PROCEEDINGS OF SPIE

Mobile colposcopy in urban and underserved suburban areas in Baja California

Marta Madiedo, Sonia Contreras, Octavio Villalobos, Bruce S. Kahn, Amit Safir, et al.

SPIE.

Mobile Colposcopy in Urban and Underserved Suburban Areas in Baja California

Marta Madiedo[1], Sonia Contreras[2], Octavio Villalobos[1], Bruce S. Kahn[3], Amit Safir[4], and David Levitz[*4]

[1]Fronteras Unidas Pro-Salud, Tijuana, Baja California, Mexico
[2]International Community Foundation, San Diego, CA
[3]Department of Obstetrics & Gynecology, Scripps Clinic Medical Group, 3811 Valley Centre Dr., San Diego, CA 92130, USA
[4]MobileODT Ltd., Gershon Shatz 41, Tel Aviv 67017 Israel

ABSTRACT

Cervical cancer is the leading cause of cancer death for women in low resource settings, often affecting the most economically disenfranchised segment of the population. The key challenge with cervical cancer is the lack of an effective screening program for many of the at-risk, difficult-to-reach women. Outreach programs that utilize mobile clinics to increase access to screening and care in Baja California have been developed. However, many barriers such as quality assurance, efficient referral remained a challenge in this region. Visualization-based co-tests together with cytology (Pap smears) as a primary screen have been proposed. Here, the mobile colposcope of the enhanced visual assessment (EVA) is used to capture an image immediately following a Pap smear. EVA images were reviewed by expert colposcopists. Initial or preliminary data from pilot services showed that Pap false positives and Pap false negatives maybe reduced by expert review of EVA images. This suggests that reviewing of EVA images may be instrumental in catching inaccurate Pap results, thereby improving care. Thus, there is a need to further explore the benefits of using EVA as additional information when conducting Pap smear screenings.

Keywords: Low resource settings, colposcopy, translational research, imaging

1. INTRODUCTION

Cervical cancer is the leading cause of cancer death for women in low-resource settings[1]. The most common type of cervical cancer takes approximately 20 years to develop from an initial infection by the human papilloma virus (HPV), through cervical dysplasia (precursor lesions), to mature cancers that put the patient's life at risk[2]. Over the last 50 years, Organization for Economic Cooperation and Development (OECD) nations have implemented national screening programs based on the Pap smear and more recently screening for human papilloma virus (HPV) infection, followed by colposcopy and colposcopically-guided biopsy, and have greatly reduced the risk posed by cervical cancer[3]. In this pathway of care, patients with a positive biopsy results are then referred to treatment with either an ablative or excisional therapy.

In most low-income countries, this pathway of care is non-existent given the few resources available to the health system. However, many middle-income countries have attempted to emulate the pathway of care offered by OECD nations, albeit with mixed success. Pap screening is offered in several clinics around the Tijuana region, as well as in mobile clinics that are part of outreach programs. Patients with an abnormal Pap screen come to a Tijuana clinic, where colposcopy and biopsy services are available. Because there are limited colposcopy services for the underserved, uninsured populations in Tijuana, is only one colposcopy clinic in Tijuana, and the prevalence of cervical

---

[*] Address all correspondence to Bruce Kahn, kahn.bruce@scrippshealth.org. Phone: (858) 764-3225; Fax: (858) 764-9097

dysplasia in this region are some of the highest in the world[4], there is a tremendous need to make screening more efficient. Also, it is essential to address the barriers patients and health systems faced to receive and provide timely and effective screening and treatment for cervical cancer. Efficient screening can reduce the number of patients referred to the clinic and reduce the patient backlog.

To address the need to promote efficient and quick referral and to reduce the patient backlog in Tijuana and many other many middle-income health systems, the enhanced visual assessment (EVA) system was developed[5]. The EVA system (Fig. 1) consists of a mobile colposcope built around a smartphone, a smartphone app, and an online image portal that stores de-identified patient images for annotation and documentation. To date, the EVA system has been used in 17 countries. However, for many health systems, some questions remain regarding how it should be integrated into the pathway of care.

This paper presents preliminary results of a novel implementation of the EVA system in the pathway of care in Baja California, when it is used as a screening co-test along with Pap smears. Examples of how images recorded using EVA can be used for quality assurance / quality improvement (QA/QI) of the images are discussed, focusing on catching Pap false positives and Pap false negatives. Finally, an overview is given of new features that are being developed into the app, and how they can be used to adapt the current pathway of care.

