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奈达铂与紫杉醇联合同期放疗对中晚期宫颈癌的临床疗效分析*

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摘要 目的:探讨紫杉醇-奈达铂联合同期放疗治疗中晚期宫颈癌的临床疗效。**方法:**选择2012年1月~2013年12月62例中晚期宫颈癌患者,随机分成观察组和对照组,各31例,两组患者均行盆腔三维适型放疗+腔内后装放疗,观察组在此基础上同时再行奈达铂、紫杉醇全身化疗。**结果:**两组近期疗效比较,差异具有统计学意义($P<0.05$)。两组患者不良反应主要表现为骨髓抑制和胃肠道反应。随访一年,两组患者一年生存率比较差异显著($P<0.05$)。**结论:**本研究采用放疗联合紫杉醇+奈达铂化疗治疗中晚期宫颈癌有效率高,耐受性好,值得临床推广应用。

关键词:奈达铂;紫杉醇;中晚期宫颈癌;同步放化疗

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Analysis of Clinical Efficacy of Nedaplatin, Paclitaxel combined with Concurrent Radiotherapy in Advanced Cervical Cancer*

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ABSTRACT Objective: To observe the clinical effect of paclitaxel-Nedaplatin combined with concurrent chemotherapy and radiotherapy on the treatment of advanced cervical cancer. **Methods:** 62 patients with advanced cervical cancer who were treated in our hospital from January 2012 to December 2013 were selected and randomly divided into the observation group and the control group, with 31 cases in each group. All patients underwent pelvic irradiation and intracavitary radiation therapy, and the patients in the observation group were treated with nedaplatin and paclitaxel chemotherapy. **Results:** The differences in short-time curative effect of two groups were statistically significant ($P<0.05$); The main adverse reactions of two groups were bone marrow and gastrointestinal system response; The differences in one-year survival rate of two groups after one-year follow-up were statistically significant ($P<0.05$). **Conclusion:** Nedaplatin-paclitaxel combined with concurrent radiotherapy is efficient and tolerant in the treatment of advanced cervical cancer, and it is worthy of clinical application.

Key words: Nedaplatin; Paclitaxel; Middle and advanced cervical cancer; Concurrent radiotherapy

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前言

宫颈癌是全球第三大妇科恶性肿瘤,每年全球新发病例高达52.9万,其中85%的新增病例出现在发展中国家,宫颈癌患者每年死亡病例超过27万^[1,2]。对于中晚期宫颈癌患者来讲,临床数据证实,单纯放疗的效果并不令人满意,25%~60%的患者在放疗后出现局部复发或远处转移。近几年来,化疗药物在中晚期宫颈癌治疗中的应用愈加广泛。临床上采用同期放化疗,进行中晚期宫颈癌治疗,取得了一些效果,受到临床医生和患者的广泛关注^[3,4]。我科2012年1月~2013年12月经本院病理检查确诊的31例中晚期宫颈癌患者采用奈达铂、紫杉醇联合同期放疗。另选择31例中晚期宫颈癌作为对照,单纯放疗。观察该同期放化疗对中晚期宫颈癌的治疗效果,同时观察药物的不良反应。

1 资料与方法

1.1 一般资料

研究对象为2012年1月~2013年12月经本院病理确诊的62例中晚期宫颈癌患者。年龄32~68岁,平均年龄(46.7±8.9)岁;根据宫颈癌(FIGO)分期:IIb期13例,IIIa期21例,IIIb期23例,IVa期5例;病理分型:腺癌24例,鳞癌36例,腺鳞癌2例;分化程度:低度分化19例,中度分化34例,重度分化9例。

1.2 治疗方法

两组患者均行盆腔三维适型放疗+腔内后装治疗,观察组在放疗同时行奈达铂、紫杉醇全身化疗,两组患者的治疗方法具体如下:

对照组:①盆腔外照射:采用6MV-X直线加速器进行盆腔

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外照射,5次/周,疗程5周,4周后直肠挡铅,总剂量为50 Gy。
 ② 腔内照射:盆腔外照射治疗4周后,开始采用192 Ir放射源进行腔内放疗,宫腔管与阴道双球交替进行,2次/周,每次剂量5 Gy,总剂量30 Gy。

