Risk Management and Healthcare Policy

Dovepress
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ORIGINAL RESEARCH

Assessment of the Real-Time Photoelectric Detection Device (TruScreen) in Screening for Cervical Precancerous Lesions in Middle-Aged Women: An Observational Study

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Objective: To evaluate the efficacy of a real-time photoelectric element (TruScreen) for identifying cervical precancerous lesions in middle-aged women.

Methods: We conducted a retrospective analysis of data collected from 100 women aged 25–55 years who underwent colposcopy at Beijing Obstetrics and Gynecology Hospital between June and July 2018. We obtained the results of the ThinPrep cytologic test/HPV tests and TruScreen tests conducted before colposcopy as well as the histopathological results from postoperative multi-site biopsies. Patients were divided into two groups based on histopathological findings: CIN II or higher, and CIN I. We analyzed the diagnostic efficacy of different testing methods, alone and in combination, for cervical precancerous lesions.

Results: TruScreen demonstrated good specificity (74.4%) and sensitivity (86.4%) for detecting CIN II or higher lesions, superior to those of TCT alone (sensitivity, 81.8%; specificity, 38.2%) and HPV testing alone (sensitivity, 81.8%; specificity, 28.2%). When different testing methods were combined, the sensitivity of TCT+HR-HPV, TruScreen+HR-HPV, and TruScreen+HR-HPV+TCT reached 100%, while the highest specificity was observed with TruScreen+HR-HPV (25.6%).

Conclusion: TruScreen showed high accuracy and specificity for screening cervical precancerous lesions in middle-aged women. The sensitivity and specificity can be improved when combined with HR-HPV test and TCT test. TruScreen has low sampling requirements for clinicians and does not require laboratory doctors or pathologists equipped with PCR equipment to verify. Given its minimal dependence on medical conditions, TruScreen can be considered a potential supplementary screening tool for cervical precancerous lesions.

Keywords: cervical precancerous lesion screening, truscreen, ThinPrep cytologic test, human papillomavirus DNA

Introduction

Cervical cancer is a malignant tumor with the fourth highest incidence and mortality rates among women, with approximately 660,000 cases and 350,000 deaths worldwide.[1] Cervical cancer is one of the cancers with definite etiology now. Moreover, it takes nearly ten years for cervical cancer to progress from precancerous lesions to invasive cancers. The survival rate of women diagnosed and treated early is nearly 100%; therefore, it is possible to prevent cervical cancer.[2] ThinPrep Cytologic test (TCT) and human papillomavirus (HPV) screening are commonly used screening methods for cervical cancer worldwide, but each method has its own defects.[3] TCT has high sensitivity and specificity, yet it is not only susceptible to subjective factors, such as the operator's proficiency and bias of reading smears, but also requires specific laboratory equipment. In addition, patients must wait a long time to obtain reported results. The specificity of HPV detection is very low. Detection of HPV infection does not necessarily represent invasive cervical

Received: 26 February 2025
Accepted: 27 May 2025
Published: 31 May 2025

cancer or precancerous cervical lesions. However, in clinical settings, patients with positive results undergo further examination, which leads to overtreatment and brings a heavy psychological burden to patients. There is a need for a better noninvasive test to screen patients for cervical precancerous lesions.

TruScreen (TS) is a new screening tool for cervical cancer. First, the TS touches the cervical surface gently with a special sensor. Light of four different wavelengths was used to irradiate the cervical tissue. These light waves can penetrate the surface layer of the cervix and reach the basal and stromal layers. Subsequently, the light signals were collected for calculation and analysis based on the distinct characteristics of light reflection, transmission, absorption, and scattering exhibited by different tissues. The above-mentioned outcomes will be analyzed and compared using large datasets, and finally, the diagnosis results will be obtained. TS is instant, convenient, fast, and painless and has been promoted in Australia, Europe, and several Asian countries.[4] In recently published clinical studies, TS was considered for further examination following Pap smear.[5] The combination of TS and HPV testing demonstrated good performance in diagnosing CIN2 or higher grades in patients with cervical cytology showing ASCUS/LSIL.[6] In the Chinese full-age study, TruScreen combined with HPV16/18 detection of CIN2+ shows high specificity and sensitivity and is considered to be used for rapid diagnosis of cervical lesions.[7]

High-grade squamous intraepithelial lesions typically occur in the squamocolumnar junction of the cervix. With increasing age, the squamocolumnar junction gradually receded into the cervical canal, making it difficult to observe. Unlike cervical lesion screening in elderly patients, the squamocolumnar transformation zone in middle-aged women is usually type I–II, which allows better utilization of optical detection instruments and avoids misdiagnosis caused by a narrow field of view.

