

# 壮药金回剂治疗宫颈上皮内瘤变、HPV 感染合并宫颈炎症的疗效分析

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**摘要** 目的 探讨壮药金回剂治疗宫颈上皮内瘤变、HPV 感染合并宫颈炎症的疗效。方法 将符合纳入标准的宫颈上皮内瘤变、HPV 感染合并宫颈炎症患者 随机分为 2 组,各 35 例。观察组 壮药金回剂宫颈上药 qod 对照组 安达芬栓宫颈上药 qod 比较两组临床疗效。结果 CIN<sub>1</sub> 观察组有效率为 89.29% 对照组为 65.38% 差异有显著性(P<0.05) 而 CIN<sub>2</sub> 差异无显著性。HPV 转阴 观察组转阴率为 68.57% 对照组为 45.71% 差异有显著性(P<0.05) 宫颈炎改善情况比较 观察组有效率为 94.29% 对照组为 77.14% 差异有显著性(P<0.05)。全部患者在治疗过程中均未发现需要注意的不良反应。结论 壮药金回剂治疗宫颈上皮内瘤变、HPV 感染合并宫颈炎症,可恢复宫颈屏障功能,HPV 转阴率高,疗效好。

**关键词** 宫颈上皮内瘤变; HPV 感染; 宫颈炎; 壮药金回剂; 疗效

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## Efficacy Analysis of Zhuang Medicine Jin-hui Mixture in Treating Cervical Intraepithelial Neoplasia HPV Infection Associated with Cervical Inflammation

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**ABSTRACT Objective:** To investigate the effect of Zhuang medicine Jin-hui mixture in treating cervical intraepithelial neoplasia, HPV infection with cervical inflammation. **Methods:** Patients who got cervical intraepithelial neoplasia and HPV infection associated with cervical inflammation, were divided into two groups randomly, 35 cases in each group. Observer group were treated with Zhuang medicine Jin-hui mixture on the cervix, qod. Control group were treated with Recombinant human Interferon  $\alpha$ -2b Suppository, on the cervix, qod. Compare the clinical efficacy between the two groups. **Results:** For CIN<sub>1</sub>, the efficiency was 89.29% in the observation group, and 65.38% in the control group, with significant difference (P<0.05); and for CIN<sub>2</sub>, there was no significant difference. There was a HPV negative rate of 68.57% in the observation group, and 45.71% in the control group; the difference was significant (P<0.05). In the observation group, 94.29% had cervicitis improved, but only 77.14% in the control group were improved, and the difference was significant (P<0.05). There were no adverse reactions that should be noted in the whole treating. **Conclusion:** Zhuang medicine Jin-hui mixture has good effect in treating cervical intraepithelial neoplasia, HPV infection associated with cervical inflammation. It could help restoring the function of the cervix.

**Key words:** Cervical intraepithelial neoplasia; HPV infection; Cervical inflammation; Zhuang medicine jin-hui mixture; Efficacy

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宫颈上皮内瘤变(CIN)发展可变成宫颈浸润癌,它反映宫颈癌发生发展中的连续过程。而 CIN 和宫颈癌的发病与人乳头瘤病毒(HPV)感染密切相关,持续的高危型 HPV 感染是 CIN 和宫癌发病的必要条件<sup>[1]</sup>。因此有效的预防和治疗生殖道 HPV 感染是切断宫颈癌前期病变发生有效方法,有研究表明高病毒载量可以增加患 CIN 的危险性,HPV16 的病毒载量可以用来

预测患宫颈癌的危险性<sup>[2]</sup>。我们自 2010 年 5 月到 2011 年 12 月用壮药金回剂治疗该病,并设立对照组进行观察和分析,疗效满意,现报道如下。

### 1 临床资料

#### 1.1 一般资料

入选病例均来自广西中医学院附属瑞康医院妇产科、皮肤科门诊就诊患者。年龄 16~50 岁,将入选病例分为两组。观察组 35 例,平均年龄(35.18±12.36)岁;对照组 35 例,平均年龄(33.67±10.29)岁。2 组患者临床资料及一般情况、孕次、产次及 CIN 分级无显著性差异。

#### 1.2 诊断标准

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参照《实用妇产科学》<sup>[3]</sup>及 TBS 诊断系统<sup>[4]</sup>。①已婚或有性生活的妇女,16-50 岁;②临床检查符合炎症、CIN 诊断标准并且 HPV 阳性者;③就诊前 2 月宫颈局部未接受物理治疗,前 2 周末进行药物及其他相关治疗;④PCR 或组织病理检查确诊;⑤患者本人同意接受治疗并按时随访,签署知情同意书。