观察组:在盆腔外照射与腔内放疗的基础上同时进行化疗。具体为:放疗过程中每周奈达铂(20 mg/m²)+紫杉醇(35 mg/m²)进行静脉输注,1次/周,治疗6周。

1.3 疗效评价指标

根据世界卫生组织(WHO)《实体瘤疗效评价标准》^[5,6]进行疗效评价,根据WHO制定的《抗癌药物常见毒副反应分级标准》评价不良反应及其毒副作用。

1.4 随访及生存情况评价

对所有患者通过电话和门诊等方式进行随访,随访频率为每两个月一次,末次随访时间为2015年6月。记录患者两组患者疾病无进展生存期(PFS)和总生存期(OS),计算其中位生存时间(MST)和生存率。

1.5 统计学分析

利用SPSS 15.0软件进行数据统计分析,其中计数资料采用 χ^2 检验,计量资料表示为($\bar{x} \pm s$),采用t检验。 $P < 0.05$ 表示数据比较差异显著。

2 结果

2.1 疗效比较

治疗结束后,3个月评价:观察组:CR:12例(38.7%)、PR:16例(51.6%)、SD:2例(6.5%)、PD:1例(3.2%),该组治疗有效率为90.3%(28/31),疾病控制率为96.8%(30/31);对照组:CR:5例(16.1%)、PR:12例(38.7%)、SD:11例(35.5%)、PD:3例(9.7%),该组治疗有效率为54.8%(17/31),疾病控制率为90.3%(28/31)。两组近期疗效比较,差异具有统计学意义($P < 0.05$);疾病控制情况比较,二者无明显差异。

观察组CR与SD分别为38.7%和6.5%,对照组CR与SD分别为16.1%和35.5%,两组比较差异显著($P < 0.05$),两组PR与PD比较无明显差异($P > 0.05$)。

2.2 不良反应比较

不良反应主要是骨髓抑制及胃肠道反应。恶心呕吐是发生率最高的不良反应,两组合计发生56例,发生率为90.3%(56/62)。对照组和观察组中性粒细胞减少发生率分别为54.8%(17/31)和83.9%(26/31),两组比较差异具有统计学意义($P < 0.05$);放射性直肠炎发生率分别为41.9%(13/31)和71.0%(22/31),两组比较差异具有统计学意义($P < 0.05$);血小板减少发生率分别为35.5%(11/31)和41.9%(13/31);贫血发生率分别为58.1%(18/31)和77.4%(24/31);恶心呕吐发生率分别为83.9%(26/31)和96.8%(30/31);放射性膀胱炎发生率分别为25.8%(8/31)和35.5%(11/31),两组血小板减少、贫血、恶心呕吐和放射性膀胱炎等发生率指标比较,差异均不显著($P > 0.05$)。本次研究中所有患者均未出现过敏反应和其他严重不良反应。

2.3 生存情况和复发转移情况分析

对两组患者进行治疗后随访的结果表明,随访一年,观察组患者生存率为100%(31/31),无复发转移病例;对照组患者

生存率为83.9%(26/31),复发转移率为16.1%(5/31),其中3例发生远处转移(骨转移2例,腹膜转移1例),1例发生复发,两组患者一年生存率比较差异显著($\chi^2 = 5.44, P = 0.020 < 0.05$)。

随访二年,观察组患者生存率为61.3%(19/31),复发转移率为38.7%(12/31),其中7例发生远处转移(骨转移4例,腹膜转移3例),5例发生复发;对照组患者生存率为41.9%(13/31),复发转移率为58.1%(18/31),其中11例发生远处转移(骨转移7例,腹膜转移4例),7例发生复发。两组患者两年生存率比较无显著差异($\chi^2 = 2.32, P = 0.127 > 0.05$)。