In this retrospective study, we analyzed the data of 100 middle-aged women aged 25-55 years. We evaluated the diagnostic efficacy of TS alone and in combination with HPV and TCT for cervical intraepithelial neoplasia in middle-aged women.

Methods

Participants

This retrospective study included 100 women who attended the outpatient department of the Beijing Obstetrics and Gynecology Hospital, Capital Medical University, Beijing, China, between June 2018 and July 2018. The women who participated in the study ranged in age from 25 to 55 years with a mean age of 39 years. These selected cases were treated for various reasons such as contact bleeding and irregular vaginal bleeding. All patients underwent TCT, HPV DNA, and TS tests, and the final pathological results were considered to be the gold standard. Exclusion criteria for the study were as follows: 1) acute cervicitis; 2) sexual activity within 24 hours; 3) menstrual period, pregnancy, and within 4 months after birth; 4) taking a Pap smear, TCT, or HPV in the last 3 weeks; 5) history of total hysterectomy, cervical surgery, cervical biopsy within 3 months, and physical therapy within 6 months; 6) suffering from photosensitive diseases (such as porphyria or lupus erythematosus), undergoing experimental photodynamic therapy, or otherwise exposed to photosensitive drugs; 7) receiving radiotherapy in the pelvic area, receiving chemotherapy, or receiving chemotherapy in the past 5 weeks.

The data from this study were derived from clinical information obtained from patients after a normal clinical examination. We performed a retrospective analysis of anonymized information, which did not include further interventions for the patients; therefore, the need for patient consent was waived. This study was reviewed and approved by the Ethics Committee of Beijing Obstetrics and Gynecology Hospital (No.2018-QX-001-01) and complied with the Declaration of Helsinki.

TruScreen

According to the instructions in the training manual, professional operators use the TS to screen the cervix. All patients ensured that TS was performed at least 3 weeks after TCT or HPV testing. The detection process involves fully exposing the cervix with a vaginal speculum to ensure that no drugs can be used on the cervix before TS detection, and no lubricants (alcohol, iodine, lubricants, etc) other than normal saline can be used when using the speculum. Based on this optical principle, the operator uses a hand controller with a disposable sensor to detect various parts of the cervical

surface. After detection was completed, the test results were printed and replaced with new sensors. The test results are divided into:[1] "abnormal" indicates that there are abnormal cells in the cervix;[2] "normal" indicates that there are no abnormal cells in the cervix.

TCT

A special cervical collection brush was extended into the cervical canal and rotated clockwise five times, and the exfoliated cells were collected and placed in a small bottle containing a cell fixative solution. Cytology slides will be automatically produced and diagnosed by pathologists. Cytology adopts the classification standard recommended by the 2001 Bethesda System (TBS)[7], which can be divided into 1) negative for intraepithelial lesions or malignancy, 2) atypical squamous cells of undetermined significance (ASCUS), 3) atypical squamous cells, cannot exclude high-grade squamous intraepithelial lesion (ASC-H), 4) low-grade squamous intraepithelial lesion (LSIL), 5) high-grade squamous intraepithelial lesion (HSIL), 6) squamous carcinoma, 7) atypical glandular cells (AGC), 8) atypical glandular cells, favoring neoplastic cells, and 9) adenocarcinoma. Results higher than ASCUS (ASCUS+) or AGC (AGC+) were considered as positive.

HPV-DNA Test

A special sampling brush for cervical secretion was extended into the cervical canal until sufficient samples were obtained and then placed in a small bottle containing preservation solution. After hybridization and capture by professionals, the HPV DNA load is detected, and the HPV typing report of HPV concurrently. HPV DNA detection results were divided into HPV–, HPV 16/18+ (positive results for either type 16 or 18 without the 12 other types), and HR-HPV+ (positive results for 14 hR-HPVs without other low-risk HPV types).