Mobile colposcope   App   Online image portal
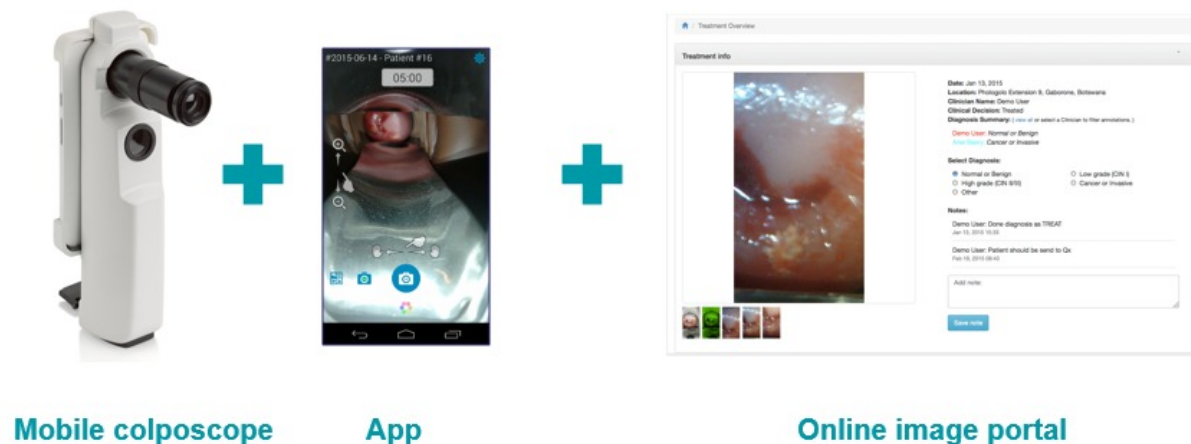
Fig. 1: The EVA system, consisting of a mobile colposcope built around a smartphone, an internet-connected app controlling image acquisition, and an online image portal storing the images for documentation and analysis.

2. METHODS

2.A. EVA system specifications
The EVA system (MobileODT, Israel) consists of a mobile colposcope built around a smartphone, together with a smartphone app, and an online image portal. In this study, mobile colposcope v2.3 was used, which included a 2nd generation Moto G (Motorola) smartphone, a case made of medical grade plastic, a telescopic lens, and a cool white LED for illuminating the cervix. The app controlling image capture and upload was the CervDx app (MobileODT) that ran on Android v5.1. Images captured with the mobile colposcope were uploaded to the online image portal for further review through a wireless connection

2.B. Outreach program
EVA systems were deployed through a cervical cancer screening outreach program by Fronteras Unidas Pro-Salud. In the deployment, EVA was used as a primary screen co-test, together with cytology, augmenting the standard of care (Fig. 2). The mobile clinics were part of a cervical cancer screening outreach program to underserved areas in suburban Tijuana. Altogether, two EVA systems were deployed in the mobile clinics. The clinicians in the mobile clinics included both medical students and nurses. Colposcopy experts trained them initially.

2.C. Screening methodology

Patients were screened for cervical cancer both by cytology (Pap smears) and visualization (EVA). During screening, data was collected as follows: First, a speculum was inserted into the vagina. Cytology samples were acquired routinely using spatulas, following the standard of care. Next, acetic acid was applied to the cervix using a cervical swab. After two minutes, the acetic acid highlights cervical dysplasia by the acetowhitening process, in which suspect areas turn white. At that point, the EVA system was used to capture cervical images.
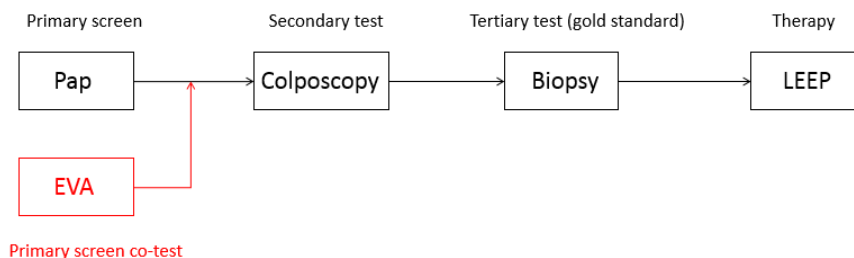

Fig 2: Standard of care for cervical cancer detection and treatment in Baja California (black) with experimental EVA primary screen co-test (red).

