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Development and validation of novel digitalized cervicography system

Soo-Nyung Kim[1]*, Yun Hwan Kim[2]*, Kye-Hyun Nam[3], Seon-Kyung Lee[4], Tae Sung Lee[5], Ho-Sun Choi[6], Sei-Jun Han[7], Seung-Cheol Kim[2]; Korean Cervicography Research Group

Department of Obstetrics and Gynecology, [1]Konkuk University Hospital, Seoul; [2]Ewha Womans University Mokdong Hospital, Seoul; [3]Soonchunhyang University Hospital, Bucheon; [4]KyungHee University Medical Center, Seoul; [5]Daegu Catholic University Medical Center, Daegu; [6]Chonnam National University Hospital, Gwangju; [7]Chosun University Hospital, Gwangju, Korea

Objective
Digital cervicography systems would be expected to reduce the costs of film cervicography, and provide the opportunity for "telemedicine-based" screening. We aimed to develop web-based digital cervicography system, and validate it compared with conventional film cervicography.

Methods
A hundred cases from five centers were prospectively included, and cervical images (analogue, digitalized by scanning analogue, and digital) were taken separately using both analogue (Cerviscope) and digital camera (Dr. Cervicam) in each patient. Nine specialists evaluated the three kinds of images of each case with time interval between evaluations of each image. To validate novel digitalized system, we analyzed intra-observer variance among evaluation results of three kinds of images.

Results
Sixty-three cases were finally analyzed after excluding technically defective cases that cannot be evaluable on analogue images. The generalized kappa for analogue versus digital image was 0.83, for analogue versus scanned image 0.72, and for digital versus scanned image was 0.71; all were in excellent consensus.

Conclusion
Digitalized cervicography system can be substituted for the film cervicography very reliably, and can be used as a promising telemedicine tool for cervical cancer screening.

Keywords: Cervicography; Diagnosis; Digital; Telemedicine; Uterine cervical neoplasms

Introduction

Since the cervicography was developed by Stafle in 1981 [1], cervicography has been considered to be a reliable adjunct to the Pap smear. Till lately, cervicography have been used widely, and the efficacy of it is firmly established in cervical cancer screening. Recently, digital cervicography has been suggested to reduce the costs of performing conventional cervicography and also provide the opportunity for "telemedicine-based" screening. By above reasons, we developed novel digital cervicography system (DCS) in cooperation with national testing laboratory. In order to develop the DCS using internet, we achieved several serial processes such as digitalization of cervicography images,

transfer of digitalized images via network or modem, data manipulation on the web server, and evaluation of images by remote professional evaluators. As a final work, we aimed to validate our web-based DCS compared with conventional film cervicography in the present study.

Materials and methods

This work was designed by Korean Cervicography Research Group. Korean Cervicography Research Group, established in 1997, composed of 30 medical college hospital professors who are well trained colposcopists, has performed teaching and research activities for cervicography and cervical cancer prevention in Korea.

Our study was conducted prospectively at 5 institutions (Konkuk University Hospital, Ewha Womans University Mokdong Hospital, Soonchunhyang University Hospital, Daegu Catholic University Hospital, and Chosun University Hospital) from January 2013 to December 2013 after approval of institutional review board (ECT13-42A-18) in Korea (Fig. 1).

Firstly, analogue images were obtained by conventional cervicography system (Cerviscope, National Testing Lab Worldwide, Fenton, MO, USA) that has been used to take a 35-mm film photograph of the cervix after applying 5% acetic acid to the cervix. Secondly, digital images of each patient were also taken at the same time by digital camera (Dr. Cervicam, National Testing Lab, Seoul, Korea) (Fig. 2). Then, the films were transferred to a central processing facility for the development

of analogue images. Digital images made by digital camera were transmitted to DCS through internet. Lastly, digitalization of the analogue images was processed by scanning the analogue images.

Three kinds of images (analogue image, digitalized by scanning analogue image, and digital image) were evaluated by specialists with time interval between evaluations of each image. Total nine certified specialists belonging to Korean Cervicography Research Group evaluated the digital images on DCS (Fig. 3), 35-mm analogue slides, and scanned images without patient information. Cervicography findings were classified according to the diagnostic criteria approved by national testing laboratories worldwide as noted in Table 1.