Histological Analysis

For the patients with suspected cervical abnormalities in the colposcopic acetic acid and Lugol's iodine tests, biopsy was performed at the suspected lesions. For the patients without suspected cervical abnormalities, biopsies were taken from sites 3, 6, 9 and 12. Endocervical curettage (ECC) was performed in patients with a colposcopic squamous columnar junction (that) not fully exposed. Pathologists may review the patients' HPV and TCT test results if they deem it necessary for diagnosis. Histological results were diagnosed according to the World Health Organization (Fourth Edition 2014) pathological diagnostic criteria and defined as CIN I, CIN II, CIN III, and cancer. Cases lower than CIN I (including CIN I and CIN-) were considered negative, whereas those higher than CIN II (including CIN II and CIN II+) were positive.

Statistical Analysis

By comparing sensitivity, specificity, Youden index, positive likelihood ratio (+LR), negative likelihood ratio (-LR), positive predictive value (PPV), negative predictive value (NPV), plotting receiver operating characteristic (ROC) curve and analyzing area under curve (AUC), the performance of any single detection or joint detection method was assessed. For all statistical tests, a P-value less than 0.05 was considered significant. The data were analyzed using IBM SPSS Statistics 23 (SPSS, Chicago, IL, USA).

Results

The demographic and clinical characteristics of the 100 patients, including age, pathological results, and the results of the TCT, HPV, and TruScreen (TS) tests, are presented in Table 1. Cytological results were absent in two cases, and the HPV subtype in nine cases was unknown. The age range of the women included in the analysis was 25–55 years old, and the median age was 39 years. Among these, 22 cases were histologically confirmed as CIN2 + lesions, with a detection rate of CIN2 + was 22%.

The age range of CIN2 + women was 25–54 years old, with a median age of 41 years. Among the 65 cases with abnormal cervical cytology results was abnormal, despite 2 cases with missing results, the abnormal rate was 66.32%, and the numbers of AGC, ASC-US, LSIL, ASC-H, and HSIL were 2, 25, 29, 4, 5 respectively. The positivity rates of

Table 1 Clinical Baseline Characteristics

	Status	Number of Patients (n=100)
Age	Range	25–55
	≥39, n (%)	52; 52%
	< 39, n (%)	48; 48%
Histology	Benign	39
	CIN I	39
	CIN II+	22
TCT	Benign	33
	≥ASCUS/AGC	65
HPV	Normal	26
	HPV16/18 positive	31
	HR-HPV positive	74
TS	Normal	61
	Abnormal	39

high-risk HPV and the positive rate of HPV16/18+ were 74% and 31%, respectively. The positive detection rate for TS was 39%.

To evaluate the clinical accuracy of the different detection methods, we calculated the indicators related to TCT, HPV-DNA detection, and TS. (Table 2). The TS showed the highest sensitivity 86.4% and specificity (74.4%). The sensitivity of TCT is the same as that of HR-HPV, both are 81.8%, but TCT is more specific than HR-HPV, which suggests that compared to the HR-HPV, TCT is more correlated with high grade CIN in this study. TS also had the highest +LR (3.375) and optimal PPV (48.7), which proves that patients with TS are most likely to develop cervical cancer. Meanwhile, TS had the highest NPV (95.1 and the lowest (LR) of 0.182, so it can be concluded that TS has the best ability to exclude non-patients. There were no significant differences between indicators related to TCT and HR-HPV lagged the results, respectively. HPV16/18 had the lowest +LR of 0.682, indicating that this method is not suitable for clinical screening alone. The Youden index of TS was the highest, reaching 0.608, indicating that this screening method had the best effect and the greatest authenticity.

