

Efficacy and Influencing Factors of Modified Ermiao Granules in Treating Cervical HR-HPV Infection

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Objective

To evaluate the therapeutic efficacy of Modified Ermiao Granules for high-risk human papillomavirus (HR-HPV) infection and analyze the factors influencing its curative effect.

Methods

A retrospective study was conducted on 416 patients with cervical HR-HPV infection who met the inclusion and exclusion criteria at Jiangsu Provincial Hospital of Traditional Chinese Medicine from February 2021 to February 2024. Among them, 316 cases in the experimental group received Modified Ermiao Granules, and 100 cases in the control group were administered conventional Western medicine. The Full Analysis Set (FAS) and Per-Protocol Set (PPS) were adopted for statistical analysis, with Logistic regression, Propensity Score Matching (PSM), and Inverse Probability of Treatment Weighting (IPTW) applied to control confounding factors.

Table 4 Sensitivity Analysis of Negative Conversion Rate: Absolute Values of SMD (FAS) for Each Covariate

Item	Statistic	P value	Point Estimate	95%CI
Majority value fills in the absolute value of SMD after PSM matching				
course of disease *	0.169	0.000	0.169	(0.169, 0.252)
History of cervical surgery	0.000	0.999	0.000	(-0.000, 0.000)
Should the HPV Vaccination Status be administered?	0.675	0.000	0.675	(0.675, 1.000)
Is pregnancy confirmed?	0.000	0.999	0.000	(-0.000, 0.000)
degree of cervical lesion*	0.120	0.000	0.120	(0.120, 0.240)
The absolute value of SMD after IPTW weighting using majority filling				
course of disease *	0.169	0.000	0.169	(0.169, 0.252)
History of cervical surgery	0.000	0.999	0.000	(-0.000, 0.000)
Should the HPV Vaccination Status be administered?	0.675	0.000	0.675	(0.675, 1.000)
Is pregnancy confirmed?	0.000	0.999	0.000	(-0.000, 0.000)
degree of cervical lesion*	0.120	0.000	0.120	(0.120, 0.240)

*: Baseline variables were imputed.

Table 5. Multivariate Analysis of Factors Associated with High-Risk HPV Clearance

Item	Outcome Type	Statistic	P value	Point Estimate	95%CI
HPV genotype	α-9 deny	3.2924	0.0696	1.615	(0.962, 2.709)
HPV genotype group (baseline)	Yes				
	No lesion				
Cervical lesion severity-baseline	HSIL	3.1288	0.0769	3.241	(0.881, 11.930)
	LSIL	0.1764	0.6745	1.111	(0.679, 1.817)
age stratification	>44 years old	0.0252	0.8739	1.140	(0.226, 5.746)
	Under 24 years old	0.9541	0.3287	1.283	(0.778, 2.117)

Table 3 This study systematically verified the impact of Modified Ermiao Granules and covariates on the HPV negative conversion rate via logistic regression analysis across three study populations: the full analysis set (FAS), the per-protocol set (PPS), and the propensity score matching set after mode imputation (PSM). Gajwei Ermiao Granules significantly improve the HPV seroconversion rate. The age range of 24 to 44 years and a baseline HSIL status were favorable influencing factors for HPV seroconversion, with consistent results observed in both FAS and PPS populations. The core conclusions are presented in the three tables above. Table 4 To control for the potential influence of confounding factors, two methods were employed to achieve inter-group balance: non-reciprocal propensity score matching (PSM) and propensity score-based inverse probability of treatment weighting (IPTW). Table 5 This Table presents the results of a multivariate analysis examining factors associated with the clearance of high-risk human papillomavirus (HPV) infection.

Results

The total HR-HPV negative conversion rate in the experimental group (70.25%) was significantly higher than that in the control group (31.00%, P<0.001) (Fig.1). Logistic regression analysis demonstrated that Modified Ermiao Granules was a significant favorable factor for HR-HPV negative conversion (OR=5.256, 95%CI:3.228-8.559, P<0.0001) (Tab.1). Subgroup analysis showed that the granule exhibited better efficacy in patients infected with specific HR-HPV subtypes, aged 24-44 years, or with baseline high-grade squamous intraepithelial lesion (HSIL) (Tab.1-2,5).