To validate DCS compared with conventional film cervicography, we analyzed intraobserver variance among evaluation results of conventional analogue images taken by Cerviscope, scanned images obtained from conventional analogue one, and digital images taken by Dr. Cervicam. The degree of consensus was calculated by using kappa statistics. Generally, kappa value of 0 is indicating no agreement and range of 0 to 0.20 is considered slight (or poor), 0.21 to 0.40 fair, 0.41 to 0.60 moderate, 0.61 to 0.80 substantial (or good), and 0.81 to 1.00 almost perfect (or very good) agreement, respectively [2]. Statistical analysis was performed using DBSTAT ver. 5.0 (dBSTAT Co., Chuncheon, Korea).
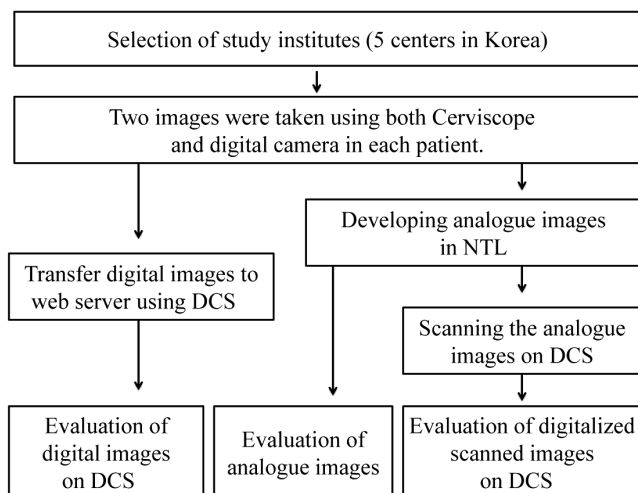

Fig. 1. Study schema. DCS, digital cervicography system; NTL, national testing laboratory.

Fig. 2. Digital camera for cervicography, Dr. Cervicam (courtesy of Dr. Cervicam, National Testing Lab, Seoul, Korea).
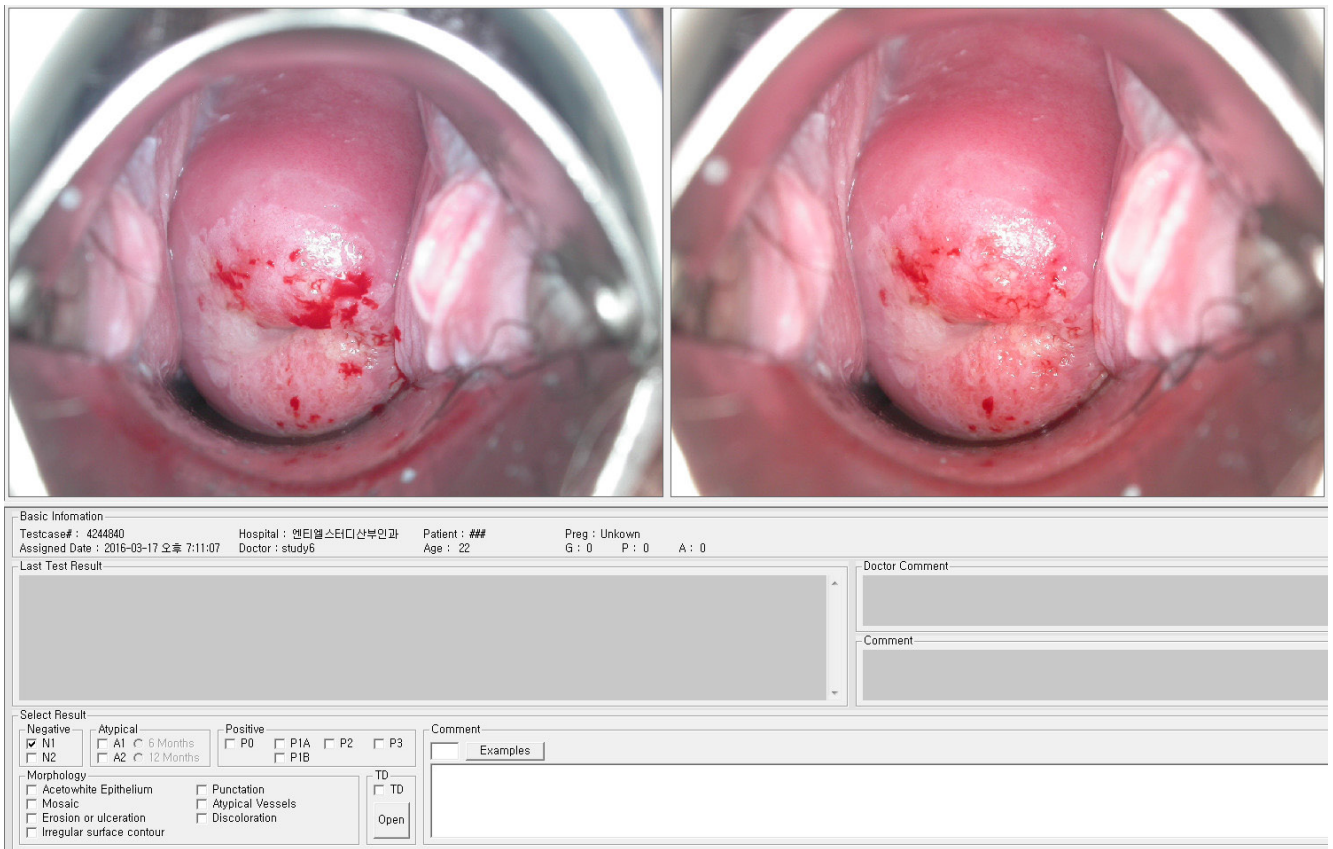
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Fig. 3. Digital cervicography system window for evaluators.

