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TACE 与手术治疗原发性大肝癌的临床疗效比较 *

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摘要 目的:比较经导管肝动脉化疗栓塞(transcatheter arterial chemoembolization, TACE)和手术治疗原发性大肝癌(肿瘤最大直径 ≥ 5 cm)的临床疗效和安全性。**方法:**回顾性分析 48 例经 TACE 或手术(Operation)治疗的原发性大肝癌患者,其中 TACE 组 25 例,Operation 组 23 例,治疗后随访 24 个月,评价和比较其治疗效果、生存曲线、镇痛剂的日平均用量及不良反应的发生情况。**结果:**治疗后 3 个月,TACE 组患者的 Karnofsky 评分($P=0.033$)显著高于 Operation 组,而血清甲胎蛋白(AFP)水平($P=0.022$)显著低于 Operation 组。此外,TACE 组的镇痛药杜冷丁的日均使用量显著低于 Operation 组($P=0.031$),便秘的日均发生次数($P=0.045$)显著少于 Operation 组。治疗后 24 个月,TACE 组和 Operation 组的生存率分别为 48.0 % 和 17.4 %,TACE 组显著高于 Operation 组($P=0.0415$, 95 % CI of ratio: 1.006 to 1.994)。**结论:**TACE 治疗原发性大肝癌的临床疗效可能优于手术治疗,且安全性高。

关键词:经导管肝动脉化疗栓塞;原发性大肝癌;手术;临床疗效

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Comparison of the Therapeutic Effect of TACE and Operation in the Treatment of Patients with Primary Large Hepatocellular Carcinoma*

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ABSTRACT Objective: To compare the therapeutic effect and safety of transcatheter arterial chemoembolization (TACE) and operation in the treatment of patients with large hepatocellular carcinoma (the maximum diameter of tumor ≥ 5 cm). **Methods:** 48 cases of large hepatocellular carcinoma were retrospectively investigated, in which 25 cases were treated with TACE, and 23 cases were treated with operation. After 24-month's follow-up, the effectiveness, survival curves, average daily dose of analgesics and side effects were compared between the two groups. **Results:** Three months after the treatment, the Karnofsky score of TACE group was significantly higher than that of the operation group ($P=0.033$), but the AFP level was obviously lower than that of the operation group ($P=0.022$). In addition, the daily dose of analgesic dolantin ($P=0.031$) and incidence of coprostasis ($P=0.045$) of TACE group were lower than those of the operation group. After 24-month's follow-up, the survival rates of TACE group and operation group were 48.0 % and 17.4 % respectively, and the survival rate of TACE group was significantly higher than that of the operation group ($P=0.0415$, 95 % CI of ratio: 1.006 to 1.994). **Conclusion:** The effectiveness and safety of TACE may be better than those of operation in the treatment of large hepatocellular carcinoma.

Key words: Transcatheter arterial chemoembolization(TACE); Primary Large hepatocellular carcinoma; Operation; Clinical efficacy

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前言

肝癌是我国最常见的恶性肿瘤之一,大多数肝癌患者确诊时已属晚期,且多伴有肝内或远处转移,给治疗带来极大困难^[1]。大肝癌(large hepatocellular carcinoma)是指癌肿最大直径 ≥ 5 cm 的肝癌^[2],有包膜或假包膜形成的大肝癌或巨大肝癌,其肿瘤生物学特性与小肝癌相同。经导管肝动脉化疗栓塞(transcatheterarterial chemoembolization, TACE)是目前治疗大肝癌的重要方法之一^[3],可延长患者的存活时间,提高其生活质量^[4]。但关于 TACE 与手术治疗大肝癌的疗效差异,目前尚缺乏系统

性的研究。本研究旨在比较 TACE 与手术治疗原发性大肝癌疗效,以期原发性大肝癌的临床治疗提供更多的参考依据。

1 资料与方法

1.1 临床资料

本研究患者来自宁夏医科大学总医院肝胆外科 2010 年 1 月至 2011 年 12 月收治的原发性大肝癌患者 48 例,分别接受 TACE 和手术(Operation)治疗,患者的一般情况如表 1 所示,两组的性别、年龄等比较均无统计学差异,具有可比性($P>0.05$)。纳入标准:①符合肝癌临床症状和体征,经 AFP、B 超、CT、

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MRI、肝血管造影和 / 或肝脏穿刺活检,明确诊断为肝癌;②最大瘤体直径 ≥ 5 cm; ③符合中国抗癌协会肝癌专业委员会标准;④无明显心肺等器官功能不全,可耐受手术或 TACE;⑤治疗前未接受抗癌治疗;⑥肿瘤未显著侵犯门静脉或下腔静脉;⑦根据国际抗癌联盟 (UICC) 标准,TNM 分期在 T2 以上;⑧Karnofsky 评分 ≥ 60 。排除标准:①不符合上述标准;②不愿进行 TACE 或手术治疗。

