

doi: 10.13241/j.cnki.pmb.2021.19.036

## 三种宫颈癌筛查方法的临床效果比较及筛查阳性者认知状况调查 \*

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**摘要 目的:**研究三种宫颈癌筛查方法的临床效果比较及筛查阳性者认知状况。**方法:**选取 2018 年 3 月~2019 年 12 月有阴道镜检查指征并完成阴道镜检查和宫颈活检的 287 例患者作为研究对象。对所有研究对象在阴道镜检查前均开展宫颈液基细胞学 (TCT) 检查、人乳头瘤病毒 - 脱氧核糖核酸 (HPV-DNA) 检查以及细胞 DNA 定量检查。以活检后病理检查结果为金标准, 分析上述三种宫颈癌筛查方式的灵敏度、特异度以及准确度。此外, 采用自拟的调查问卷的方式明确宫颈癌筛查阳性患者的认知状况。**结果:**以病理学结果为金标准, 宫颈上皮内瘤变 2(CIN2) 及以上为阳性, TCT 检查宫颈癌前病变的灵敏度、特异度以及准确度分别为 68.63% (35/51)、78.81% (186/236)、77.00% (221/287)。HPV-DNA 检查宫颈癌前病变的灵敏度、特异度以及准确度分别为 94.12% (48/51)、59.32% (140/236)、65.51% (188/287)。细胞 DNA 定量检查宫颈癌前病变的灵敏度、特异度以及准确度分别为 72.55 (37/51)、86.86% (205/236)、84.32% (242/287)。HPV-DNA 检查的灵敏度高于 TCT 检查和细胞 DNA 定量检查 ( $P < 0.05$ ), 细胞 DNA 定量检查的特异度及准确度均较 TCT 检查和 HPV-DNA 检查更高 ( $P < 0.05$ )。了解宫颈癌筛查的人数占比为 92.16%, 了解定期筛查宫颈癌的重要性人数占比 17.65%, 了解宫颈癌筛查方式人数占比为 9.80%, 了解 HPV 相关知识人数占比 0.00%, 了解宫颈癌筛查可早期检出病变人数占比为 15.69%。**结论:**HPV-DNA 检查应用于宫颈癌筛查中具有较高的灵敏度, 而细胞 DNA 定量检查具有较高的特异度以及准确度, 筛查阳性者的认知状况有待提高。

**关键词:**宫颈癌;筛查;宫颈液基细胞学检查;人乳头瘤病毒;细胞 DNA 定量检查

中图分类号:R737.33 文献标识码:A 文章编号:1673-6273(2021)19-3773-05

## Comparison of Clinical Effects of Three Screening Methods for Cervical Cancer and Investigation of Cognitive Status of Positive Screening Patients\*

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**ABSTRACT Objective:** To study the clinical effect comparison of three screening methods for cervical cancer and the cognitive status of positive screening patients. **Methods:** A total of 287 patients with indications for colposcopy and completed colposcopy and cervical biopsy from March 2018 to December 2019 were selected as the study subjects. Cervical thinprep cytologic test (TCT) examination, human papillomavirus-deoxyribonucleic acid (HPV-DNA) examination and quantitative cell DNA examination were performed for all subjects before colposcopy. Taking the pathological examination results after biopsy as the gold standard, the sensitivity, specificity and accuracy of the above three cervical cancer screening methods were. In addition, a self-designed questionnaire was used to determine the cognitive status of positive cervical cancer screening patients. **Results:** Using the pathological results as the gold standard, cervical intraepithelial neoplasia 2 (CIN2) and above were positive, the sensitivity, specificity and accuracy of TCT examination were 68.63% (35/51), 78.81% (186/236) and 77.00% (221/287), respectively. The sensitivity, specificity and accuracy of HPV-DNA examination in cervical precancerous lesions were 94.12% (48/51), 59.32% (140/236) and 65.51% (188/287), respectively. The sensitivity, specificity and accuracy of quantitative detection of cervical precancerous lesions by quantitative cell DNA examination were 72.55 (37/51), 86.86% (205/236) and 84.32% (242/287), respectively. The sensitivity of HPV-DNA examination was higher than that of TCT examination and quantitative cell DNA examination ( $P < 0.05$ ), and the specificity and accuracy of quantitative cell DNA examination were higher than that of TCT examination and HPV-DNA examination ( $P < 0.05$ ). The number of people who understanding cervical cancer screening accounted for 92.16%, the number of people who understanding the importance of regular cervical cancer screening accounted for 17.65%, the number of people who understanding cervical cancer screening methods accounted for 9.80%, the number of people who understanding HPV related knowledge accounted for 0.00%, and the number of people who understanding cervical cancer screening could detect lesions early accounted for 15.69%. **Conclusion:** The application of HPV-DNA examination in cervical cancer screening has a high sensitivity, while the quantitative cell DNA examination has a high specificity and accuracy, and the cognitive status of screening positive patients needs to be improved.