### 1.3 排除标准

①合并严重的阴道炎、盆腔炎;②合并有高血压、糖尿病及严重心、肺、肝、肾、脑病变和血液、内分泌系统病变者及精神病患者;③妊娠期或哺乳期妇女;④对治疗药物过敏者。

## 2 治疗方法

观察组采用壮药金回合剂(铁包金、墓头回、飞龙掌血、桂莪术、大青叶、马齿苋、白芷)将上药共研成细末,过 120 目筛,钴 60 射线消毒灭菌后装瓶备用。于月经干净 3 天后开始来院治疗,用窥阴器暴露宫颈,用盐水棉球清洁阴道与宫颈内分泌物,用压舌板把药粉置入宫颈及阴道上端,有糜烂者先予注射器刺局部放血,以棉球擦净。至下次放药时清洗。对照组在经净 3 天后阴道上重组人干扰素  $\alpha$ -2b 栓(安达芬栓),隔日一次。10 次为 1 个疗程,2 个疗程后观察其白带情况及临床反应,每疗程结束后来院观察 1 次,停药 3 天后观察疗效。治疗期间要求禁性生活。

## 3 观测指标及疗效判定

### 3.1 观测指标

①观察患者赤白带下的减少情况、宫颈局部糜烂的好转情况;②所有病例根据 TCT 检测结果和病理组织学诊断判定 CIN 的疗效;③血、尿常规、肝、肾功能;④有无过敏情况。

### 3.2 疗效判定

3.2.1 CIN 的疗效判定标准 ①痊愈:宫颈液基细胞学及宫颈活体组织检查结果示非典型增生消失。②好转:宫颈液基细胞学及宫颈活体组织检查结果示非典型增生由 II 级变为 I 级。③无效:宫颈液基细胞学及宫颈活体组织检查结果示宫颈上皮细胞无变化,或病情进展。

3.2.2 HPV 转阴 ①HPV 测定为阴性;②HPV 测定为阳性。

3.2.3 宫颈糜烂疗效判定标准 参照《中药新药治疗宫颈糜烂的临床研究指导原则》进行疗效判定:①痊愈:糜烂面消失,宫颈变得光滑者;②显效:糜烂面较疗前缩小 2/3 以上者;③有效:糜烂面较疗前缩小 1/3 到 2/3 者;④无效:糜烂面较疗前缩小不足 1/3 或无明显变化者。

## 4 统计学处理

所有数据用 SPSS 13.0 软件进行统计分析,计数资料率比较,采用 Ridit 检验或采用  $X^2$  检验,  $P < 0.05$  为差异有显著性。

## 5 结果

### 5.1 两组 CIN 疗效比较

两组 CIN 比较,观察组痊愈率为 85.71%,对照组为 57.69%,差异有显著性( $X^2=5.277$ ,  $P=0.022$ ,  $P < 0.05$ );观察组有效率为 89.29%,对照组为 65.38%,差异有显著性( $X^2=4.456$ ,  $P=0.035$ ,  $P < 0.05$ )。CIN 比较,观察组痊愈率为 28.57%,对照组为 22.22%,差异无显著性( $X^2=0.085$ ,  $P=0.771$ ,  $P > 0.05$ );观察组有效率为 57.14%,对照组为 44.44%,差异无显著性( $X^2=0.254$ ,  $P=0.624$ ,  $P > 0.05$ )。

表 1 两组 CIN 疗效比较 (%)

Table 1 The efficacy comparison of two CIN groups (%)

组别 Group	分级 Classification	例数 Cases	痊愈 Recovered	好转 Improve	无效 Invalid	有效率 Efficient rate
观察组 Observation group	CIN	28	24(85.71)	1(3.57)	3(10.71)	89.29
对照组 Control group	CIN	26	15(57.69)	2(7.69)	9(34.62)	65.38
观察组 Observation group	CIN	7	2(28.57)	2(28.57)	3(42.86)	57.14
对照组 Control group	CIN	9	2(22.22)	2(22.22)	5(55.56)	44.44

### 5.2 两组 HPV 转阴疗效比较

( $x^2=5.757$ ,  $P=0.016$ ,  $P < 0.05$ );

