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奈达铂联合调强放疗对局部晚期鼻咽癌的疗效的作用分析 *

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摘要 目的:分析奈达铂联合强调放疗在局部晚期鼻咽癌患者中的疗效。**方法:**选择我院局部晚期鼻咽癌患者 87 例,随机分为两个组,分别是奈达铂组(A 组)和顺铂组(B 组),对两组患者接受治疗后的近期疗效、远期疗效以及毒性反应进行比较分析。**结果:**A、B 两组患者鼻咽原发灶完全缓解(CR)率分别为 91.8%、86.8%(P=0.632>0.05),颈部淋巴结转移灶的完全缓解(CR)率分别为 87.8%、84.2%(P=0.864>0.05),均不存在统计学显著性差异。A、B 两组患者 3 年的总生存率(OS)分别为:81.6%、78.9%,P=0.762;局部控制率(LC)分别为:93.9%、94.7%,P=0.890;两组患者 3 年的区域控制率(RC)分别为:98.0%、97.3%,P=0.849;两组患者 3 年的无远处转移生存率(DMFS) 分别为:79.6%、76.3%,P=0.724。A 组患者 Plt 下降发生率为 46.9% 显著高于 B 组发生率 34.2%(P<0.05),具有统计学显著性差异;A 组患者恶心呕吐的发生率 36.7% 显著低于 B 组患者的发生率 76.3%(P<0.05),具有统计学显著性差异;其余毒性反应的发生率均不存在统计学显著性差异(P>0.05)。**结论:**奈达铂联合强调放疗治疗局部晚期鼻咽癌的近期疗效与远期疗效与顺铂相当,但是奈达铂胃肠道不良反应发生率较顺铂低,血小板的降低程度比顺铂更加严重。

关键词:奈达铂;强调放疗;局部晚期鼻咽癌

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Effect Analysis of Nedaplatin Combined IMRT for Locally Advanced Nasopharyngeal Carcinoma*

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ABSTRACT Objective: To analyze the medical effect of intensified radiotherapy combined with nedaplatin on patients with locally advanced nasopharyngeal cancer. **Methods:** 87 cases with locally advanced nasopharyngeal cancer who were treated in our hospital were selected and randomly divided into two groups. Then the short term curative effect, long term curative effect, and toxic reactions of the patients in the two groups were observed and compared between two groups after treatment. **Results:** The Complete Re-mission (CR) rates of the nasopharyngeal primary lesion in the patients of Group A and B are respectively 91.8%, 86.8%(p=0.632>0.05); The Complete Remission (CR) rates of the metastases in the patients' cervical lymph nodes are respectively 87.8%, 4.2%(p= 0.864>0.05). All the rates indicate no evidently statistical difference. The Overall Survival (OS) rates within three years of the patients in Group A and Group B are respectively 81.6%, 78.9%, P=0.762; Local Controlling (LC) rates are respectively 93.9%, 94.7%, P=0.890. The Regional Controlling (RC) rates are respectively 98.0%, 97.3% P=0.849. Distance Metastasis Free Survival (DMFS) rates are respectively 79.6%, 76.3%, P=0.724. The Plt reduction rate of Group A is 46.9%, obviously higher than 34.2%, the reduction rate of Group B (P<0.05), which has great statistical difference. Occurrence rate of nausea and vomiting in Group A is 36.7%, obviously lower than 76.3%, the occurrence rate of nausea and vomiting in Group B(P<0.05), which has great statistical difference; the occurrence rates of toxic reaction have no big statistical difference (P>0.05). **Conclusion:** Nedaplatin combined with radiotherapy for locally advanced nasopharyngeal emphasize short-term efficacy and long-term efficacy with cisplatin quite, but nedaplatin incidence of gastrointestinal adverse reactions compared with cisplatin low platelet levels decreased more than cisplatin severe.

Key words: Nedaplatin; Emphasizes radiotherapy; Locally advanced nasopharyngeal carcinoma**Chinese Library Classification:** R739.63 **Document code:** A**Article ID:** 1673-6273(2014)06-1139-05

前言

鼻咽癌是起源于鼻咽上皮细胞的一种恶性肿瘤,由于鼻咽

处于较深位置,患者的早期症状不明显,同时由于鼻咽周围的解剖结构较为特殊,肿瘤细胞容易通过各种空隙侵润到周围重要的器官,在临床中大部分的患者在初次诊断时已经发展成

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为局部区域晚期肿瘤^[1-3]。本研究运用奈达铂联合调强放疗对局部晚期鼻咽癌的疗效进行分析,与传统用药顺铂进行比较,现报告如下:

