

• 肿瘤介入 Tumor intervention •

肝癌伴下腔静脉癌栓行 TACE 联合下腔静脉放射性支架或裸支架治疗的对照研究

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【摘要】目的 探讨 TACE 联合下腔静脉放射性支架植入治疗肝细胞肝癌伴下腔静脉癌栓的安全性及有效性。**方法** 对 61 例肝细胞肝癌伴下腔静脉癌栓患者的资料行回顾性分析,放射性支架采用 ^{125}I 粒子条捆载裸支架的方法,共对 33 例患者采用此方法(A 组),28 例患者植入裸支架(B 组)。采用倾向性评分匹配(propensity score matching)对原数据进行后随机化分析以减少选择性偏倚,对两组患者的生存期,症状缓解率及不良反应进行对照分析。**结果** 两组患者术后不良反应发生率相仿,均采用内科对症处理。A 组患者较 B 组显示更长的生存期优势,A 组中位生存时间(203.0 ± 28.1) d, B 组(93.0 ± 24.3) d ($P=0.006$),倾向性评分匹配后(24 对)A 组(200 ± 31) d, B 组(66.0 ± 23) d($P=0.019$),A 组水肿缓解率 97.0%,B 组为 96.4%,多因素分析显示放射性支架植入与肿瘤客观有效率为患者预后好的独立性影响因素。**结论** TACE 联合放射性支架植入对治疗肝细胞肝癌伴下腔静脉癌栓安全有效,可能延长患者生存时间。

【关键字】 ^{125}I ; 肝细胞肝癌; 下腔静脉近程放疗

中图分类号:R735.7 文献标志码:A 文章编号:1008-794X(2017)-07-0607-06

TACE combined with implantation of IVC irradiation stent or bare stent for the treatment of HCC complicated by IVCTT: a comparative study YANG Qinghui, ZHANG Wen, LIU Qingxin, LIU Lingxiao, WANG Jianhua, YAN Zhiping, LUO Jianjun. Department of Interventional Radiology, Affiliated Zhongshan Hospital of Fudan University, Shanghai Institute of Medical Imaging, Shanghai 20032, China

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【Abstract】 Objective To investigate the safety and efficacy of transarterial chemoembolization (TACE) combined with implantation of irradiation IVC stent in treating hepatocellular carcinoma (HCC) complicated by inferior vena cava tumor thrombosis (IVCTT). **Methods** The clinical data of 61 consecutive patients with HCC complicated by IVCTT were retrospectively analyzed. Irradiation IVC stent was prepared by strapping ^{125}I particles on the bare stent, and it was employed in 33 patients (group A). Bare stent was adopted in 28 patients (group B). Propensity score matching method was used to conduct randomized analysis of the original data in order to reduce the selection bias. The survival time, remission rate of symptom and procedure-related adverse events of both groups were calculated and the results were compared between the two groups. **Results** The incidence of adverse reactions was similar in the two groups, and symptomatic treatment with internal medicine was adopted. The survival time in group A was superior to that in group B. The median survival time in group A was (203.0 ± 28.1) days, which was (93.0 ± 24.3) days in group B ($P=0.006$). Propensity score matching (24 pairs in total) cohort analysis showed that the median survival time was (200 ± 31) days in group A and (66 ± 23) days in group B ($P=0.019$). The edema remission rates in group A and in group B were 97.0% and 96.4% respectively. Multiple factor analysis revealed that irradiation stent implantation and objective tumor response were independent factors predicting a good prognosis. **Conclusion**

DOI:10.3969/j.issn.1008-794X.2017.07.008

基金项目:上海市卫生计生委 2013 年度先进适宜技术推广项目(2013SY060)、国家自然科学基金青年项目(81201170)、上海市卫生计生委科研项目(20124188)

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For the treatment of HCC associated with IVCTT, TACE combined with irradiation stent implantation is safe and effective, this therapy can prolong the patient's survival time(J Intervent Radiol, 2017, 26: 607-612)

【Keywords】 ^{125}I particle; hepatocellular carcinoma; brachytherapy in inferior vena cava