Figure 1 HR-HPV Negative Conversion Rates

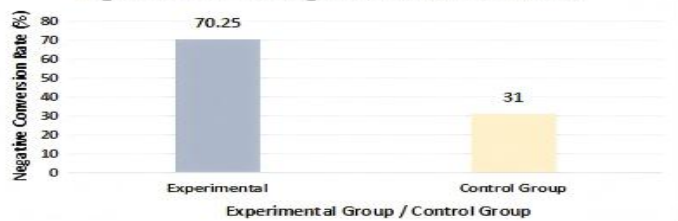


Figure 1 The negative conversion rate was 70.25% in the Experimental group receiving Modified Ermiao Granules versus 31.00% in the control group (P < 0.001), which is supported by logistic regression analyses identifying the intervention as a significant promoter of clearance

Conclusion

Modified Ermiao Granules exerts a significant effect in improving the HR-HPV negative conversion rate in patients with cervical HR-HPV infection and has a good safety profile. HR-HPV subtypes, age, and disease course are the key factors influencing the therapeutic effect of Modified Ermiao Granules.

Table 1 Negative conversion rate: Logistic analysis (FAS)

Item	Category	Outcome Type	Statistic	P value	Point Estimate	95%CI
All covariates were included in Model 1						
age stratification	Under 24 years old	24 to 44 years old	0.3779	0.5387	0.655	(0.169, 2.528)
	24 to 44 years old	>44 years old	-2.190	0.0400	1.532	(1.020, 2.301)
course of disease	Less than 1 year	More than 1 year	0.9195	0.8888	1.633	(0.682, 1.637)
Medical History	yes	no	0.0330	0.8559	1.039	(0.681, 1.578)
Concomitant Medication	yes	no	0.6089	0.4032	1.573	(0.544, 4.552)
HPV vaccination status	Yes or No/Missing	no	0.6814	0.4091	0.829	(0.530, 1.295)
Combination Therapy	yes	no	2.1639	0.1413	1.408	(0.893, 2.221)
Maternity and Pregnancy History	Is pregnancy confirmed?	yes	0.0003	0.9864	0.995	(0.550, 1.771)
	Whether vaginal delivery occurred?	Yes or No/Missing	0.8532	0.3557	1.222	(0.799, 1.868)
Maternity and Pregnancy History	Has there been a miscarriage?	yes	0.0531	0.8177	1.048	(0.704, 1.566)
Maternity and Pregnancy History	Whether vaginal delivery occurred?	Yes or No/Missing	0.9068	0.3435	0.974	(0.872, 1.155)
Maternity and Pregnancy History	Pregnancy (times)	yes	1.2176	0.2698	1.178	(0.801, 1.679)
History of cervical surgery	Production (times)	yes	0.0139	0.9061	0.971	(0.599, 1.574)
Cervical lesion severity-baseline	HSIL	No lesion	5.0167	0.0251	4.217	(1.197, 14.855)
Cervical lesion severity-baseline	LSIL	No lesion	0.8528	0.4873	1.190	(0.753, 1.881)
Cervical lesion severity-baseline	No lesion	No lesion	44.4883	0.0000	5.256	(3.228, 8.559)
Use of Modified Ermiao Granules	Yes or No/Missing	no				

Table 2 Negative conversion rate: Logistic analysis (PPS)