\* 基金项目:陕西省重点研发计划项目(2018SF-064)

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(收稿日期:2021-03-25 接受日期:2021-04-19)

**Key words:** Cervical cancer; Screening; Cervical thinprep cytologic test; Human papillomavirus; Quantitative cell DNA examination

**Chinese Library Classification(CLC): R737.33 Document code: A**

**Article ID: 1673-6273(2021)19-3773-05**

## 前言

宫颈癌属于临幊上较为常见的女性生殖系统恶性肿瘤之一，且随着人们生活方式的不断改变以及生活压力的日益提升，宫颈癌的发病率正呈逐年攀升趋势，已成为严重威胁女性生命健康安全的重大疾病之一<sup>[1-3]</sup>。相关研究报道表明，宫颈癌的发生、发展过程较为缓慢，正常而言从宫颈上皮内瘤变(CIN)进展至浸润癌需10~15年的时间，而这段时间是可干预以及阻断的时期，为临幊早期诊治宫颈癌提供了最佳时机<sup>[4-6]</sup>。宫颈癌筛查手段的日新月异，寻求一种积极有效的筛查手段显得尤为重要。目前，临幊上应用较为广泛的宫颈癌筛查手段包括宫颈液基细胞学(TCT)检查<sup>[7-9]</sup>、人乳头瘤病毒-脱氧核糖核酸(HPV-DNA)检查<sup>[10-12]</sup>以及细胞DNA定量检查<sup>[13-15]</sup>等，差异性筛查方式在宫颈癌筛查中的应用效果势必不同。此外，有研究报道发现<sup>[16]</sup>，女性对宫颈癌防控知识的掌握程度在一定程度上影响了宫颈癌的防治工作开展。鉴于此，本文通过研究三种宫颈癌筛查方法的临床效果比较及筛查阳性者认知状况，旨在为宫颈癌的早期筛查以及认知干预提供参考依据，现作以下报道。

## 1 对象与方法

### 1.1 一般资料

选取2018年3月~2019年12月有阴道镜检查指征并完成阴道镜检查和宫颈活检的287例患者作为研究对象。年龄26~64岁，平均( $47.25 \pm 8.34$ )岁；体质量指数(BMI)19~29 kg/m<sup>2</sup>，平均( $22.43 \pm 1.35$ )kg/m<sup>2</sup>；文化程度：初中及初中以下120例，高中或中专100例，大专及以上67例；产次0~4次，平均( $1.22 \pm 0.13$ )次；孕次0~7次，平均( $2.04 \pm 0.32$ )次。入组标准：(1)均于医院接受并完成阴道镜检查和宫颈活检；(2)入组前并未接受手术切除、化疗以及放疗等抗肿瘤治疗；(3)无临床病历资料缺失；(4)性生活无异常。剔除标准：(1)入组前7d内接受过抗生素治疗者；(2)既往有宫颈治疗史者；(3)伴有其它恶性肿瘤者；(4)妊娠期或哺乳期女性；(5)3d内接受过阴道清洗或应用阴道内药物干预者；(6)正参与其它研究者。入组人员均于同意书上签字，医院伦理委员会知悉并批准。

### 1.2 研究方法

所有研究对象进入阴道镜室，在阴道镜检查前完成宫颈毛

刷取材。(1)TCT检查：采用宫颈刷于受试者宫颈鳞状上皮交界部位顺时针旋转2~3圈，采集脱落细胞，并将此宫颈细胞和刷头均置入标本瓶内，以新柏氏全自动液基薄层细胞制片仪(ThinPrep 5000型)完成薄层液基细胞图片的制备，病理医生阅片，以Bethesda报告系统(TBS)诊断。阳性结果判定：低度鳞状上皮内病变(LSIL)及以上。(2)HPV-DNA检查：采用杂交捕获二代检测系统及其相应配套采样器获取受检者的宫颈细胞标本，将标本以及刷头同时放置于保存液内，借助上述检测系统对13种常见高危型HPV进行检测。(3)细胞DNA定量检查：采用宫颈刷于受试者宫颈鳞状上皮交界部位顺时针旋转2~3圈，采集脱落细胞，并将此宫颈细胞和刷头均置入标本瓶内。实验所用设备及试剂均购自麦克奥迪(厦门)医疗诊断系统有限公司。采用全自动细胞图像分析仪对上述制备完成后的玻片进行扫描，将同一玻片上的淋巴细胞核DNA含量视作正常2倍体对照细胞，确保对照细胞和分析细胞固定、染色的同时性，且在一致光照条件下完成测量。(4)采用自拟的调查问卷方式明确宫颈癌筛查阳性患者的认知状况：主要内容包括下述几点：①了解宫颈癌筛查；②了解定期筛查宫颈癌的重要性；③了解宫颈癌筛查方式；④了解HPV相关知识；⑤了解宫颈癌筛查可早期检出病变。

