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临床研究 CLINICAL RESEARCH

新辅助放化疗对中晚期食管鳞癌病理分期及预后的影响

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■背景资料
食管鳞癌新辅助放化疗能否延长患者的术后生存期众说纷纭, 本文选择可以外科治疗的食管鳞癌患者, 进行新辅助放化疗的前瞻性研究, 并探讨其对该类患者切除率、病理分期、并发症及术后1, 3和5 a生存率的影响.

Effects of neoadjuvant radiochemotherapy on pathological stage and prognosis of middle and advanced esophageal carcinoma

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Abstract

AIM: To evaluate the effects of neoadjuvant radiochemotherapy on the pathological stage and prognosis of middle and advanced esophageal carcinoma.

METHODS: Between January 1991 and December 2000, 473 patients with middle and advanced esophageal carcinoma were randomly divided into four groups; neoadjuvant radiotherapy (n = 118), neoadjuvant chemotherapy (n = 119), neoadjuvant radiochemotherapy (n = 118) and control (surgery alone) (n = 118). The differences in resection rates, pathological stage, treatment-related complications and survival rates were statistically analyzed.

RESULTS: The data showed that the radical resection rate for patients in the radiotherapy, chemotherapy and radiochemotherapy groups was increased compared with that of the control group (97.5%, 86.6% and 98.3% *vs* 73.7%, all $P < 0.01$). The pathological stages of the radiotherapy and radiochemotherapy groups were more significantly regressed than that of the control group ($P < 0.01$). The chemotherapy group did not show the same effect. Treatment-related complications of the three neoadjuvant groups showed no significant difference from that of the control group ($P > 0.05$). The 3-year survival rates of the radiotherapy and radiochemotherapy groups were significantly higher than that of the control group (69.5% and 73.7% *vs* 53.4%, both $P < 0.01$). The 5-yr survival rate of the radiochemotherapy group was higher than that of the radiotherapy group, but did not demonstrate statistical significance (45.0% *vs* 40.7%, $P > 0.05$).

CONCLUSION: The rational application of neoadjuvant radiochemotherapy appears to provide a modest survival benefit and to improve the quality of life for patients with middle and advanced esophageal carcinomas.

Key Words: Esophageal carcinoma; Neoadjuvant radiochemotherapy; Pathological stage; Prognosis

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摘要

目的: 评估新辅助放化疗对中晚期食管鳞癌病理分期及预后的影响.

方法: 1991-01/2000-12中晚期食管鳞癌患者473例, 随机分为4组, 新辅助放疗组(n = 118)、新辅助化疗组(n = 119)、新辅助放化疗组(n = 118)及对照组(单纯手术)(n = 118). 统计分析4组在切除率、病理分期、并发症、生

■研发前沿
本研究主要探讨新辅助放化疗对中晚期食管鳞癌病理分期及预后的影响, 为提高根治性切除率和延长这类患者的生存期提供了比较有价值的论据.

存期等方面的差别.

结果: 放疗组、化疗组、放化组与对照组相比均可提高根治性切除率(97.5%, 86.6%, 98.3% *vs* 73.7%, 均P<0.01); 放疗组、放化组与对照组相比有明显降期作用(P<0.01); 而化疗组没有明显降期作用. 放疗组、化疗组、放化组与对照组相比, 手术并发症无明显增加(P>0.05), 放疗组、放化组的3 a生存率相比对照组显著提高(69.5%, 73.7% *vs* 53.4%, 均P<0.01). 放化组的5 a生存率优于放疗组, 但无统计学意义(45.0% *vs* 40.7%, P>0.05).

结论: 合理应用新辅助放化疗可提高中晚期食管鳞癌患者生存期并提高其生存质量.