1 资料与方法

1.1 临床资料

选择2008年1月~2010年1月来我院治疗的局部晚期鼻咽癌患者87例,其中男性患者54例,女性患者33例,年龄在28~76岁之间,平均年龄为50.3岁,按照随机数表将87例患者随机分为两个组,分别是奈达铂组(A组)和顺铂组(B组),其中A组患者49例,B组患者38例。入组患者标准为:①经病理确诊为鼻咽癌的患者,且为初治、并未发现癌细胞远处转移;②患者未接受过化疗、放疗、免疫治疗以及外科治疗;③按照我国2008年鼻咽癌分期为III、IVa期的患者;④患者一般状况良好,其功能状态(PS)的评分≤1;⑤患者肝肾功能均良好;⑥患者血常规正常:血小板计数(Plt)≥100×10⁹/L,白细胞计数(WBC)≥4×10⁹/L;⑦患者心电图检查未出现明显异常;⑧入组患者均不存在其他明确的化疗禁忌症。排除患者标准:①合并有严重的心、肝、肾等重要器官的并发症;②对奈达铂有过敏反应的患者;③在一个月之内接受过其他的抗肿瘤治疗的患者;④哺乳期的妇女以及孕妇。两组患者在年龄、性别、临床分期、病理类型等一般资料上不存在统计学显著性差异($p>0.05$),具有可比性。所有患者在入组前均签署了知情同意书,愿意配合本研究。

1.2 放疗方法

两组患者均采用相同的放疗方法和剂量,均采用6MV X线照射,均接受根治性外照射放疗,在患者的下颈部以及锁骨上的靶体积采用的是下颈前切野常规照射,在鼻咽以及上颈部靶体积采用的是7野IMRT技术进行照射。患者的头肩颈使用热塑膜固定,采取仰卧位,将CT模拟定位机由患者的头顶到患者锁骨下3cm处进行增强扫描,再在IMRT工作站的CT图像上面对靶体积进行逐层勾画。高危临床靶体积(CTV1):为鼻炎大体肿瘤体积(GTVnx)向前、两侧、上下各外扩约0.5~1.0cm,再向后外扩约0.3~0.5cm(扩张距离主要由肿瘤与脑干、脊髓等组织的距离以及肿瘤的累及情况决定)。低危临床靶体积(CTV2):为高危临床靶体积(CTV1)向前、两侧、上下各外扩约0.5~1.0cm,再向后外扩约0.3~0.5cm(扩张距离主要由肿瘤与脑干、脊髓等组织的距离以及肿瘤的累及情况决定),同时包括颈部阳性淋巴结(GTVnd)及其所在的淋巴引流区和需要进行预防性照射的阴性的淋巴引流区。通畅设置约5~7个野,其中鼻炎大体肿瘤体积(GTVnx)的总剂量70Gy/30f,颈部阳性淋巴结(GTVnd)的总剂量66Gy/30f,高危临床靶体积(CTV1)的总剂量60Gy/30f,低危临床靶体积(CTV2)的总剂量54Gy/30f,下颈预防照射使用的常规野衔接,其剂量50Gy/25f。

1.3 化疗方法

两组患者在放疗的同时均接受同期化疗,A组患者运用80mg/m²奈达铂化疗6~7个疗程,B组患者运用80mg/m²顺铂同样化疗6~7个疗程,在每次化疗前患者均接受了常规的5-羟基胺受体阻断剂进行止吐治疗。所有患者在放疗结束1月后或者运用顺铂后1月均对患者给予PF方案进行辅助化疗,辅助

化疗时间为3个周期。患者每次进行化疗前均需要复查患者的肝肾功能、血象、心肌酶等,复查无出现明显化疗禁忌症之后再继续下一个周期的化疗,每个疗程21天。

1.4 评价标准

按照世界卫生组织(WHO)评价标准,采用B超、纤维鼻咽镜或者间接鼻咽镜等,将化疗后患者分为CR(完全缓解)、PR(部分缓解)、NC(无效或者稳定)和PD(疾病进展)。系统毒性采用WHO提供的抗肿瘤药物毒性反应的分级标准进行,分别平均患者在每个疗程中出现的毒性反应等级,记录毒性反应。

1.5 随访

入组患者均随访3年(36个月),至2013年2月截止,87例患者均未失访,随访率为100%。

1.6 统计学处理

采用统计学软件SPSS 19.0对数据进行统计分析,计量资料采用($\bar{x}\pm s$)进行表示,进行t检验;计数资料采用百分比进行表示,进行 χ^2 检验;采用Kaplan-Meier生存曲线对患者的生存率、局部控制率进行分析; $P<0.05$ 作为具有统计学显著性差异。