To develop a perfect method with both high specificity and high sensitivity, we also analyzed the screening effect of various joint detections in this study (summarized in Table 3). For TCT+HR-HPV, TS+HR-HPV+TCT, and TS+HR-HPV, all three joint methods achieved a sensitivity of 100%, yet their specificities were remarkably low at only 5.3%, 4.1%, and 25.6%, respectively. Among all the combined screening tests, TS+HPV had the highest Youden index of 0.39, indicating that this joint method is the best for determining the total ability of real patients and non-patients. It is worth mentioning that although the +LR and PPV of TCT+TS were inferior to those of TS+ HPV, which means that the true

Table 2 The Performance of Different Primary Screening Methods

		Number	CIN I	CIN II	Sensitivity (%)	Specificity (%)	Youden index	+LR	–LR	PPV (%)	NPV (%)	Asymptotic 95% Confidence Interval
TCT	–	33	29	4	81.8	38.2	0.2	1.323	0.476	22.7	87.9	0.481–0.735
	+	65	47	18								
HPV16/18	–	69	52	17	22.7	66.7	–	0.682	1.159	16.1	75.4	0.314–0.580
	+	31	26	5								
HR-HPV	–	26	22	4	81.8	28.2	0.1	1.139	0.645	24.3	84.6	0.415–0.679
	+	74	56	18								
TS	–	61	58	3	86.4	74.4	0.608	3.375	0.182	48.7	95.1	0.702–0.905
	+	39	20	19								

Table 3 The Performance of Different Joint Detection Method

		Number	CIN I	CIN II	Sensitivity (%)	Specificity (%)	Youden index	+LR	-LR	PPV (%)	NPV (%)	Asymptotic 95% Confidence Interval
TCT+HPV16/18	-	16	14	2	90.9	18.4	0.093	1.114	0.495	24.4	87.5	0.427–0.687
	+	82	62	20								
TCT+HR-HPV	-	4	4	0	100	5.3	0.053	1.056	-	23.4	100	0.407–0.670
	+	94	72	22								
TCT+TS	-	23	22	1	95.5	28.9	0.244	1.343	0.142	28.0	95.7	0.513–0.749
	+	75	54	21								
TS+HPV 16/18	-	44	41	3	86.4	52.6	0.39	1.823	0.259	33.9	93.2	0.580–0.810
	+	56	37	19								
TS+HR-HPV	-	20	20	0	100	25.6	0.256	1.344	-	27.5	100	0.489–0.729
	+	80	58	22								
TS+HR-HPV+TCT	-	3	3	0	100	4.1	0.041	1.042	-	23.2	100	0.400–0.664
	+	95	73	22								

Table 4 The Area of Different Joint Detection Method Under ROC Curve

	Area Under ROC Curve	Asymptotic 95% Confidence Interval	
		Lower Bound	Upper bound
TCT	0.6	0.481	0.735
TS	0.8	0.702	0.905
TS+HPV16/18	0.688	0.580	0.810
TS+HR-HPV	0.681	0.489	0.729

positive probability of this method was not as high as that of TS+HPV, it still had the lowest -LR of 0.142 and the second highest NPV of 95.7%.

For a more comprehensive and intuitive analysis, we calculated the area under the curve (AUC) (Table 4) for the first two methods with the highest Youden indices in single and combined screening. Compared with all kind of other methods, the single TS method had the maximum AUC of 0.8 (95% CI: 0.702–0.905). In addition, TS alone presented high rates of sensitivity, specificity, +LR, and PPV (86.4%, 74.4%, 3.375, and 48.7%, respectively), and the highest Youden index (0.507). The AUC of TS+HPV16/18+ (0.688) was the second highest, but its specificity, +LR, PPV, NPV, and Youden index were not as high as those of TS screening alone. TS+HR-HPV, whose Youden index and AUC ranked third, had 100% sensitivity and NPV, proving that this method is more closely related to pathological negativity.

Discussion

As one of the most common gynecological tumors, cervical cancer is seriously harmful to women's health. Cervical cancer has a long, reversible precancerous stage, indicating that it is a preventable and curable disease. Therefore, identifying effective screening methods to detect cervical precancerous lesions as early as possible and intervene and treat them can effectively reduce the incidence and mortality of cervical cancer.

Effective non-invasive detection of precancerous lesions is considered an effective means of reducing the incidence of cervical cancer, including advanced-stage cervical cancer, and efforts have mainly focused on improving the diagnostic accuracy of colposcopy images. Vega[8] demonstrated that hyperspectral colposcopy provides more information than conventional colposcopy does. Artificial intelligence (AI) has been used to diagnose colposcopy images. Ruiz[9] showed that AI-assisted colposcopy image diagnosis had a significantly higher accuracy than physician interpretation. Pešut et al[10] investigated the relationship between the expression levels of different proteins in cervical liquid-based cytology samples and the severity of precancerous cervical lesions.