关键词: 食管肿瘤; 新辅助放化疗; 病理分期; 预后

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0 引言

食管鳞癌新辅助放化疗(neoadjuvant radiochemotherapy)是否能延长患者的术后生存期众说纷云[1-2], 我们通过前瞻性研究[3], 选择1991-01/2000-12收治的可以外科治疗的食管鳞癌患者1080例, 把其中愿意接受该项研究的473例临床分期属Ⅱb期或更晚的患者随机分为新辅助放疗组(放疗组)、新辅助化疗组(化疗组)和新辅助放化疗组(放化组)及对照组(单纯手术), 并比较各组的切除率、病理分期、并发症和术后1, 3和5 a生存率.

1 材料和方法

1.1 材料 Ⅱb期或更晚的食管鳞癌患者473例, 剔除非鳞癌患者, 随机分为放疗组、化疗组、放化组和对照组. 术前各组的一般情况相似(表1).

1.2 方法 放疗组采用瓦里安6MV医用电子直线加速器, 每次单次剂量2 Gy, 每周5次, 总量40 Gy. 化疗组采用PFM方案, 即丝裂霉素C(MMC)8-10 mg, iv, d 1; 顺铂(DDP)20-30 mg, iv, d 1-5; 5-氟尿嘧啶(5-FU)1000-1250 mg, iv, d 1-5. 放化组先采用化疗组的方案进行治疗, 待化疗结束后1-2 wk进行放疗, 放疗方案同放疗组. 临床反映评估一般于放疗结束后2 wk复查内镜、食管超声和CT. 评估参照WHO制订的标准, 分为临床症状完全缓解(ycCR), 部分缓解(ycPR), 缓解不明显(ycMR)和无变化(ycNC). CT作为常规的检查应用在每位患者的评估上, 由有经验的放射科专家负责评估肿瘤的长径和肿瘤侵犯管径的深度在新辅助放化疗前后的变化. 所有检查结果由主持实验的肿瘤学家收集和评估, 并由肿瘤外科, 内科以及放疗科组成的专家委员会讨论通过. 对照组患者接受综合评估后限期手术, 术式采用标准的经胸食管鳞癌切除术加二野淋巴结清扫, 消化道重建采取胃代食管, 胃拖入胸腔或颈部与食管残端吻合. 手术切除标本在24 h内用50 g/L甲醛固定, 整体标本制作成石蜡标本, 将石蜡标本切成5 μm的薄片并用HE或PAS染色, 供病理检查, 切片取材要求包含肿瘤所在的食管全壁, 吻合圈, 近端和远端切除组织以及所有检出的淋巴结. 所有的病理标本由两位有经验的病理学家参照UICC标准进行病理分期. 病理反应评估分为病理完全缓解(ypCR), 大部分缓解(ypSR), 部分缓解(ypPR), 缓解不明显(ypMR)和无病理变化(ypNC). ypCR的标准为病理检查中没有发现残留的有活力的肿瘤细胞; ypSR指有活力的肿瘤细胞所占百分比<10%; ypPR指有活力的肿瘤细胞占10%-50%; ypMR指有活力的肿瘤细胞占>50%, ypNC指没发现肿瘤细胞有任何消退的迹象.

统计学处理 应用SPSS10.0软件进行统计学分析, 采用卡方检验, 确切概率法和logrank法. P<0.05有统计学意义.

2 结果

本组中晚期食管鳞癌放疗组、化疗组、放化组的根治性切除率分别为97.5%、86.6%和98.3%, 与对照组(73.7%)相比均有显著统计学意义(χ^2_1 = 32.53, P_1<0.001; χ^2_2 = 6.90, P_2<0.01; χ^2_3 = 34.90, P_3<0.005). 放疗组、放化组术后病理分期中Ⅱa期的比例分别为50.8%, 54.2%, 与对照组(0%)比较有显著统计学意义(χ^2_1 = 80.45, P_1<0.005, χ^2_2 = 76.45, P_2<0.005)(表3). 放疗组、化疗组、放化组的临床完全缓解率分别为27.2%, 1.7%和33.89%, 放化组、放疗组与化疗组比较有显著统计学意义(P<0.05). 放疗组、化疗组、放化组的病理完全缓解率分别15.2%, 1.7%和22.3%(表2). 各组1 a生存率比较均无显著统计学意义(P>0.05), 3 a生存率比较, 放疗组(69.5%)与对照组(53.4%)相比有显著统计学意义(χ^2 = 13.32, P = 0.005); 化疗组为57.1%, 与对照组相比无显著统计学意义(χ^2 = 0.34, P>0.05); 放化组(73.7%)与对照组相比有显著统计学意义(χ^2 = 10.43,