Item	Category	Outcome Type	Statistic	P value	Point Estimate	95%CI
All covariates were included in Model 1						
age stratification	Under 24 years old	24 to 44 years old	0.2830	0.5947	0.693	(0.179, 2.679)
	24 to 44 years old	>44 years old	-4.9218	0.0265	1.603	(1.057, 2.433)
course of disease	Less than 1 year	More than 1 year	0.0498	0.8233	1.054	(0.664, 1.673)
Medical History	yes	no	0.0255	0.8732	1.035	(0.675, 1.588)
Concomitant Medication	yes	no	0.2826	0.5950	1.345	(0.451, 4.013)
HPV vaccination status	Yes or No/Missing	no	0.7740	0.3790	0.811	(0.509, 1.293)
Combination Therapy	yes	no	1.8161	0.1778	1.382	(0.863, 2.212)
Maternity and Pregnancy History	Is pregnancy confirmed?	yes	0.0164	0.8980	0.962	(0.536, 1.737)
Maternity and Pregnancy History	Whether vaginal delivery occurred?	Yes or No/Missing	0.6667	0.4142	1.199	(0.776, 1.822)
Maternity and Pregnancy History	Has there been a miscarriage?	yes	0.0037	0.9167	1.049	(0.698, 1.579)
Maternity and Pregnancy History	Whether vaginal delivery occurred?	Yes or No/Missing	0.9072	0.3233	0.994	(0.869, 1.137)
Maternity and Pregnancy History	Pregnancy (times)	yes	1.2491	0.2637	1.182	(0.801, 1.655)
History of cervical surgery	Production (times)	yes	0.2394	0.6246	0.884	(0.539, 1.449)
Cervical lesion severity-baseline	HSIL	No lesion	5.1600	0.0230	4.321	(1.234, 15.265)
Cervical lesion severity-baseline	LSIL	No lesion	0.6628	0.4263	1.210	(0.766, 1.937)
Cervical lesion severity-baseline	No lesion	No lesion	42.9935	0.0000	5.184	(3.170, 8.479)
Use of Modified Ermiao Granules	Yes or No/Missing	no				

Table 3 Negative conversion rate: Logistic analysis (PSM)

Item	Category	Outcome Type	Statistic	P value	Point Estimate	95%CI
All covariates were included in Model 1						
age stratification	Under 24 years old	24 to 44 years old	0.8402	0.3593	0.503	(0.116, 2.188)
	24 to 44 years old	>44 years old	1.9469	0.1629	1.380	(0.878, 2.169)
course of disease	Less than 1 year	More than 1 year	0.1313	0.7171	1.097	(0.664, 1.813)
Medical History	yes	no	0.1324	0.7159	1.093	(0.678, 1.760)
Concomitant Medication	yes	no	0.0572	0.8110	1.149	(0.588, 5.093)
HPV vaccination status	Yes or No/Missing	no	0.1368	0.7115	1.115	(0.626, 2.066)
Combination Therapy	yes	no	1.6484	0.2083	1.290	(0.840, 2.080)
Maternity and Pregnancy History	Is pregnancy confirmed?	yes	0.0029	0.9571	1.018	(0.540, 1.917)
Maternity and Pregnancy History	Whether vaginal delivery occurred?	Yes or No/Missing	0.2541	0.6142	1.129	(0.784, 1.613)
Maternity and Pregnancy History	Has there been a miscarriage?	yes	0.0781	0.7912	1.062	(0.680, 1.658)
Maternity and Pregnancy History	Whether vaginal delivery occurred?	Yes or No/Missing	0.6087	0.2933	0.981	(0.850, 1.132)
Maternity and Pregnancy History	Pregnancy (times)	yes	0.9732	0.3229	1.174	(0.854, 1.614)
History of cervical surgery	Production (times)	yes	0.2185	0.6482	1.132	(0.672, 1.907)
Cervical lesion severity-baseline	HSIL	No lesion	2.3289	0.1270	2.798	(0.746, 10.451)
Cervical lesion severity-baseline	LSIL	No lesion	0.015	0.9263	1.179	(0.780, 1.865)
Cervical lesion severity-baseline	No lesion	No lesion	35.8458	0.0000	6.435	(3.125, 9.452)
Use of Modified Ermiao Granules	Yes or No/Missing	no				

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