观察组转阴率为 68.57%,对照组为 45.71%,差异有显著性

表 2 两组 HPV 转阴疗效比较 (%)

Table 2 The efficacy comparison of two groups' HPV negative (%)

组别 Group	转阴 Negative	无效 Nvalid	转阴率 Negative rate
观察组 Observation group	24	11	68.57
对照组 Control group	14	21	40.00

### 5.3 两组宫颈炎改善情况比较

观察组痊愈率为 28.57% ,对照组为 20.00% ,差异无显著性

( $\chi^2=0.699$   $P=0.403$   $P>0.05$ ) ;观察组有效率为 94.29% ,对照组为 77.14% ,差异有显著性( $\chi^2=4.200$   $P=0.040$   $P<0.05$ )。

表 3 两组宫颈炎改善情况比较(%  $n=35$ )

Table 3 Comparison of two groups of cervicitis improved (%  $n=35$ )

组别 Group	痊愈 Recovered	显效 Markedly	有效 Effective	无效 Invalid	有效率 Efficient rate
观察组 Observation group	10(28.57)	8(22.86)	15(42.86)	8(22.86)	94.29
对照组 Control group	7(20.00)	6(17.14)	14(40.00)	8(22.86)	77.14

## 6 讨论

宫颈炎症时宫颈局部的屏障功能下降 ,又增加了 HPV 的易感性 ,HPV 感染阳性率均随宫颈病变程度的加重<sup>[5-7]</sup> ,较多研究证实 HPV 在宫颈癌发病的过程中起到非常重要的作用<sup>[8-9]</sup>。而 HPV 病毒更容易破坏机体的免疫系统 ,使病毒持续存在。而增高近年 ,通过半定量的方法检测 HPV 16 DNA 载量发现 HPV 16 DNA 载量与宫颈原位癌呈正相关 ,即高水平 HPV 16 DNA 载量持续感染更容易发展为宫颈癌<sup>[10-12]</sup>。目前已分离出 100 余种 HPV DNA ,其中 40 多种与宫颈病变有关<sup>[13]</sup>。国外有学者认为<sup>[14-16]</sup> ,HPV 的亚型较多 ,亚型不同 ,对宫颈疾病的影响不同 ,HPV 多重感染者出现持续感染的危险性更大 ,而 HR-HPV 的持续感染虽不会促进宫颈病变的发展 ,但是宫颈病变发生的原因。而何桂蓉等<sup>[17]</sup>研究发现 HPV16 与 HPV 次要高危型感染是宫颈炎与宫颈癌前病变的主要诱因 ,高危型 HPV 病毒载量与宫颈癌前病变无明显相关性。这些均表明 HPV 感染与 CIN 有较大的关系。由于皮肤基底细胞中的 HPV 抗原性弱 ,使 HPV 病毒易逃避机体免疫系统的识别和清除 ,目前的抗病毒药还无法彻底清除 HPV 病毒。

壮医学认为 ,宫颈上皮内瘤变、HPV 感染合并宫颈炎症多由外感毒邪 ,龙路、火路失调 ,外邪凝聚肌肤而致。主要病理因素为毒邪秽浊 ,故祛毒 ,通调龙路、火路乃基本治法。壮药金回合剂中所含茵陈包金、墓头回、飞龙掌血、桂莪术、大青叶、马齿苋等均是广西特色壮药 ,在《中国壮药志》<sup>[18]</sup>、《壮医特色疗法》<sup>[19]</sup>、《实用壮医内科学》<sup>[20]</sup>等多部壮医药著作中收录。铁包金味苦、微涩 ,性平 ,具有解毒消肿、镇痛、除湿、通调火路功效 ,同时抗肿瘤作用明显 ,墓头回 ,性味苦、微酸、涩、凉 ,可清热解暑之功尤甚 ;飞龙掌血有散瘀、除湿、消肿解毒、通调火路之效。桂莪术性温味辛 ,活血化痰、能破瘀消痰、通调火路。大青叶清热解毒 ,现代研究表明有较好的抗病毒的作用 ;白芷生肌敛疮。诸药合用 ,祛湿解毒 ,改善局部环境 ,修复宫颈皮肤屏障功能 ,使之不利于病毒接种 ,对 CIN 也有较好的疗效。临床观察结果表明 ,壮药金回合剂治疗 CIN 、HPV 转阴及宫颈炎改善情况优于安达芬栓。但其作用机制有待进一步研究。

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