■相关报道
食管鳞癌选用新辅助放化疗是否能提高切除率和延长生存期尚无定论. Hermann *et al*研究认为辅助放化疗可以降低肿瘤分期, 提高中晚期食管鳞癌的手术切除率. Schneider *et al*研究显示多种基因在新辅助治疗后的食管鳞癌切除标本中的表达水平大幅下降.

表 1 食管鳞癌患者3组术前一般情况比较(*n*)

分组	*n*	性别		年龄				病灶归段			
		男	女	40–49	50–59	60–69	≥70	颈段	胸上段	胸中段	胸下段
放疗	118	70	48	12	36	48	22	8	35	60	15
化疗	119	65	54	14	36	50	19	6	33	63	17
放化	118	60	58	15	40	42	21	5	28	61	24
对照	118	67	51	15	35	47	21	5	32	59	22
合计	473	262	201	56	147	187	83	19	128	243	78

■创新盘点
本文将中晚期食管鳞癌的大宗病例分组, 进行新辅助放化疗的对照研究, 其结论是: 合理应用新辅助放化疗可提高中晚期食管鳞癌患者生存期和生存质量, 是食管癌综合治疗中的一个重要手段.

P<0.005). 5 a生存率比较4组无显著统计学意义(*P*>0.05)(表3).

3 讨论

食管鳞癌应进行综合治疗以提高切除率和延长患者的术后生存期[4-7]. Hermann *et al*[8]研究认为辅助放化疗可以降低肿瘤分期, 提高中晚期食管鳞癌的手术切除率, 另有研究认为辅助放化疗可改善患者术后生活质量和延长生存期[9-12], 但同时有增加并发症和死亡率的危险[13-14]. 目前仍缺乏足够证据证明辅助放化疗可以提高食管鳞癌术后5 a生存率[15-16]. 本研究显示术前放疗和同时进行的放化疗能显著降低食管鳞癌的临床病理分期, 并能显著提高Ⅱb期及更晚期患者的根治性切除率; 化疗虽能提高手术切除率, 但降低手术病理分期的作用有限(*P*>0.05). 新辅助放疗组和新辅助放化组都可有效提高食管鳞癌患者的临床和病理完全缓解率, 而化疗组则无明显作用. 放化组在临床和病理缓解率上虽均高于放疗组, 但无显著统计学意义(χ^2 = 3.21, *P*>0.05). 分析术后1, 3和5 a生存率, 说明术前放疗和放化疗组能显著提高食管鳞癌患者术后3 a生存率, 但均不能提高5 a生存率.

本研究说明中晚期食管鳞癌单纯外科治疗已经不能再提高手术切除率和生存期, 合理应用综合治疗方法如辅助放化疗可以增加手术切除率和疗效[17-18]. 但应注意到影响辅助放化疗的疗效的因素是十分复杂的, 比如患者的全身情况、新辅助治疗的方法以及手术相关因素等等[19-21]. 如食管鳞癌患者与食管腺癌患者的转归与预后通常有明显差异, 鳞癌患者一般年龄较大且有烟酒等不良嗜好, 而腺癌患者则有可能出现心血管方面的危险[22-24]. 这些因素都可能影响治疗结果, 有时甚至是致命的. 同时, 术者的手术方式以及熟练程度对食管鳞癌的预后也有关联, 随着手术例数的增加和手术技术的提高, 食管鳞癌患者的手术死亡率以及并发症的发生率呈下降趋势[25-26]. 还应注意到, 只有部分食管鳞癌患者在新辅助治疗中得益[27-29]. 因此, 引发