Table 1. Cervigraphy diagnostic classification

Category	Result
Negative	No lesion is visible
Atypical 1	A trivial lesion inside the transformation zone is visible, but colposcopy is not recommended because of the benign appearance or site of the lesion
Atypical 2	A trivial lesion outside the transformation zone is visible, but colposcopy is not recommended because of the benign appearance or site of the lesion
Technically defective	Not adequate for evaluation
Positive 0	Probably normal, but colposcopy preferable to rule out significant lesion
Positive 1A	Compatible with trivial disease, but colposcopy recommended because part of the lesion extends into the canal
Positive 1B	Compatible with a low-grade lesion
Positive 2	Compatible with a high-grade lesion
Positive 3	Compatible with cancer

Results

A hundred cases from five centers were prospectively collected. Among them, 37 cases were excluded because the cases were technically defective or not appropriate for evaluation due to mucus, blood, hair, or prolapsed vaginal sidewalls on analogue or digital cervicography images. Accordingly, total 63 cases and associated 567 images were finally analyzed to assess intraobserver consensus.

The generalized kappas for the cervicography readings were

Table 2. Agreement of paired observations between all pairs of observers for analogue and digital images

Analogue image	Digital image						Total
	Negative	Atypical	Positive 0	Positive 1	Positive 2	Positive 3	
Negative	392	4	2	2	0	0	400
Atypical	1	56	0	5	0	0	62
Positive 0	4	0	9	0	5	1	19
Positive 1	6	2	0	23	6	0	37
Positive 2	0	1	0	4	36	0	41
Positive 3	0	0	1	0	2	5	8
Total	403	63	12	34	49	6	567

Table 3. Agreement of paired observations between all pairs of observers for analogue and scanned images

Analogue image	Scanned image						Total
	Negative	Atypical	Positive 0	Positive 1	Positive 2	Positive 3	
Negative	369	26	2	3	0	0	400
Atypical	10	46	1	5	0	0	62
Positive 0	4	0	14	0	1	0	19
Positive 1	3	5	0	25	4	0	37
Positive 2	1	4	0	5	31	0	41
Positive 3	0	0	4	0	0	4	8
Total	387	81	21	38	36	4	567