### 1.3 观察指标

以活检后病理检查结果为金标准，病理结果显示CIN2及以上即为阳性，分析三种宫颈癌筛查方式的灵敏度、特异度以及准确度。灵敏度=真阳性/(真阳性+假阴性)×100%；特异度=真阴性/(真阴性+假阳性)×100%；准确度=(真阳性+真阴性)/总人数×100%。

### 1.4 统计学处理

将SPSS 22.0软件作为数据处理工具，计数资料以%表示，三种检查方法的诊断价值比较采用确切概率法检验， $P < 0.05$ 为差异有统计学意义。

## 2 结果

### 2.1 TCT检查宫颈癌前病变的效果分析

TCT检查宫颈癌前病变的灵敏度、特异度以及准确度分别为68.63%(35/51)、78.81%(186/236)、77.00%(221/287)，见表1。

表1 TCT检查宫颈癌前病变的效果分析

Table 1 Effect analysis of TCT examination in cervical precancerous lesions

Pathological examination	n	TCT examination	
		Positive	Negative
Positive	51	35	16
Negative	236	50	186
Total	287	85	202

### 2.2 HPV-DNA检查宫颈癌前病变的效果分析

HPV-DNA检查宫颈癌前病变的灵敏度、特异度以及准确

度分别为94.12% (48/51)、59.32% (140/236)、65.51% (188/287)，见表2。

表 2 HPV-DNA 检查宫颈癌前病变的效果分析  
Table 2 Effect analysis of HPV-DNA examination in cervical precancerous lesions

Pathological examination	n	HPV-DNA examination	
		Positive	Negative
Positive	51	48	3
Negative	236	96	140
Total	287	144	143

### 2.3 细胞 DNA 定量检查宫颈癌前病变的效果分析

细胞 DNA 定量检查宫颈癌前病变的灵敏度、特异度以及

准确度分别为 72.55% (37/51)、86.86% (205/236)、84.32% (242/287)，见表 3。

表 3 细胞 DNA 定量检查宫颈癌前病变的效果分析  
Table 3 Effect analysis of quantitative cell DNA examination in cervical precancerous lesions

Pathological examination	n	Quantitative cell DNA examination	
		Positive	Negative
Positive	51	37	14
Negative	236	31	205
Total	287	68	219

### 2.4 三种检查方法的诊断价值比较

HPV-DNA 检查的灵敏度高于 TCT 检查和细胞 DNA 定量检查( $P<0.05$ )，细胞 DNA 定量检查的特异度及准确度均较

TCT 检查和 HPV-DNA 检查更高，且 TCT 检查的特异度及准确度较 HPV-DNA 检查更高( $P<0.05$ )，见表 4。

表 4 三种检查方法的诊断价值比较  
Table 4 Comparison of diagnostic value of three examination methods

Examination methods	Sensitivity	Specificity	Accuracy
TCT examination	68.63%	78.81%	77.00%
HPV-DNA examination	94.12%*	59.32%*	65.51%*
Quantitative cell DNA examination	72.55% <sup>a</sup>	86.86%* <sup>a</sup>	84.32%* <sup>a</sup>

Note: compared with TCT examination, \* $P<0.05$ ; compared with HPV-DNA examination, <sup>a</sup>  $P<0.05$ .

### 2.5 宫颈癌筛查阳性者认知状况

解宫颈癌筛查的人数占比为 92.16%，了解定期筛查宫颈癌的重要性人数占比为 17.65%，了解宫颈癌筛查方式人数占比为 9.80%，了解 HPV 相关知识人数占比为 0.00%，了解宫颈癌筛查可早期检出病变人数占比为 15.69%，见表 5。