表 1 入组病例的一般情况比较

Table 1 Comparison of the baseline characteristics of all the patients

Characteristics	TACE (25 cases)	Operation (23 cases)	P
Sex			0.433
Male(%)	18(72.0 %)	16(70.0 %)	
Age(years)	60.3 $\pm$ 5.9	61.2 $\pm$ 6.1	0.532
HBsAg			0.345
-	3	3	
+	22	20	
AFP(μ g/L)	1120 $\pm$ 320	1250 $\pm$ 420	0.252
ALT(U)	105 $\pm$ 35	103 $\pm$ 28	0.354
AST(U)	88 $\pm$ 63	79 $\pm$ 47	0.221
Tumor Number			0.451
Single	8	6	
Multiple	17	17	
Tumor Size(cm)	8.2 $\pm$ 2.1	8.0 $\pm$ 2.9	0.332
γ -GT(U/L)	138 $\pm$ 45	142 $\pm$ 49	0.241
Ascites			0.461
Little	20	19	
Median	5	4	
Great	0	0	

1.2 治疗方法

手术前当天给予阿扎司琼 (盐酸阿扎司琼氯化钠注射液)、奥美拉唑、甘草酸单铵、甘草酸二胺、PAMA 等预防性止血处理。在数字减影血管造影(DSA)设备支持下,采用 Seldinger 技术穿刺右侧股动脉,选择性插管分别至腹腔干动脉及肠系膜上动脉,高压注射造影剂进行动脉造影,观察肝脏内病灶的供血状况,然后进行选择性或超选择插管至肿瘤供血动脉,经导管灌注吡喃阿霉素 40 mg~60 mg,丝裂霉素 6 mg~8 mg,再根据肿瘤的供血状况、患者肝功能、肿瘤的大小和位置等,选择越过正常肝脏组织的肿瘤供血动脉分支给予适量的碘化油结合明胶海绵进行栓塞,首次 TACE 后 6-8 周,视首次治疗效果,可重复治疗一次。手术组行术前常规检查,一般情况好,肝功 A 级或 B 级。经术前保肝治疗下行根治性肝切除,手术类型包括左外叶切除术、左外叶切除术+左内叶切除术、左半肝切除术、右半肝切除和肝中叶部分切除术。两组均于术前使用抗生素预防感染。

1.3 疗效评价

首次治疗后 3 个月,TACE 组死亡 1 例,存活 24 例,Operation 组死亡 3 例,存活 20 例。对存活病例进行 Karnofsky 评分,检测 AFP 含量,并记录日均杜冷丁使用量和便秘发生次数,使用视觉评分量表(visual analog scale, VAS)评价疼痛情况。治疗

开始后随访 24 个月,观察两组的生存率,绘制生存曲线。

1.4 统计学分析

试验病例一般情况的均衡性检验和疗效分析中,分类资料采用 χ^2 检验,连续性资料数值采用均数 $\pm$ 标准差表示 (Means $\pm$ SD),使用 t 检验,两组生存率的差异采用 Log-rank 检验,以 $P<0.05$ 为差异具有统计学意义。

2 结果

2.1 两组临床疗效的比较

治疗后 3 月,TACE 组的 Karnofsky 评分显著高于 Operation 组,表明 TACE 组病例治疗后的生活质量明显优于 Operation 组;TACE 组血清 AFP 水平显著低于 Operation 组,表明 TACE 组肝癌细胞残留量少于 Operation 组;TACE 组的镇痛药杜冷丁的日均使用量显著低于 Operation 组,表明 Operation 组由于手术或癌痛,疼痛程度比 TACE 组更明显,因此需要使用更多镇痛药物,见表 2。首次治疗 24 个月后随访观察,TACE 组存活 12 人,生存率为 48.0%,手术组存活 3 人,生存率为 17.4%,两组的生存率比较存在明显差异($P=0.0415$, 95% CI of ratio: 1.006 to 1.994),表明 TACE 治疗大肝癌的远期生存率显著高于常规手术切除,见图 1。

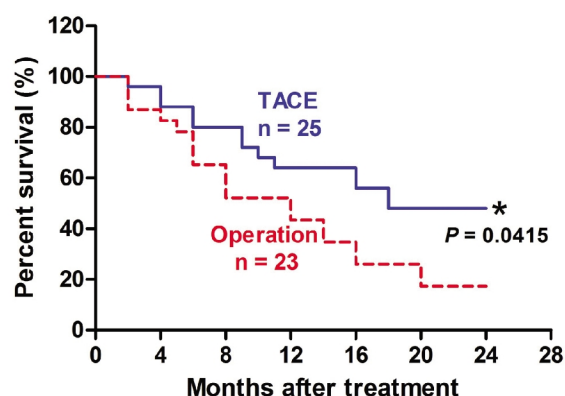


图 1 两组治疗后 24 个月的生存率比较

Fig. 1 Comparison of the survival rates between TACE group and operation group after 24-month follow-up