表 2 食管鳞癌患者辅助治疗结果比较(*n*)

分组	*n*	临床评估				病理检查			
		ycCR	ycPR	ycMR	ycNC	ypCR	ypSR	ypMR	ypNC
放疗	118	32[a]	53	24	9	18	42	40	18
化疗	119	2	12	97	8	2	12	66	29
放化	118	33[a]	51	25	9	22	43	35	18
对照	118	0	0	0	118	0	0	0	118
合计	473	74	116	142	141	47	108	127	181

[a]*P*<0.05 *vs* 化疗.

表 3 食管鳞癌患者手术切除情况, 并发症, 术后病理分期和术后生存率比较

分组	*n*	切除情况*n*			病理分期*n*				手术并发症*n*					术后生存率*n*(%)		
		根治	姑息	探查	Ⅱa	Ⅱb	Ⅲ	Ⅳ	瘘	狭窄	出血	乳糜胸	死亡	1 a	3 a	5 a
放疗	118	115[b]	2	1	60[b]	16	41	1	1	1	1	0	1	104(88.1)	82(69.5)[b]	48(40.7)
化疗	119	103[b]	14	2	3	15	97	4	0	0	1	2	1	101(84.9)	68(57.1)	36(32.8)
放化	118	116[b]	2	0	64[b]	16	37	1	3	2	1	1	1	103(87.3)	87(73.7)[b]	53(45.0)
对照	118	87	25	6	0	6	103	4	1	1	2	1	1	105(89.0)	63(53.4)	37(31.4)
合计	473	423	41	9	127	53	278	10	5	4	5	4	4			

[b]*P*<0.01 *vs* 对照.

■应用要点
对中晚期食管鳞癌患者术前进行综合评估, 合理选用放疗或放化疗可提高该类患者的切除率, 降低肿瘤分期, 提高患者生存期和改善生存质量.

了一个关键性的问题, 在治疗之前如何区分这些可能的受益者而使其得到有效治疗, 而非受益者可免遭不必要的打击和减少治疗带来的高额费用? 在食管鳞癌的治疗中, 许多学者意识到, 患者是否在新辅助治疗中得益可能存在着基因表达的差异, 带有某种分子标志的人群可能对新辅助治疗敏感[30]. Schneider *et al*[31]研究显示多种基因在辅助放化疗后有改变, 如胸苷酸合成(TS), 二氢嘧啶脱氢酶(DPD), 错配切除修复蛋白1(ERCC1), 谷胱甘肽硫转移酶Pi(GST-Pi), 表皮生长因子受体(EGFR)以及HER2基因在新辅助治疗后的食管鳞癌切除标本中的表达水平大幅下降; Xi *et al*[32]研究表明, 行辅助放化疗的食管鳞癌患者术后标本环氧合酶-2(COX-2)蛋白高表达预示治疗反应差和预后不良, 但目前尚无确凿证据证明某些基因可以指导新辅助治疗. 总之, 本研究结果显示, 辅助放化疗作为一种新的治疗食管鳞癌的方法, 对提高其切除率, 降低肿瘤分期, 提高患者的生存期和改善生存质量都有积极的意义. 在肿瘤分子生物学研究突飞猛进的时代, 应当结合肿瘤的分子生物学特性, 遵照循证医学的原则, 有针对性地制定个体化的治疗方案, 更加“精确”地治疗每个食管鳞癌患者, 以最大化的提高疗效. 这将是未来食管鳞癌辅助放化疗研究的主要方向, 他必将给食管鳞癌患者带来真正的福音.

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■同行评价
本文采用大样本前瞻性研究的方法研究了新辅助放化疗对中晚期食管鳞癌的影响, 研究方法恰当, 内容丰富, 设计合理, 有较高的学术价值.

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