2 结果

2.1 近期疗效比较

周期完成后对两组患者进行疗效评价,其近期疗效结果见表1,A、B两组患者鼻咽原发灶完全缓解(CR)率分别为91.8%、86.8%($P=0.632>0.05$),无统计学显著性差异;A、B两组患者颈部淋巴结转移灶的完全缓解(CR)率分别为87.8%、84.2%($P=0.864>0.05$),无统计学显著性差异。

表1 近期疗效比较

Table 1 Comparison of recent efficacy

Groups	n	CR	
		Primary site	Cervical lymph nodes
A	49	45	43
B	38	33	32
P		0.632	0.864

2.2 远期疗效比较

A组患者共死亡9例,出现了3例患者局部复发,1例患者出现淋巴结复发,10例患者出现远处转移;B组患者共死亡8例,出现了2例患者局部复发,1例患者出现淋巴结复发,9例患者出现远处转移。两组患者3年的总生存率(OS)分别为:81.6%、78.9%, $P=0.762$;两组患者3年的局部控制率(LC)分别为:93.9%、94.7%, $P=0.890$;两组患者3年的区域控制率(RC)分别为:98.0%、97.3%, $P=0.849$;两组患者3年的无远处转移生存率(DMFS)分别为:79.6%、76.3%, $P=0.724$ (见图1~4)。

2.3 毒性反应

在放疗、化疗期间两组患者毒性反应比较结果见表2,在两组患者中较常见的毒性反应主要有骨髓的抑制、口干、胃肠道的反应等。对各不良反应的比较结果可知,A组患者Plt下降发生率为46.9%显著高于B组发生率34.2%($P<0.05$),具有统计学显著性差异;A组患者恶心呕吐的发生率36.7%显著低于B组患者的发病率76.3%($P<0.05$),具有统计学显著性差异;其余毒性反应的发生率均不存在统计学显著性差异($P>0.05$)。

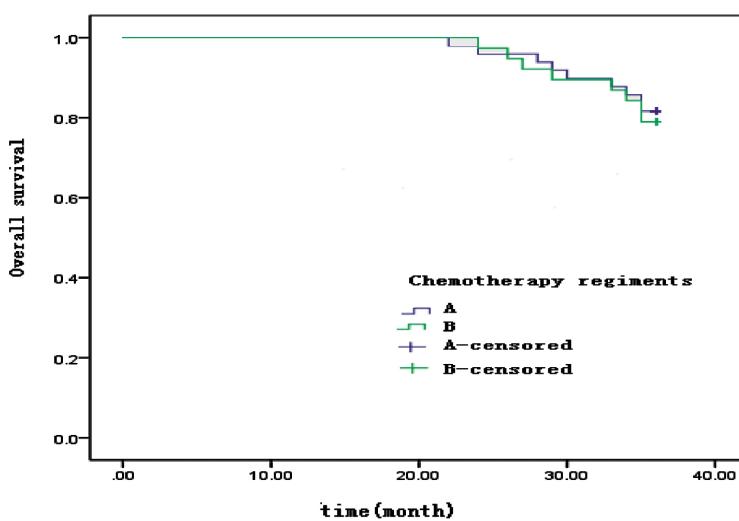


图1 化疗方案总生存率 Kaplan-Meier 生存曲线

Fig.1 Kaplan-Meier survival curve of overall survival according to chemotherapy regimens

