆总管上段、肝总管、肝内胆管明显扩张,胆囊肿大

表 1 肝外胆管癌影像学表现和定位定性诊断准确率

Tab 1 Imaging findings and diagnostic accuracy rates of tumor location and tumor quality in patients with extrahepatic cholangiocarcinoma [n (%)]

Imaging examination	n	Imaging findings		Accuracy rate of tumor location	Accuracy rate of tumor quality
		Biliary dilatation	Tumor		
US	96	96 (100)	68 (70.8)	70 (72.9)	68 (70.8)
CT	83	80 (96.4)	50 (60.2)	63 (75.9)	61 (73.5)
MRCP	29	29 (100)	20 (69.0)	29 (100)	25 (86.2)
ERCP	21	11 (52.4)	0	15 (71.4)	13 (61.9)
PTC	13	11 (84.6)	0	10 (76.9)	7 (58.3)
χ <sup>2</sup> values			2.340	10.065	6.232
P values			0.310	0.039	0.182

US : ultrasonography ; CT : computed tomography ; MRCP : magnetic resonance imaging cholangiopancreatography ; ERCP : endoscopic retrograde cholangiopancreatography ; PTC : percutaneous transhepatic cholangiography.

## 2.2 CA19-9, CEA 测定

2.2.1 血清和胆汁中 CA19-9 及 CEA 浓度 胆管癌组与对照组血清和胆汁 CA19-9 及 CEA 的比较,前者均明显高于后者 ( $P < 0.01$ ,  $P < 0.05$ ). 胆管癌组中,胆汁 CA19-9 含量高于对照组 ( $P < 0.1$ ),但其胆汁 CEA 含量与对照组相比无明显差别 (Tab 2).

表 2 血清和胆汁中 CA19-9 及 CEA 含量测定结果

Tab 2 CA19-9 and CEA concentrations in serum and bile  
( $\bar{x} \pm s_x$ )

Group	n	CA19-9(ku/L)	CEA( $\mu\text{g/L}$ )
Serum			
EHCC	51	490 $\pm$ 150 <sup>a</sup>	22.0 $\pm$ 2.4 <sup>b</sup>
BBD	42	20 $\pm$ 5	14.8 $\pm$ 0.8
Bile			
EHCC	22	(5.5 $\pm$ 1.6) $\times 10^4$ <sup>c</sup>	45.4 $\pm$ 5.0 <sup>d</sup>
BBD	33	(2.4 $\pm$ 0.7) $\times 10^4$	52.9 $\pm$ 3.9

$t_a = 3.124$ ,  $^aP = 0.003 < 0.01$ ;  $t_b = 2.588$ ,  $^bP = 0.011 < 0.05$ ;  $t_c = 1.746$ ,  $^cP = 0.099$ ,  $> 0.05$ ,  $< 0.1$ ;  $t_d = -1.202$ ,  $^dP = 0.235 > 0.1$  vs BBD. EHCC: extrahepatic cholangiocarcinoma; BBD: benign biliary diseases.

2.2.2 CA19-9 及 CEA 的 ROC 曲线 将胆管癌组与对照组浓度有明显差异的血清 CA19-9, CEA 和胆汁 CA19-9 行 ROC 曲线 (Fig 6). 血清 CA19-9 ROC 曲线下面积 (AUC) 为 0.942,  $P = 0.000 < 0.001$ ; 血清 CEA 为 0.516,  $P = 0.868 > 0.05$ ; 胆汁 CA19-9 为 0.746,  $P = 0.009 < 0.01$ . ROC 曲线及 AUC 显示诊断胆管癌的准确性: 血清 CA19-9 > 胆汁 CA19-9 > 血清 CEA, 血清 CA19-9 是诊断胆管癌可靠的肿瘤标志物.

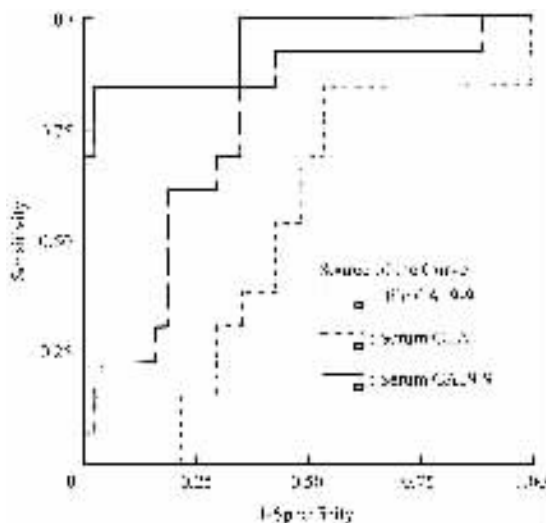


Fig 6 ROC curves of serum CA19-9, serum CEA and bile CA19-9

图 6 血清 CA19-9, CEA 和胆汁 CA19-9 的 ROC 曲线

2.2.3 CA19-9 及 CEA 对胆管癌的诊断价值 对 93 例进行了血清 CA19-9 及 CEA 的测定,对 55 例进行了胆汁 CA19-9 及 CEA 含量的测定,其敏感性和特异性等各项指标详见 Tab 3.

表 3 CA19-9 及 CEA 对胆管癌的诊断价值

Tab 3 Diagnostic values of CA19-9 and CEA levels for cholangiocarcinoma [%(n)]