Table 4. Agreement of paired observations between all pairs of observers for digital and scanned images

Digital image	Scanned image						Total
	Negative	Atypical	Positive 0	Positive 1	Positive 2	Positive 3	
Negative	372	25	2	4	0	0	403
Atypical	10	47	1	5	0	0	63
Positive 0	1	0	11	0	0	0	12
Positive 1	3	7	0	21	3	0	34
Positive 2	1	2	5	8	33	0	49
Positive 3	0	0	2	0	0	4	6
Total	387	81	21	38	36	4	567

displayed. The consensus in the different categories of interpretations in analogue and digital images is shown in Table 2. 521/567 (91.9%) pairs of interpretations of the cervicographic diagnosis were identical, and the kappa value was 0.83; reflecting "almost perfect agreement". Table 3 shows the levels of consensus for the six categories of interpretation between the analogue and scanned images. The level of consensus was 489/567 (86.2%), and the generalized kappa was 0.72 for six categories; reflecting "substantial agreement". Table 4 presents the consensus of the diagnosis between the digital and scanned images. In 488/567 (86.1%) cases, the evaluators had completed consensus in the diagnosis. The Kappa value between the digital and scanned images was 0.71; reflecting "substantial agreement".

Discussion

In the present study, we sought to validate the web-based DCS compared with conventional film cervicography, and found very good consensus between two systems.

There have been little investigations about the quality com-

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parison between film and digital cervicography, although a few studies have reported the usefulness of digital cervicography. Chen et al. [3] reported that the use of digital cervicography with the Reid colposcopic index can be a significant device for screening abnormal Pap cases. Bae et at. [4] also found that there were high concordance rate between abnormal findings of digital cervicography and final precancerous lesions. However, above studies did not compared the DCSs with conventional film cervicography. As with the use of a novel test, the validity has to be weighed against the previous or standard one. The present study is the first study in literature that validated the quality of DCS compared with that of the conventional film cervicography system.

Historically, the reliability of digital photographic assessment compared with colposcopy has been reported in many studies. Harper et al. [5] reported that the interobserver consensus for the colposcopic image versus digital colposcopic image was 86%, and suggested that the technical performance and clinical feasibility of telecolposcopy can be implementable. However, Ferris et al. [6] reported fair to poor interobserver consensus among three colposcopists using digital pictures taken during the colposcopic evaluation in ASCUS-LSIL Triage Study.

Various factors may be associated with lack of consensus or reproducibility of photographic assessment. Schneider et al. [7] reported that the quality of digital colposcopic images was deemed by the reviewer to be less than optimal, so the results that correspond to the digital colposcopic image review should be interpreted with caution. Jeronimo et al. [8] also suggested that next to analogue to digital conversion, high resolution is required for a good interpretation of cervicography. However, recent advances in digital instruments make it possible to construct high-quality images.

In the present study, we used high-resolution digital camera and novel web-based software to overcome the poor reproducibility of photographic assessment. Moreover, the evaluators for this study were carefully selected who had highly trained and experienced.

DCS has many advantages of a telemedicine-based screening of cervical cancer, a rapid reporting system, a good quality control and the saving in the expenses of film for analogue images. Digital cervicography also provides excellent possibilities in analogue cervicography for documentation, teaching, patient follow-up, and measurement and judgment of the severity of cervical lesions [9,10]. Moreover, the visual explana-

tion to the patients can minimize their anxiety and could help patients be aware for the guidelines for cancer screening [3].

Although we successfully showed the very good consensus between film and DCS, there were some limitations in the present study. The present study did not evaluate the interobserver variation among 9 specialists, and did not compare the cervicographic diagnosis with the final cervical pathology. However, we did not aimed to evaluate the efficacy of cervicogarphy but validate the quality of DCS compared with standard film cervicography system.

In conclusions, we found that there is very good intraobserver consensus between conventional film cervicography and DCS. Therefore, introducing DCS should be promoted for the better cervical cancer "telescreening".

Conflict of interest

No potential conflict of interest relevant to this article was reported.

Acknowledgments

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