At present, persistent infection with high-risk human papillomavirus (HR-HPV) accounts for 99.7% of cervical cancers, of which HPV 16 and HPV 18 are the two most dangerous genotypes.[11] Thus, we performed HPV16/18+ and

HR-HPV screenings in this study. The results showed that the sensitivity and specificity of HPV16/18 screening alone were 22.7% and 66.7%, respectively, and the Youden index was negative, proving that this method has poor reliability and cannot be used as a single clinical screening method. HR-HPV alone had a presentable sensitivity of 81.8%, and the sensitivity of TCT + HR-HPV and TS + HR-HPV reached 100%; however, the specificity of these methods was disappointing (28.2%, 5.3%, and 25.6%, respectively). This may be because most HPV infections can be eliminated by effective treatment and control.[12] Only 10% of the infected individuals will progress to CIN, and serious cases will further develop into invasive cancer, which will take approximately 10–15 years.[13] Therefore, this results in a high sensitivity of screening for HR-HPV, but the results include a large number of transiently infected individuals, which will increase unnecessary psychological pressure and follow-up treatment for these people, especially young women, HPV screening leads to the overdiagnosis of regressive CIN2.[14] Currently, TCT is another primary method of cervical cancer screening. We obtained results with a sensitivity of 81.8% and specificity of 38.2%, which is not in line with the high sensitivity and low specificity of TCT. To a large extent, TCT is likely to depend on the experience and technical level of examiners, is subjective, and lacks quality control, which leads to fluctuations in the sensitivity and specificity of TCT.[15] In addition, TCT has no unified and authoritative consensus on the treatment of atypical squamous cells with unknown significance (ASC-US), which makes it difficult for doctors to determine whether patients need further diagnosis, which will cause excessive medical treatment or delay the treatment time.[16] Compared with other single or combined screening methods, TS had the highest sensitivity (86.4%) and specificity (74.4%) in our study. From the ROC curve, the maximum AUC area of TS was 0.8, which proves that TS is more suitable for the clinical screening of cervical cancer. Yang et al's meta-analysis yielded TruScreen had a sensitivity of 76% (95% CI:73–80%), specificity of 69% (95% CI:67%–71%), and AUC of 0.7859, and concluded that the diagnostic accuracy of TS was moderate.[17] In addition, compared to TCT, TS can effectively screen patients with ASCUS. Zanardi et al studied 37 cases of ASCUS have been confirmed and found that the consistency between TS and pathological results was 81%.[18] Li et al studied 16 patients with ASCUS; the consistency between TCT and pathological results was only 38.1%, whereas that of TS was 66.67%. Meanwhile, the consistency test showed that there was significant consistency between the TCT and TS (Kappa = 0.181, P = 0.016).[19] In a study by Yang et al, TS served as a further examination for patients with abnormal liquid-based cytology results.[6] TS is a new screening technology for cervical cancer based on the photoelectric physiological basis of biological tissues, so it can report the detection results in real time, as it is noninvasive, fast, simple, and not affected by human factors, and is more suitable for promotion in areas with poor medical conditions. Long et al confirmed that TS is more suitable for use in areas where a Pap smear does not exist or where medical conditions are unreliable.[20] TS is not only limited by the medical site but is also hardly affected by subjective factors. In addition, it only requires the minimum training requirements for operators. In the study by Wang, TS was highlighted for its simplicity of operation, making it a suitable option for cervical cancer screening in HPV-positive patients during the COVID-19 pandemic.[7]

Currently, several novel technologies are gradually being applied in clinical practice for the identification of cervical precancerous lesions. Colposcopy-assisted recognition systems have been employed in the identification of colposcopy images to enhance the detection rate of cervical precancerous lesions by medical professionals.[21] In a meta-analysis, the sensitivity and specificity of artificial intelligence (AI)-assisted colposcopy detection both exceeded 80%.[22] However, other studies have suggested that the sensitivity and specificity of AI for identifying cervical intraepithelial neoplasia grade 2 or worse (CIN2+) are 42.9% and 46.7%, respectively.[23] This indicates that the recognition efficiency of current AI algorithms is not stable, with significant variations in the detection rates of CIN2+ across different datasets. Recently, various liquid biopsy methods have shown great promise as an easily accessible minimally invasive tool for early detection and disease monitoring.[24] Circulating tumor DNA (ctDNA) and gene methylation detection in blood have been applied in the detection of cervical precancerous lesions.[25] DNA methylation testing is gradually emerging as one of the triage methods for high-risk HPV infections.[26] In a meta-analysis, its sensitivity and specificity for CIN2+ were 0.68 and 0.75, respectively.[27] In cervical cancer detection, the overall pooled receiver operating characteristic (ROC) curve reached 0.770 (29). Currently, no studies have combined these methods, and more comprehensive observational studies using multiple methods in the same population are needed.