Index	Serum CA19-9	Serum CEA	Bile CA19-9	Bile CEA
Sensitivity	86(44/51)	26(13/51)	50(11/22)	32(7/22)
Specificity	86(36/42)	95(40/42)	94(31/33)	61(20/33)
Positive predictive value	88(44/50)	87(13/15)	85(11/13)	35(7/20)
Negative predictive value	84(36/43)	51(40/78)	74(31/42)	57(20/35)
Accuracy	86(80/93)	57(53/93)	76(42/55)	49(27/55)
False positive rate	14(6/42)	5(2/42)	6(2/33)	39(13/33)

## 3 讨论

肝外胆管癌早期症状不典型,出现明显临床表现时大部分患者已属中晚期<sup>[4,5]</sup>. 肝外胆管癌的早期诊断与治疗可以改善胆管癌的预后<sup>[6,7]</sup>,但目前肝外胆管癌存在较为明显的误诊、漏诊现象.

由于肝外胆管癌缺乏敏感性强和特异性高的检查方法,因此常依赖于影像学检查作为胆管癌定位诊断的主要手段<sup>[8,9]</sup>. 在各种影像学诊断技术中,US 检查既经济又为非侵袭性,具有很高的软组织分辨力,对于肝门部胆管癌,不易受肠道气体干扰,肿块显示率最高,并可显示肝内及肝门淋巴结转移、门静脉受侵犯等情况,因此,US 检查应为首选;但由于胃肠道气体等的影响,对于中下段胆管癌显示效果较差. CT 扫描不受胃肠道气体及肥胖干扰,但由于层面间遗漏等原因,本组肿块确诊率略低于超声. US 联合 CT 虽可满足病变性质及梗阻部位的诊断要求,但对细小的病变不能做出诊断. ERCP 及 PTC 具有良好的空间分辨率,有助于详细分析梗阻端的形态,对定性及定位诊断均有很高的特异性,但有一定创伤性及并发症,而且其显影诊断效果与操作者的技术熟练程度及病变的部位有关,ERCP 检查的失败率为 3% ~ 9%<sup>[10]</sup>. MRCP 是一种无创性检查方法,它能清楚地显示肝内、外胆管扩张,肿瘤部位、大小,肝外胆管截断或狭窄,并可多方位旋转,多角度观察,显影成功率高. 本组资料结果证明 MRCP 对肝外胆管癌的定位和定性诊断均优于 US,CT,ERCP 和 PTC,与文献报道相近<sup>[8,10]</sup>,但单纯 MRCP 不能很好地显示病变和周

### 围组织的关系,影响定性诊断及术前评估。

CA19-9 是诊断胆管癌和监测该病治疗反应的有效肿瘤标志物<sup>[7,11]</sup>,我们还发现血清 CA19-9 在肝外胆管癌诊断中的阳性率高于 US,CT 和 CEA,而且 CA19-9 水平进行性升高在临床症状出现之前,并可作为术后判断肿瘤复发的指标<sup>[8,12,13]</sup>。本组资料亦显示血清 CA19-9 的测定是胆管癌术前可靠的定性诊断方法。虽然血清 CEA 的测定值在胆管癌组与对照组也有差别(前者是后者的 1.5 倍),但 AUC 为 0.516  $P > 0.05$  而且敏感性仅 26% 准确度仅 57%,说明血清 CEA 不是诊断胆管癌有效的肿瘤标志物。胆管癌组胆汁 CA19-9 的测定值是对照组的 2.3 倍,但无统计学差别( $P > 0.05$ );胆汁 CA19-9 AUC 为 0.746,  $P < 0.01$ ,但其敏感性仅 50% 且胆汁 CA19-9 的测定程序复杂,影响因素较多,测定值不稳定,费用较高,所以我们认为,胆汁 CA19-9 的测定不是诊断胆管癌有效的手段。胆汁 CEA 的测定值在胆管癌组与对照组根本无显著差别。

我们认为,肝外胆管癌的诊断步骤为 ①US 结合临床资料进行初步筛选;②US 阳性者进行血清 CA19-9 测定;③采用 MRCP 或 CT 进行定位诊断。

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编辑 王睿