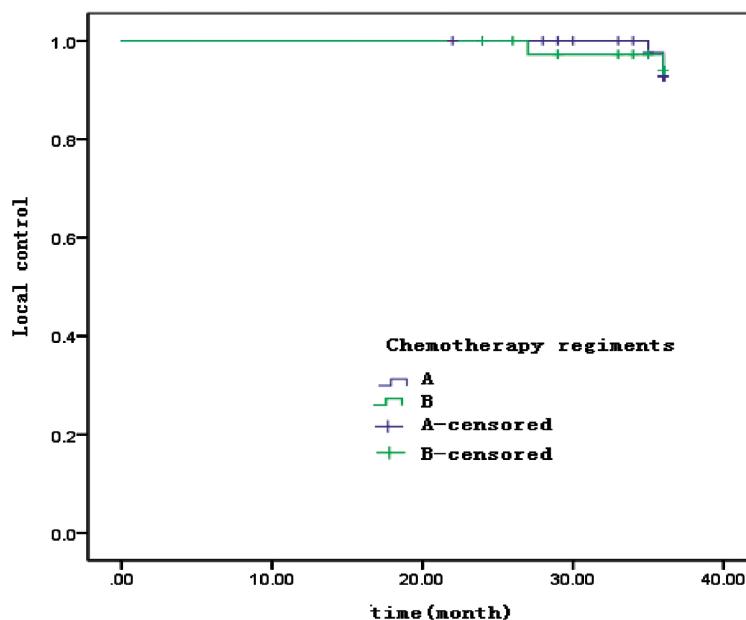


图2 化疗方案局部控制率 Kaplan-Meier 生存曲线

Fig.2 Kaplan-Meier survival curve of local control rate according to chemotherapy regimens

3 讨论

近年来,由于强调放疗(IMRT)技术能够实现高剂量运用于靶区域同时低剂量运用于周围正常组织,已经有越来越多的报道表明IMRT技术在鼻咽癌的治疗中已获得了较好的疗效^[4-6]。患者在接受鼻咽癌二维放射治疗之后口干是最常见的并发症之一,患者口干的程度主要与患者的唾液腺受照射的剂量和体积相关,鼻咽癌患者常规放射之后几乎100%的患者都发生了严重的口干,由于采用IMRT技术能够使腮腺受到照射的剂量和体积明显降低,因此接受IMRT的患者其口干的发生率明显降低,同时随着腮腺分泌功能的逐渐复原,患者的生活质量得到了极大的提高。近年来,有学者研究比较了传统放疗技术、三维适形放疗技术以及IMRT技术对鼻咽癌放疗的疗效比较,结果显示IMRT能够较好地区分正常组织以及周围的敏

感组织,在对局部晚期鼻咽癌患者的治疗当中显现出了更好的靶区包围,同时也提示出了鼻咽癌是IMRT运用的最佳的适应症之一^[7-10]。IMRT在治疗鼻咽癌时能够使其高剂量区的分布性状同患者病变的靶区相一致,在靶区域之外则迅速降低了照射剂量,从而达到提高对肿瘤组织的剂量而减少对正常组织的剂量,能够使得肿瘤的局部控制率得到显著地提高^[11]。

奈达铂是一种与顺铂相似的药物,是第二代有机铂类的抗肿瘤药物,其药物的作用机制为与水相结合能够产生出多种离子型的物质,该物质与DNA结合从而抑制了DNA的复制而发挥出抗癌活性,奈达铂的水溶性是顺铂的10倍,有研究表明奈达铂肾毒性以及胃肠道的不良反应发生率均比顺铂有着明显降低^[12-15]。临床研究表明,奈达铂对多种实体瘤均有着较好的效果,包括了头颈部的肿瘤、食管癌、非小细胞肺癌以及子宫颈癌等^[16-20]。

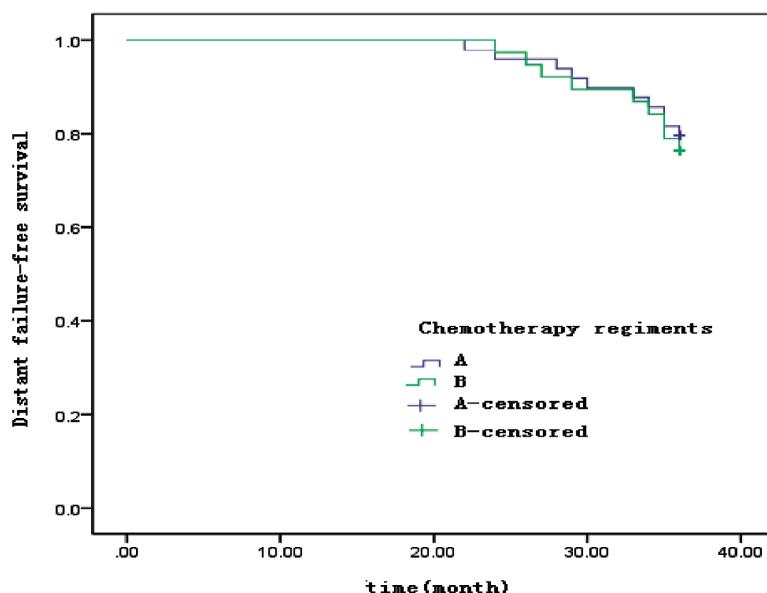


图3 化疗方案区域控制率 Kaplan-Meier 生存曲线

Fig.3 Kaplan-Meier survival curve of regional control rate according to chemotherapy