Since Truscreen requires manipulation on the cervical surface, it is more suitable for subjects with a clear transformation zone of the cervix. Middle-aged women are the most common group for cervical lesion screening and detection; therefore, we selected 100 middle-aged women as research subjects for this study. Among the currently recommended cervical lesion

screening methods, HPV screening has relatively low specificity for cervical lesions, and the results of TCT are dependent on the experience of pathologists. Truscreen can effectively provide objective visual information of the cervix and, when combined with other tests, can enhance the specificity and sensitivity of other examinations. Although Truscreen alone has high sensitivity and specificity, combining it with HPV or TCT testing can effectively avoid missed diagnoses, which is particularly important in the diagnosis and treatment of precancerous lesions. Further studies are needed to validate the effectiveness of combining different methods.

Limitations

This study has several limitations. Firstly, as a retrospective study lacking quality control, the data may have been influenced by recall bias. The study included a small number of middle-aged patients with suspected cervical lesions who underwent colposcopy and pathological biopsy within a 2-month period at our hospital. The limited sample size and short inclusion period necessitate validation through larger-scale studies. Furthermore, since all included patients underwent colposcopy, there is currently a lack of clinical observational studies on subjects with no significant abnormalities detected by HPV and TCT testing. Although TruScreen is easy to operate and involves multi-point sampling, it requires a certain training duration, and results may vary when used by different physicians.

Conclusion

In conclusion, our study demonstrated that TruScreen has relatively good diagnostic accuracy for cervical cancer screening. TruScreen is not only less constrained by the medical site but is also minimally affected by subjective factors. Additionally, it requires minimal training for operators. Therefore, TruScreen may serve as a supplementary method to existing cervical precancerous lesion screening approaches, particularly in settings with limited medical resources or under special circumstances when access to healthcare is restricted. However, further large-scale, prospective studies are needed to validate its real-world effectiveness.

Abbreviations

CIN, cervical intraepithelial neoplasia; TS, TruScreen; HPV, human papillomavirus; HR-HPV, high-risk human papillomavirus; TCT, ThinPrep cytologic test.

Ethical Approval

The study was conducted in accordance with the ethical standards of the Declaration of Helsinki and was approved by the ethics committees of Beijing Obstetrics and Gynecology Hospital, Capital Medical University (2018-QX-001-01). The ethics committee felt that this study exempted the patients from obtaining informed consent.

Acknowledgments

This study was funded by Beijing Siwei Xiangtai Technology Co., Ltd. The research team expresses its gratitude to Beijing Siwei Xiangtai Technology Co., Ltd for the financial support provided, but emphasizes that the sponsor had no influence on the scientific integrity and objectivity of the study results. All contributors have been mentioned in the text.

The principal investigator of this study, Wang Jd, declares that the costs for the use of instruments in this study were fully sponsored by Beijing Siwei Xiangtai Technology Co., Ltd. However, the company did not participate in the diagnosis or subsequent treatment of the subjects involved in this study. The collection, analysis, and interpretation of all study data were independently completed by the research team without interference from the sponsor. The presentation and interpretation of the study results are based entirely on the objectivity and independence of scientific research.

Author Contributions

All authors made a significant contribution to the work reported, whether in the conception, study design, execution, acquisition of data, analysis, and interpretation, or in all these areas, took part in drafting, revising, or critically reviewing the article; gave final approval of the version to be published; have agreed on the journal to which the article has been submitted; and agree to be accountable for all aspects of the work.

Disclosure

All authors declare that there are no conflicts of interest that could have influenced the design of the study, the collection of data, the analysis of data, the interpretation of results, or the writing and publication of this paper.

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