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Application of TruScreen in detecting ASCUS patients

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ABSTRACT

Objective: To explore the application of cervical cancer screening system, TruScreen in detecting atypical squamous cell of undetermined significance (ASCUS) patients. **Methods:** A total of 42 cases were selected, who were diagnosed as ASCUS by thinprep cytologic test (TCT). Area from site 15 to 20, site 21 to 32 were detected by TruScreen. And the result was compared with those of cases which had positive pathological result of cervical biopsy. **Results:** There were 16 cases with abnormal pathological result in ASCUS cases, including 6 cases with cervical intraepithelial neoplasia (CIN) Ⅰ, 6 cases with CIN Ⅱ, 3 cases with CIN Ⅲ and 1 case with infiltrating carcinoma. The consistency between TCT and pathological test was 38.10% (16/42). The positive rate of TruScreen at site 15-20 was 61.91% (26/42). There was significant difference in consistency with pathological test between TCT and TruScreen (x^2=4.762, P=0.029). The positive rate of TruScreen at site 21-32 was 66.67% (28/42)(Kappa=0.181, P=0.016). There was significant difference in consistency with pathological test between TCT and TruScreen (x^2=9.4919, P=0.002).And no case was missed when site 21-32 of patients with CIN Ⅱ and above were detected by TruScreen. **Conclusions:** TruScreen is effective in detecting ASCUS patients.

1. Introduction

Cervical cancer is a malignant tumor with the second highest incidence following breast cancer. The morbidity and mortality of cervical cancer in China account for 1/3 of the incidences in the world[1]. It is reported there is 459 000 new cases every year, most of which occurs in China (13 1500 cases, 28.7%)[2].

It takes 58 months for development of cervical intraepithelial neoplasia (CIN) Ⅰ to cancer in situ, and 38 months and 12 months for CIN Ⅱ and CIN Ⅲ, respectively[3]. And it takes about 10 years for precancerous lesion to develop into infiltrating carcinoma[4]. It is also reported that the incidence is 0.69%-6.20% 4.3%-13.3%, and 12.0%-65.0% for CIN Ⅰ, CIN Ⅱ and CIN Ⅲ to deterioate into cancer, respectively[5]. The five-year survival rate of cervial cancer patients with surgery at early stage is 80%-90%. So prompt and highly efficient screening is the key to decrease morbidity and to increase cure rate.

The sensitivity and specificity of liquid-based cytological test (TCT) are 73%-94%, and 58%-76%, respectively. It is reported 92.9% cases with squamous intraepithelial lesion (HSIL) and 100.0% squamous cell cancer (SCC) were diagnosed by TCT, compared with 77.8% and 90.9% by traditional smear[6-8].

Cervical cancer is closely related to high risk human papilloma virus(HR-HPV). It is reported HPV DNA was detected in 95%-100% patients[9], and cervical cancer is hardly found in patients with negative HPV[10]. Now hybrid capture (HC) Ⅱ is regarded as a method with high sensitivity and specifity. It shows highest sensitivity and highest negative preditive value in some research, and has high consistency to the result of hispathological test[11-15].

TruScreen is new real-time photoelectric screening method for cervical cancer. It has been approved in clinical application in Australia, and later gets the certification in Europe and Japan[16]. As cervical lesion occurs, epithelial cell nucleus enlarges, with increasing density and irregular shape, *etc*. These changes are collected by penetrating

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photoelectric wave, then analyzed by database. It is in time, convenient, rapid, and free of wound and pain.

TruSreen has been applied since 2007. It is reported by Singer, Zanardi, Itzkowic, Abdul *et al*[16-19] and researchers in China[20-23] that combination screening of TruScreen and cervical smear is of high sensitivity, specificity and consistency with pathological result.

2.Materials and methods

2.1. Subjects

A total of 42 cases, who were admitted from December 2010 to May 2011 and were diagnosed as atypical squamous cell of undetermined significance (ASCUS) by TCT, were selected. The age was 22-53 years old.