肝细胞肝癌(HCC)是最常见的原发性肝癌,是居男性肿瘤致死率第2,女性肿瘤致死率第6的疾病^[1]。据报道在外科手术患者中HCC伴肝静脉癌栓的发生率约4%^[2],患者往往预后较差,如不治疗中位生存期常不足3个月^[3,4]。

下腔静脉(IVC)恶性梗阻常伴随下肢及阴囊水肿,目前尚无标准的治疗方案^[2,4-8]。肝段切除联合IVC重建术可选择性用于肝功能储备较好的患者的姑息性治疗^[5-7]。TACE可以安全用于此类患者,放射治疗可以提高IVC癌栓的局控率,但是无论TACE或放疗都不能缓解IVC梗阻症状^[9-14]。IVC支架植入作为HCC伴IVC癌栓(IVCTT)的姑息性治疗方法,不能提高患者生存时间^[15-17]。前期实验及临床研究已验证了放射性支架对腔内恶性梗阻的近距离放疗的疗效^[18-27],本研究进一步探讨TACE联合放射性支架对HCC伴IVCTT的安全性及有效性。

1 材料与方法

1.1 患者资料

本研究经院内伦理委员会审理并批准。对2010年10月至2014年12月共61例HCC伴IVCTT患者的资料行回顾性分析(图1)。肝细胞肝癌诊断标准按照美国肝病委员会诊断指南,下腔静脉癌栓由腹部超声及腹部增强CT/MRI联合诊断^[28]。所有患者BCLC分级为C级^[8],肝功能Child-Pugh分级A-B,Eastern Cooperative Oncology Group performance status(ECOG)评分小于2分。排除标准(1)下腔静脉癌栓放疗后;(2)右心房癌栓;(3)失访患者;(4)有第二原发肿瘤患者;患者治疗前均签署治疗知情同意书,放射性支架植入组33例(54.1%)(A组),裸支架植入组28例(45.9%)(B组)。

1.2 方法

1.2.1 TACE 行腹腔动脉及肠系膜上动脉造影,明确肿瘤位置及血供情况,用2.7F微导管(Renegade, Boston Scientific, Natick, MA)超选择插管于肿瘤滋养动脉,用2种化疗药混入5~20ml超液化碘油(Lipiodol, France),化疗药剂量及碘油量根据患者肝功能及肿瘤血管情况调整,透视下以0.5~1 ml/min的速率注入,后用适量明胶海绵颗粒加强栓塞。