## 3 讨论

迄今为止，有关宫颈癌的具体病因以及发病机制尚未完全阐明，目前普遍认为可能和遗传、基因突变以及 HPV 感染等密切相关，尤其是 HPV 感染和宫颈癌的发生、发展的关系已得到过多项研究报道证实<sup>[17-19]</sup>。HPV 感染多发生于年轻或(和)性生活相对活跃的女性人群，其中 80% 左右感染均是一过性，普遍会在 1 年内消失，若 HPV 长期存在，且和宫颈上皮细胞染色体整合，则会引起宫颈癌的发生，而这一过程相对漫长，若能对患者进行早期有效的筛查，可能有利于宫颈癌的防治<sup>[20-22]</sup>。巴氏涂片属于传统的宫颈癌筛查手段之一，但受多种因素的影响，该筛查方式的阳性率较低，临床应用局限性较大<sup>[23-25]</sup>。随着近年来医疗水平的日益发展，TCT、HPV-DNA 检查以及细胞 DNA 定

量检查等筛查手段应运而生，且在筛查宫颈癌中的价值均优于巴氏涂片<sup>[26-28]</sup>。然而，关于上述三种筛查手段的临床应用价值高低尚且存在一定的争议，具有一定的研究价值。

TCT 主要是通过液基薄层技术，有效清除了玻片上的异物，从而有助于医生更加清晰地观察细胞形态以及结构变化，同时防止了刮板之上大量细胞丢失，且该筛查方式操作简便，临床应用价值较高。HPV-DNA 检查主要是基于 HPV 感染和宫颈关系而开发的一种核酸探针杂交技术，且杂交捕获法是目前相对先进的检测手段，可有效检出患者的 HPV 感染情况，继而为宫颈癌的筛查提供可靠依据<sup>[29,30]</sup>。细胞 DNA 定量检查可从客观、精确的角度实现对细胞核 DNA 倍体值得测定，继而明确肿瘤生物学特征信息，且自动化分析在一定程度上避免了阅片医师主观因素的影响。本研究结果发现：三种筛查方式均有一定的应用效果，其中 HPV-DNA 检查具有灵敏度较高的特点，而细胞 DNA 定量检查具有特异度以及准确度较高的特点。然而，国内一项研究报道显示，HPV-DNA 检查应用于宫颈癌筛查中的灵敏度可能在 60~70%，特异度约为 80~95%，这和本研究结果存在明显的差异，考虑原因可能和下述几项有关：(1)

表 5 宫颈癌筛查阳性者认知状况  
Table 5 Cognitive status of positive cervical cancer screening patients

Survey content	n	Cases of correct cognition	Proportion
Understanding cervical cancer screening	51	47	92.16%
Understanding the importance of regular cervical cancer screening	51	9	17.65%
Understanding cervical cancer screening methods	51	5	9.80%
Understanding HPV related knowledge	51	0	0.00%
Understanding cervical cancer screening could detect lesions	51	8	15.69%

HPV 感染并非一定会导致细胞形态的异常改变，患者是否会展成宫颈癌仍受感染持续时长以及免疫状态等因素影响。(2) 两项研究纳入的患者 CIN 分级以及检查结果阳性判定标准不同。所以 HPV-DNA 检查存在一定的假阳性以及假阴性，分析原因可能和宫颈活检取材操作准确与否以及阅片医生主观性等因素有关。另外，细胞 DNA 定量检查亦存在一定的假阳性以及假阴性病理，究其原因，可能包括下述几个方面：(1)染色过程中的操作失误会引起细胞严重退变，DNA 分子结合了过多的染色剂即会出现假阳性；而酸化不全，化学键并未彻底打开，DNA 分子染色不理想，即会引起假阴性。(2)细胞 DNA 定量检查硬件以及软件系统出现某些问题，从而会导致误诊情况的发生。为了获得更加精准的调查数据以用于指导临床治疗，本研究还对专门对宫颈癌筛查阳性者进行调查，结果显示了解宫颈癌筛查的人数占比较高，为 92.16%，但是了解定期筛查宫颈癌的重要性、了解宫颈癌筛查方式、了解 HPV 相关知识、了解宫颈癌筛查可早期检出病变人数占比均较低，表明宫颈癌筛查阳性者的认知状况不容乐观，这也与临床实际基本相符，原因主要考虑与患者对疾病的认知能力较差以及疾病宣传力度相对较弱等因素有关。因此，在今后的工作中应加强对国内女性宫颈癌筛查相关知识的宣传普及，尤其是针对 HPV 相关知识的宣传力度需增加。

综上所述，三种筛查方式均有一定的应用效果，其中 HPV-DNA 检查具有灵敏度较高的特点，而细胞 DNA 定量检查具有特异度以及准确度较高的特点，临床实际工作中可能通过联合多项筛查，以提高宫颈癌的检出率，且需要加强关于女性宫颈癌筛查相关知识的宣教工作。

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