2.2 两组不良反应发生情况的比较

截止治疗后 3 个月,两组疼痛视觉评分(VAS)比较虽无统计学差异($P=0.432$),但 Operation 组便秘的发生次数却显著高于 TACE 组($P=0.045$),这可能是由于治疗后 3 个月内,Operation 组使用了更多的镇痛药杜冷丁所致。

表 2 首次治疗后 3 个月两组的临床疗效比较

Outcome	TACE (24 cases)	Operation (20 cases)	P value
Karnofsky	80.3 $\pm$ 5.1	75.5 $\pm$ 7.2	0.033*
AFP(μ g/L)	310 $\pm$ 128	560 $\pm$ 269	0.022*
Dolantin(mg/d)	25 $\pm$ 15	35 $\pm$ 20	0.031*
Coprostasis	4.2 $\pm$ 2.1	5.6 $\pm$ 3.4	0.045*
VAS	4.5 $\pm$ 2.1	4.8 $\pm$ 2.7	0.432

注:治疗后 3 个月,TACE 组死亡 1 例,Operation 组死亡 3 例;*:具有显著统计学差异。

Note: 3 months after treatment, 1 case died in the TACE group and 3 died in the operation group; *: significant difference.

3 讨论

肝癌是全球最常见的恶性肿瘤之一,发生率男性位居第5位,女性位居第7位,死亡率男性位居第2位,女性位居第6位。据世界卫生组织(WHO)2008年统计,全球每年新发病例748300例,死亡695900例,其中50%以上肝癌发生在中国,目前肝癌的5年生存率仅3~5%^[9]。肝细胞肝癌(hepatocellular carcinoma, HCC)是肝癌最主要的组织学类型^[6]。大肝癌是指瘤体最大直径 ≥ 5 cm的肝癌。手术一直是治疗肝癌的传统方法,但大肝癌的瘤体往往压迫、侵犯重要的管道系统,给手术增加难度^[7-9]。因此,在大肝癌切除术后早期采取有效的综合治疗手段,破坏或阻止肝内微小转移病灶的生长,是减少术后复发的关键环节。

在大肝癌治疗中,由于瘤灶体积大,肝脏需要广泛游离,尤其是靠近膈肌的巨大瘤灶。但在游离肝组织过程中,可能会发生肿瘤破裂、肿瘤肝内转移、肝脏血管破裂和肝组织破裂等并发症^[10],给治疗和恢复带来了较大困难。除手术外,TACE是目前治疗大肝癌的重要方法之一,其临床应用已超过30年,但在临床上,对其方案和作用的争议颇多。Lise等研究发现,与71例进行手术治疗的肝癌患者相比,TACE治疗的18例肝癌患者的复发率显著降低^[11]。据报道,TACE治疗肝癌的1、3和5年生存率分别为49.05%~71.9%、23.0%~62.5%和9.0%~17.0%^[12-15]。研究表明,TACE结合手术治疗大肝癌,1年、3年和5年生存率分别为88.2%、53.0%和36.1%。肝癌的分型、分期、肿瘤数量、解剖位置和基因差异等因素均可对肝癌的预后产生很大影响^[16,17]。

本研究的结果显示,与手术治疗相比,经TACE治疗的大肝癌患者治疗后3个月的Karnofsky评分显著提高、血清AFP水平明显下降,提示TACE治疗大肝癌的短期效果显著优于手术治疗。此外,经TACE治疗的大肝癌患者杜冷丁使用量和便秘发生次数,均显著少于手术治疗的肝癌患者,一方面可能由于患者未接受手术治疗,无需术后使用过多杜冷丁镇痛,另一方面,也可能由于TACE的治疗效果优于手术治疗,因此杜冷丁的用量也相对较少,患者发生便秘的次数也随之减少。治疗后,经24个月的随访,接受TACE治疗的大肝癌患者的生存率显著高于经手术治疗的肝癌患者,提示TACE治疗大肝癌的近期临床疗效优于手术治疗。分析其原因,一方面可能是本研究纳入的患者多为中晚期肝癌,或已发生肝内转移或远处转移,手术治疗已不占优势。刘辉等的研究也发现^[8],对于肿瘤直径大于5 cm及术后病理证实为低分化的患者,给予积极的TACE治疗可明显提高其近期生存率。另一方面,本研究是一项回顾性研究(retrospective study),并非严格的随机对照研究(randomized controlled trial, RCT),这也可能会对结果造成一定的偏向。

值得注意的是,虽然既往的研究发现TACE治疗肝癌可达10%~20%的完全缓解率,TACE联合其他治疗手段可治愈部分小肝癌,但TACE并不是治疗肝癌的完美手段^[9]。事实上,TACE本身并不能完全彻底地杀死所有癌细胞,且在治疗过程中可能会导致肝衰竭、肝血管损伤和胆囊炎等并发症^[20,21],如果梗阻区域不合理,或可致正常肝组织发生缺血坏死。因此,TACE治疗大肝癌的近期临床疗效可能优于手术治疗,但仍需密切关注和处理其伴发的各种不良反应。

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