1.2.2 IVC 支架植入 TACE术后行IVC支架植入

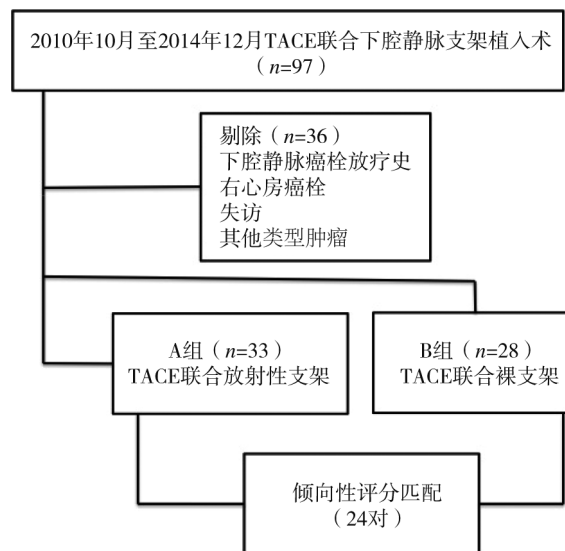
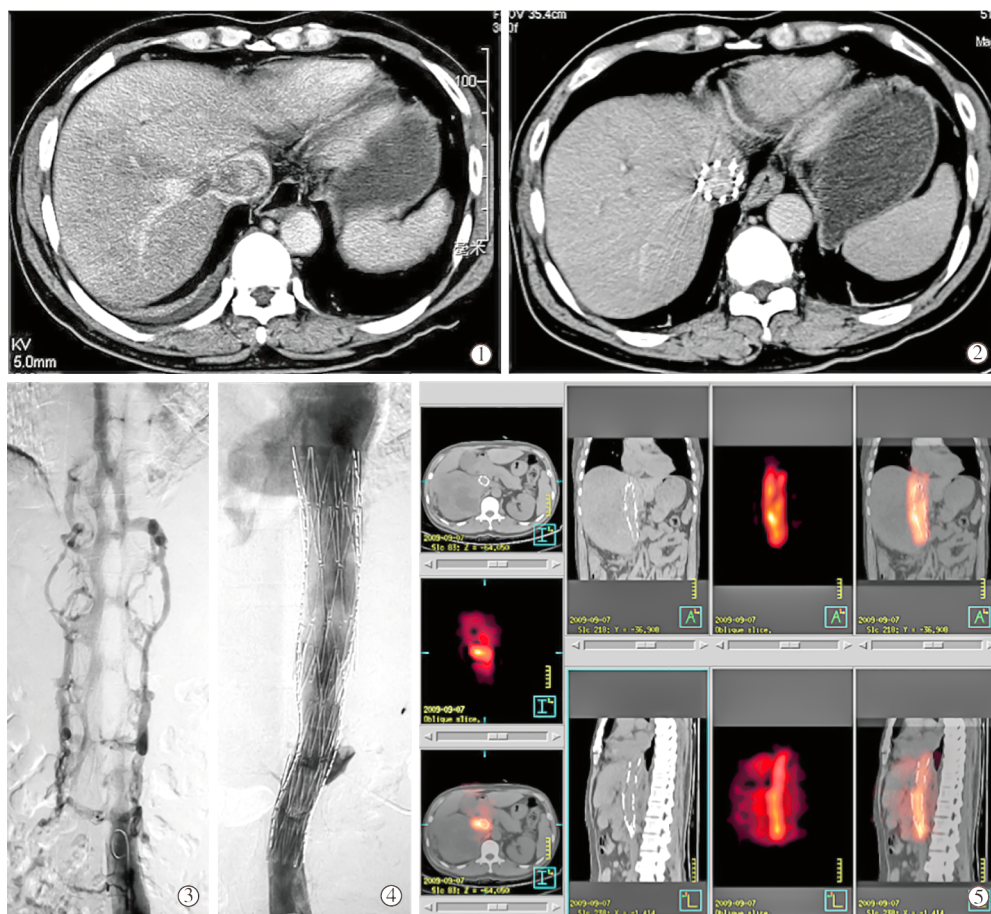


图1 治疗,随访,疗效评估示意

术,选择右侧股静脉入路,用4F Pigtail导管(Cook, USA)造影,明确下腔静脉狭窄程度及梗阻长度,选择国产Z型支架(30 mm×73 mm,北京安泰,中国)在透视下植入,记录植入后IVC直径及狭窄段压差与术前变化。A组植入 ^{125}I 粒子(0.8 mm×4.5 mm,上海新科,中国)数量(N)根据IVCTT长度(L)决定, $(N=(L/4.5+2)*2)$,粒子数量平均分配置入4F透明塑料管内(Boston, US),用外科缝线固定至支架内表面(图2),粒子条横断面方向根据癌栓侵犯范围而定,将携带粒子条的支架送入14F长鞘,推送至长鞘头端,在后前位及侧位X线透视下旋转长鞘,使粒子条紧贴于癌栓,在透视下释放支架。再次行IVC造影,造影提示IVC血液回流通畅、侧支静脉消失或明显减少为治疗结束的标准,后20mg呋塞米经导管注入,拔管结束手术。

1.2.3 随访及疗效评估 术后1d行SPECT/CT扫描明确放射性支架的位置及放射性分布。随访患者术后肝肾功能、血常规每2~3周1次,增强腹部CT/MRI每6~8周1次,评价标准采用mRECIST标准^[29],采用CTCAE(Common Terminology Criteria for Adverse Events)评估肝功能及血细胞水平变化。

水肿评分对术前及术后水肿程度进行评价,评分标准0~2分,下肢水肿情况:无症状0分,小腿水肿1分,大腿水肿2分,阴囊/外阴水肿情况:无症状0分,轻度1分,重度2分,总分记录以反映患者