2.2. Cervical cancer screening syetem detection

Cervical cancer screening syetem (Polartechnics Lt.Co., Australian) was used according to manual. Handle controler with disposable inducer was placed into vaginal to probe at site 15-20 and site 21-32.

2.3. Pathological test

The tissues with abnormal result of cervical cancer screening system, TruScreen were selected for biopsy and normal tissues from sites 3, 6, 9 and 12 were also selected for pathological examination.

2.4. Statistic analysis

Kappa consistency test and x^2 test were carried out for statistic analysis.

3. Results

Pathological results showed 16 cases with positive result, including 6 cases with CIN Ⅰ, 6 cases with CIN Ⅱ, 3 cases with CIN Ⅲ and 1 case with infiltrating carcinoma. The consistency between TCT and pathological test was 38.10% (16/42). The positive rate of TruScreen at site 15-20 was 61.91% (26/42). There were 13 cases with positive result both of pathological test and TruScreen, including 4 cases with CIN Ⅰ, 5 cases with CIN Ⅱ, 3 cases with CIN Ⅲ and 1 case with infiltrating carcinoma. And there were 13 cases with negative result in two tests. Consistency test showed significant consistency between two tests (Kappa=0.279, P=0.043). There was significant difference in consistency with pathological test between TCT and TruScreen (x^2=4.762, P=0.029).

The consistency rate between TCT and pathological test was 38.10% (16/42). The positive rate of TruScreen at site 21-32 was 71.43% (30/42), and the consistency rate between TruScreen and pathological test was 66.67% (28/42). There were 16 cases with positive result both of pathological test and TruScreen, including 6 cases with CIN Ⅰ, 6 cases with CIN Ⅱ, 3 cases with CIN Ⅲ and 1 case with infiltrating carcinoma. And there were 12 cases with negative result in two tests. Consistency test showed significant consistency between two tests (Kappa=0.181, P=0.016) . There was significant difference in consistency with pathological test between TCT and TruScreen (x^2=9.419, P=0.002).

4. Discussion

ASCUS is a cell between normal squamous cell and abnormal cell, with higher cellular reactivity but not as high as cervical squamous intraepithelial neoplasia in quality and quantity[1]. Due to incomplete tissue morphology of smear, it is difficult to determine the existence of squamous intraepithelial neoplasia. ASCUS is a common type with low repetitiveness of test. Detection rate of invasive carcinoma of cervix and precancerous lesion are low in ASCUS patients[25].

Pathological positivity of ASCUS patients is 38.1% in this study, and incidence of patients with CIN Ⅱ and above is 62.5% (10/16). It indicates ASCUS need be paid more attention to. It is proposed that vaginoscopy is necessary for ASCUS patients[26]. Some proposed that repetitive cytological test should be performed[27], and some held the point that HPV should be tested firstly, and then vaginoscopy is used if the result is positive[28]. It is reported by Song *et al* positive rate of HR HPV DNA is 40%-51%, HR HPV DNA test can be performed by HC-2 method separate ill-free people and sick patients[25].

Zanardi et al conducted a study on 37 cases diagnosed as ASCUS by cytological test. The consistency between TruScreen and pathological test was 81%. They thought TruScreen can make effective screening on ASCUS patients or patients with unclear cyological result. We use Kappa consistency test to determine the consistency between TruScreen and pathological result, and it showed significant consistency (Kappa=0.279, P=0.043 for site 15-20, and Kappa=0.181, P=0.016 for site 21-32). It indicates that result of TruScreen is consisitent to pathological result, and TruScreen is helpful in screening ASCUS patients. Besides, no case with high CIN level was missed. It indicates that in contrast to HR HPV DNA test, TruScreen is more helpful in separation of ASCUS patients. Due to limited cases, the value of TruScreen need further investigation with larger cases.

Conflict of interest statement

We declare that we have no conflict of interest.

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