观察组患者无疾病进展生存期中位值为25.1个月,对照组无疾病进展生存期中位值为16.4个月,两者比较有明显差异。

3 讨论

目前体外照射联合腔内放疗是中晚期宫颈癌放疗的标准治疗方案,但在多种因素的影响和制约下,治疗失败率可达30%~40%。同期放化疗是中晚期宫颈癌及部分大肿块的早期宫颈癌患者的标准治疗方案,其优点有:缩短总治疗时间;提高局部肿瘤控制率并减少远处转移的危险。

临床有报道证实,采用以铂类药物为主的同期化疗,对放疗起到增敏作用,提高了放疗对肿瘤细胞的杀伤作用,并且对肿瘤细胞放疗后的修复作用有抑制作用,患者治疗后的局部肿瘤复发率和转移率均明显下降。另一方面,同期放化疗在杀伤肿瘤细胞的同时,也能杀灭放疗照射野之外的亚临床、微小转移病灶,疗效优于单纯放疗。放疗过程中,照射野内的肿瘤细胞通透性明显增加,提高了化疗药物进入肿瘤细胞的含量,增强了肿瘤细胞的杀灭程度。时海峰等^[7,8]对比了同期放化疗与单纯放疗对中晚期宫颈癌患者的应用效果,结果表明,采用同期放化疗的患者近期有效率高达83.9%,显著高于单纯放疗64.5%的近期有效率,两者在胃肠道反应、骨髓抑制等副作用发生率方面比较差异不显著。该研究证实了中晚期宫颈癌患者采用同期放化疗能够提高近期疗效,患者也能耐受其毒副反应。近年来,宫颈癌同期放化疗,已经成为中晚期宫颈癌推荐的一线治疗方案,但是顺铂的胃肠道副反应较重,找寻一种高效、低毒的化疗药物对临床工作有着很重要的意义。

奈达铂属于第二代铂类化疗药物,化学结构及抗癌机制与顺铂类似,对肿瘤细胞的DNA复制产生强烈的抑制作用,进而实现肿瘤细胞杀灭的作用^[9,10]。与顺铂比较,奈达铂溶出度可高出10倍,因此其化疗效果更佳,但对肾脏、神经系统、胃肠道等毒副作用较轻。靳红等^[11-13]对比了奈达铂和顺铂在宫颈癌中的应用效果,结果显示,奈达铂对宫颈癌细胞的杀灭能力明显强于顺铂,单纯使用奈达铂治疗宫颈癌的近期有效率为46%,明显好于单纯顺铂治疗的35%,同时奈达铂的不良反应发生率更低。

紫杉醇是一种植物类化疗药物。与放疗同期使用时具有显著的放疗增敏作用,能够使肿瘤细胞保持在细胞周期的G2/M期^[14,16]。另外,紫杉醇还能够促进乏氧细胞的再氧合,诱导肿瘤细胞凋亡,提高放疗疗效^[17]。王宁^[18-20]等人采用奈达铂+紫杉醇化疗联合同期放疗治疗中晚期宫颈癌,患者治疗有效率达63.8%,显著高于单纯放疗。

本研究中治疗结束3个月评价,观察组治疗有效率为90.3%,对照组治疗有效率为54.8%,近期疗效对比,差异具有

统计学意义 ($P < 0.05$); 观察组和对照组中性粒细胞减少发生率、放射性直肠炎发生率比较差异具有统计学意义 ($P < 0.05$)。血小板减少、贫血、恶心呕吐和放射性膀胱炎等发生率指标比较, 差异均不显著 ($P > 0.05$)。两组患者一年生存率比较差异显著 ($P < 0.05$), 两年生存率比较无显著差异 ($P > 0.05$)。观察组患者无疾病进展生存期中位值为 25.1 个月, 对照组无疾病进展生存期中位值为 16.4 个月, 两者比较有明显差异 ($P < 0.05$)。

综上, 本研究采用放疗联合紫杉醇 + 奈达铂化疗治疗中晚期宫颈癌有效率高, 耐受性好, 值得临床推广。鉴于本研究观察例数和时间有限, 对其远期疗效还需要进一步观察。

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