①肝癌伴 IVCTT 治疗前(腹部增强 CT 静脉期);②肝癌伴 IVCTT 治疗后(腹部增强 CT 静脉期);③IVC 造影示血管闭塞,周围血管侧支形成;④支架植入后,IVC 造影示血流通畅,侧支消失;⑤术后 1 d SPECT 示放射性支架位置良好

图 2 肝癌伴 IVCTT 行 TACE 联合 IVC 放射性支架植入过程

水肿症状情况^[16]。

1.3 定义与统计

总体生存期是从患者手术日至患者死亡或至末次随访日期。连续变量用均值±标准差,分类变量用频率表示并采用卡方检验。总体生存期(overall survival, OS)用 Kaplan-Meier 及 log-rank 检验。 $P < 0.05$ 为差异有统计学意义,将单因素分析结果有统计学差异因素,进行多因素分析得出预后独立性因素。统计软件 SPSS 21.0(Chicago, IL)。

2 结果

2.1 基本资料

患者基本资料见表 1,倾向性评分匹配出 24 对患者,见表 2,患者基本资料差异无统计学意义,随访时间截止至 2015 年 7 月,期间,A 组患者行 TACE 术次数(2.4 ± 1.5)次,B 组(1.9 ± 1.4)次($P = 0.589$)。

2.2 安全性

术后无严重不良并发症发生,多数患者伴有短期

表 1 患者基本资料

参数	A 组(n=33)	B 组(n=28)	P 值
年龄/岁	53	51	0.363 ^a
性别(男/女)	27/6	25/3	0.488 ^b
肝硬化类型			
(HBV/HCV/其他)	22/2/9	21/2/5	0.582 ^b
肿瘤类型			
(结节型/多灶性或弥漫性)	4/29	4/24	1.000 ^b
肿瘤大小/cm(≥ 10 / <10)	13/20	13/15	0.613 ^b
IVC 梗阻程度			
(阻塞/狭窄)	12/21	11/17	0.511 ^b
AFP/(ng/ml)(≥ 400 / <400)	20/13	20/8	0.427 ^b
Child-Pugh 分级(A/B)	22/11	20/8	0.785 ^b
ECOG 评分(0/1/2)	10/20/3	6/17/5	0.557 ^b
转移(有/无)	15/18	20/8	0.068 ^b
治疗史(有/无)	22/11	14/14	0.205 ^b

的栓塞后综合征,包括发热(A 组 65.2%,B 组 63.2%, $P = 0.546$),呕吐(A 组 71.7%,B 组 73.7%, $P = 0.565$),上腹部疼痛(A 组 63.0%,B 组 57.9%, $P = 0.454$),采用内科对症,患者均在 3~5 d 内症状得到缓解。放射性支架植入后 6 个月的肝功能及血常规指标无

表 2 倾向性评分匹配后 24 对患者基本资料

特征	A 组(n=24)	B 组(n=24)	P 值
年龄/岁	52	50	0.490 ^a
性别(男/女)	21/3	21/3	1.000 ^b
肝硬化类型 (HBV/HCV/其他)	18/2/4	19/2/3	0.582 ^b
肿瘤形态 (结节形/多灶性或弥漫性)	3/21	3/21	1.000 ^b
肿瘤大小/cm(≥10/<10)	12/12	12/12	1.000 ^b
IVC 梗阻程度(阻塞/狭窄)	8/16	10/14	0.873 ^b
AFP(ng/ml) (≥400/<400)	15/9	16/8	1.000 ^b
Child-Pugh 分级(A/B)	15/9	18/6	0.534 ^b
ECOG 评分(0/1/2)	6/15/3	5/16/3	0.940 ^a
转移(有/无)	15/9	20/4	0.193 ^b
治疗史(有/无)	17/7	13/11	0.371 ^b