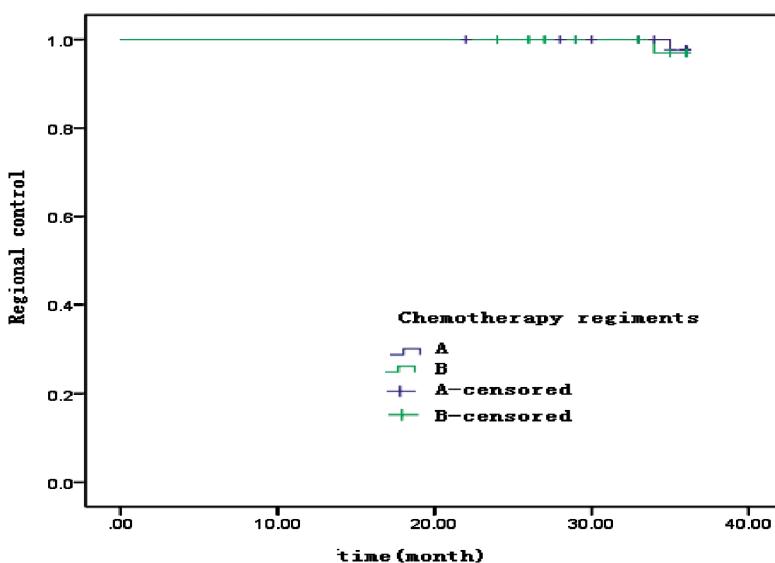


图4 化疗方案无远处转移生存率 Kaplan-Meier 生存曲线

Fig.4 Kaplan-Meier survival curve of distant failure-free survival according to chemotherapy regimens

表2 两组患者的毒性反应
Table 2 Toxic reaction of 2 groups patients

Toxicity	Group A					Group B				
	I	II	III	IV	Incidence	I	II	III	IV	Incidence
WBC decreased	3	7	9	1	40.8%	10	6	0	0	42.1%
Plt decreased	3	10	7	3	46.9%	2	8	3	0	34.2%*
Peripheral neurotoxicity	4	1	0	0	10.2%	3	1	1	0	13.2%
Nausea and vomiting	9	8	1	0	36.7%	5	9	10	5	76.3%*
Dry mouth	5	13	17	0	71.4%	6	22	0	0	73.7%
Radioactive mouth pharyngitis	23	15	11	0	100%	14	18	4	2	100%
Radioepidermitis	19	21	9	0	100%	9	16	10	3	100%
Liver damage	2	0	0	0	4.1%	2	0	0	0	5.3%

Note: Compared with group A * P < 0.05.

周蔚等^[2]研究表明奈达铂联合放疗对晚期鼻咽癌患者的近期治疗效果与顺铂相似,但是奈达铂使胃肠道的不良反应明显降低,而骨髓抑制却相对较重。这与本研究结果相似,本结果显示奈达铂联合强调放疗治疗局部晚期鼻咽癌患者同顺铂相比较,近期疗效显示:两组患者鼻咽原发灶完全缓解(CR)率分别为91.8%、86.8%(P=0.632>0.05),颈部淋巴结转移灶的完全缓解(CR)率分别为87.8%、84.2%(P=0.864>0.05),均不存在统计学显著性差异。远期疗效显示:两组患者3年的总生存率(OS)分别为:81.6%、78.9%,P=0.762;局部控制率(LC)分别为:93.9%、94.7%,P=0.890;两组患者3年的区域控制率(RC)分别为:98.0%、97.3%,P=0.849;两组患者3年的无远处转移生存率(DMFS)分别为:79.6%、76.3%,P=0.724。由结果可以看出,奈达铂和顺铂在近期疗效和远期疗效比较上无差异。而治疗中毒性反应比较结果为:A组患者Plt下降发生率为46.9%显著高于B组发生率34.2%(P<0.05),具有统计学显著性差异;A组患者恶心呕吐的发生率36.7%显著低于B组患者的发生率76.3%(P<0.05),具有统计学显著性差异;其余毒性反应的发生率均不存在统计学显著性差异(P>0.05)。表明了奈达铂发生胃肠道不良反应较顺铂低,而患者血小板的减少程度较顺铂更大。

综上所述,奈达铂联合强调放疗治疗局部晚期鼻咽癌的近期疗效与远期疗效与顺铂相当,但是奈达铂胃肠道不良反应发生率较顺铂低,血小板的降低程度比顺铂更加严重。

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