^a 独立样本 *t* 检验 ^b 卡方检验

3 级及以上不良反应(按照 CTCAE 标准),见表 3。

表 3 A 组患者术后 6 个月实验室检查

项目	术前($\bar{x}\pm s$)	术后 6 个月						P 值
		$\bar{x}\pm s$	毒副作用分级					
			0	1	2	3	4	
TB/($\mu\text{mol/L}$)	18.5 \pm 10.8	20.4 \pm 14.6	13	15	3	0	0	0.312
CB/($\mu\text{mol/L}$)	10.0 \pm 7.3	12.6 \pm 13.1	10	17	4	0	0	0.156
ALB/(g/L)	35.9 \pm 5.9	35.0 \pm 5.1	15	12	4	0	0	0.392
ALT/(U/L)	49.7 \pm 43.8	48.6 \pm 55.6	20	8	3	0	0	0.895
AST/(U/L)	69.1 \pm 58.8	71.5 \pm 83.0	16	12	3	0	0	0.823
PT/s	13.6 \pm 2.5	13.6 \pm 1.9	14	13	4	0	0	0.966
WBC/($10^9/\text{L}$)	5.5 \pm 2.5	5.4 \pm 2.3	19	9	3	0	0	0.706
PLT/($10^9/\text{L}$)	119.7 \pm 63.7	118.4 \pm 66.8	12	16	3	0	0	0.782

^a 对 A 组 30 例患者评价(其中 3 例在 6 个月内死亡),均采用配对 *t* 检验

2.3 疗效评估与生存期

A 组共植入 39 枚支架,B 组 35 枚裸支架。A 组植入 ^{125}I 粒子数为(33.6 \pm 8.2)粒、范围(18~60 粒),根据放射剂量分布软件(version 0.11,Shanghai Medical Radiation Research Institute)计算 A 组放射性支架剂量(74.3 \pm 3.1) Gy(范围 60.6~76.6 Gy)^[18-19,30]。支架植入后,IVC 平均直径 A 组为(20.1 \pm 2.3) mm,B 组(21.0 \pm 2.7) mm。A 组梗阻或狭窄段压差由术前(4.1 \pm 1.1) mmHg 降至(3.0 \pm 1.3) mmHg,B 组压差由术前(4.0 \pm 1.3) mmHg 降至(2.9 \pm 1.0) mmHg,A 组水肿评分由术前(4.3 \pm 1.0)分降至(0.4 \pm 0.5)分,B 组由术前(4.5 \pm 1.1)分降至(0.4 \pm 0.7)分(表 4),随访中 A 组和 B 组各有 1 例患者因支架再狭窄而出现再次水肿。

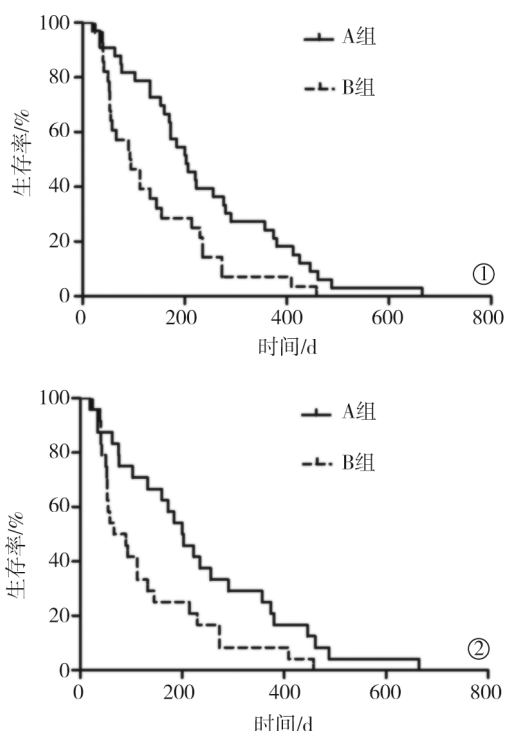
表 4 水肿症状评分

组别	术前	末次随访	P 值
A 组	4.3 \pm 1.0	0.4 \pm 0.5	<0.001
B 组	4.5 \pm 1.1	0.4 \pm 0.7	<0.001
P 值	0.873	0.280	

a: 独立样本 *t* 检验;b: 配对样本 *t* 检验

随访期间所有患者均死亡,肝内病灶客观肿瘤缓解率定义为完全缓解率(CR)+部分缓解率(PR),A 组为 24.2%(8/33),B 组为 21.4%(6/28)($P=0.520$),倾向性评分匹配后显示相似结果($P=0.500$)。

A 组总生存期是(203.0 \pm 28.1) d(95% *CI*,147.8~258.1 d),B 组是(93.0 \pm 24.3) d(95% *CI*,45.3~140.7 d)($P=0.006$),倾向性评分匹配后,A 组 200.0 \pm 31.2(95% *CI*,138.8~211.2),B 组 66.0 \pm 23.3(95% *CI*,20.4~111.6)($P=0.019$;图 3),单因素分析结果显示肿瘤大小,肝功能分级,组别,肿瘤客观缓解率及转移有统计学差异,进一步多因素结果显示放射性支架植入组及肿瘤客观缓解率是患者预后良好的独立性影响因素(表 5)。



①两组生存曲线;②为倾向性评分匹配后两组的生存曲线

图 3 两组生存曲线图

3 讨论

IVC 支架植入是 IVC 恶性梗阻的姑息性治疗方法,最近已有载有 ^{125}I 粒子放射性支架植入治疗腔内恶性梗阻的报道^[23-27], ^{125}I 粒子半衰期长、射程短的特点既能使其周围组织得到相对较高的放射剂量,又极少的造成肝脏损伤^[31-33],本研究对放射性支架组及裸支架组进行对照分析,结果显示,不良反应、水肿缓解率两组之间差异无统计学意义,放射性支架组生存时间明显延长于裸支架组,这可能归功于放射性支架的内放疗作用。

采用放射性支架治疗 IVCTT 的优势:①股静脉

表 5 患者预后的影响因素

参数	单因素分析			多因素分析		
	HR	95%CI	P 值	HR	95%CI	P 值
年龄(岁)(≥ 50 / <50)	1.226	0.600~2.506	0.576			
性别(男/女)	1.092	0.384~3.105	0.869			
肿瘤大小(cm)(≥ 10 / <10)	1.806	0.910~3.584	0.091			
肿瘤类型(多灶性或弥漫性/结节型)	3.132	1.184~8.287	0.021*	0.537	0.182~2.939	0.259
AFP(ng/ml)(≥ 400 / <400)	2.051	1.001~4.202	0.050			
Child-Pugh 分级(A/B)	0.295	0.141~0.615	0.001*	0.674	0.283~1.606	0.374
IVC 梗阻程度(阻塞/狭窄)	1.010	0.484~2.108	0.978			
ECOG 评分(0 and 1/2)	0.442	0.137~1.425	0.172			
治疗史(Yes/No)	0.772	0.574~1.039	0.087			
组别(放射性支架/裸支架)	0.296	0.147~0.596	0.001*	0.271	0.115~0.641	0.003*
肿瘤客观缓解率(CR+PR/SD+PD)	0.248	0.093~0.661	0.005*	0.275	0.087~0.871	0.028*
转移(有/无)	0.471	0.237~0.937	0.032*	0.906	0.279~2.939	0.869

* $P<0.05$ 为差异有统计学意义

入路,安全微创,放射性支架由 14 F 长鞘推至癌栓位置,使得 IVC 癌细胞得到充分的照射而凋亡。②支架植入术后血流的再通改善了 IVC 压迫症状,从而提高患者的生存质量。③放射性支架对血管的持续放射治疗作用可以预防血管内再狭窄从而延长支架通畅时间^[34]。

本研究所有患者均成功植入放射性支架,随访期间没有 ^{125}I 粒子条断裂,移位发生,粒子条相对位置根据下腔静脉癌栓侵犯范围而定,术后没有采用华法林抗凝治疗,原因是中晚期肝癌患者常常伴有凝血时间延长。

根据 Sindelar 等^[35]研究表明大静脉最大耐受剂量是 80 Gy,显然本研究中放射性支架组平均剂量为(74.3 \pm 3.1) Gy 是相对安全的,相较于 IVCTT 外照射剂量(36~45 Gy),癌栓得到更加充足的照射,且 A 组患者未见内放疗相关的不良反应。

本研究介绍了 TACE 联合放射性支架植入的介入新疗法治疗 HCC 伴 ICVT 患者,33 例患者从此方法中获益,显示了其安全有效的特点,但是本研究属单中心小样本回顾性分析,可能会影响部分研究结果。

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(收稿日期:2016-09-25)

(本文编辑:俞瑞纲)