Following the screening tests, cytology specimen were processed according to the standard of care. Expert colposcopists reviewed EVA images to determine if the cervix is abnormal or not. Patients who had abnormal screening test results with either modality were called for a follow up visit at a Level 4 colposcopy clinic in Tijuana, Baja California, which offered colposcopy and biopsy services, as well as therapy (loop electrical excision procedure, LEEP) when necessary (Fig. 2).

3. RESULTS AND DISCUSSION

To date, the screening program implementing cytology-EVA co-test is still ongoing, and hence results presented in this section are only preliminary. Overall, the biggest impact of EVA images made an impact on QA/QI of the Pap results. Specifically, review of EVA images allowed for early referral of suspicious patients that were not necessarily detected. Because the EVA image is so similar to what clinicians see during the follow on colposcopy in the Tijuana clinic, expert reviewers hope that EVA can be used as an additional triage to reduce a fraction of the patients that come in for the follow up colposcopy. This suggests that there are benefits to every party. First, the clinical workload in the colposcopy clinic, which is the bottleneck in care, has been reduced. Second, the costs associated with an unnecessary procedure are eliminated. And third, Pap-positive, EVA-negative patients will get more appropriate care.

An additional benefit came when expert reviewers evaluated a sample of the Pap negative results. Here, EVA images from 59 patients were evaluated, and of those 59, three EVA images were recalled back for review. While the Pap results are processed, an abnormal or suspicious image detected can be reviewed remotely by an expert colposcopist to determine if an expedited referral to an experienced colposcopist is necessary. Even if the Pap result is negative, a suspicious EVA image could provide additional valuable information to evaluate and if appropriate treat a patient with a lesion. Much like the Pap positive analysis, here again the EVA image and follow up colposcopy image were similar. However, in contrast to catching false positive Pap results, catching false negative Pap results is much more beneficial for the health system, as it will need to devote less resources, time, and money to a missed cancer diagnosis. And for the patient, catching a false negative early can mean effective and timely treatment that could literally save her life.

In terms of QA/QI, the training level of the clinician who captured the EVA image greatly influenced the ability of the expert reviewer to adequately conduct the triage. An example of such images is shown in Fig. 3. Fig. 3A shows a poor quality image that suffers from what appears to be defocus and possible motion artifacts and/or blur. The image in Fig. 3B, captured by an expert colposcopist, shows a much sharper view of the cervix. The implications on the image reviewer's ability to triage are significant, and this suggests that better EVA training is needed.

Future work will involve synchronous review and consultation by the multiple clinicians. An example of the proposed clinical workflow is shown in Fig. 4. Features enabling synchronous review and consultation are currently being developed and integrated into the CervDx app, and should begin clinical testing in the next year.
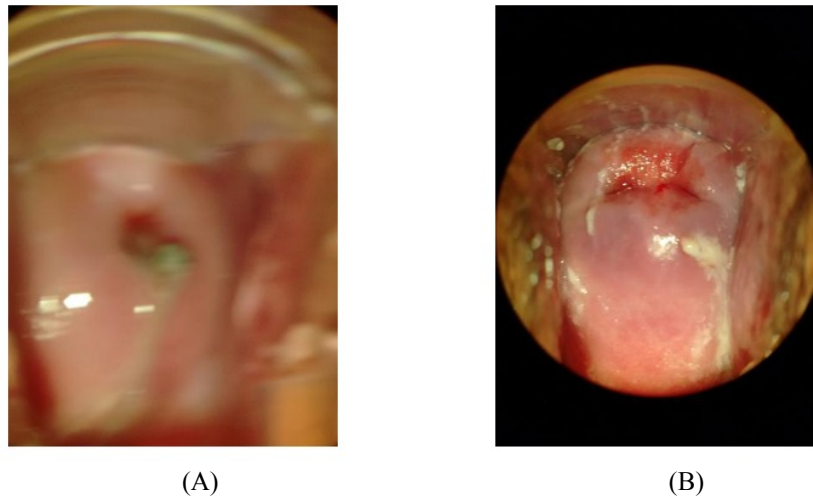
(A)   (B)

Fig. 3: Comparison of colposcopy images acquired using EVA by a medical student (A) and expert colposcopist (B).
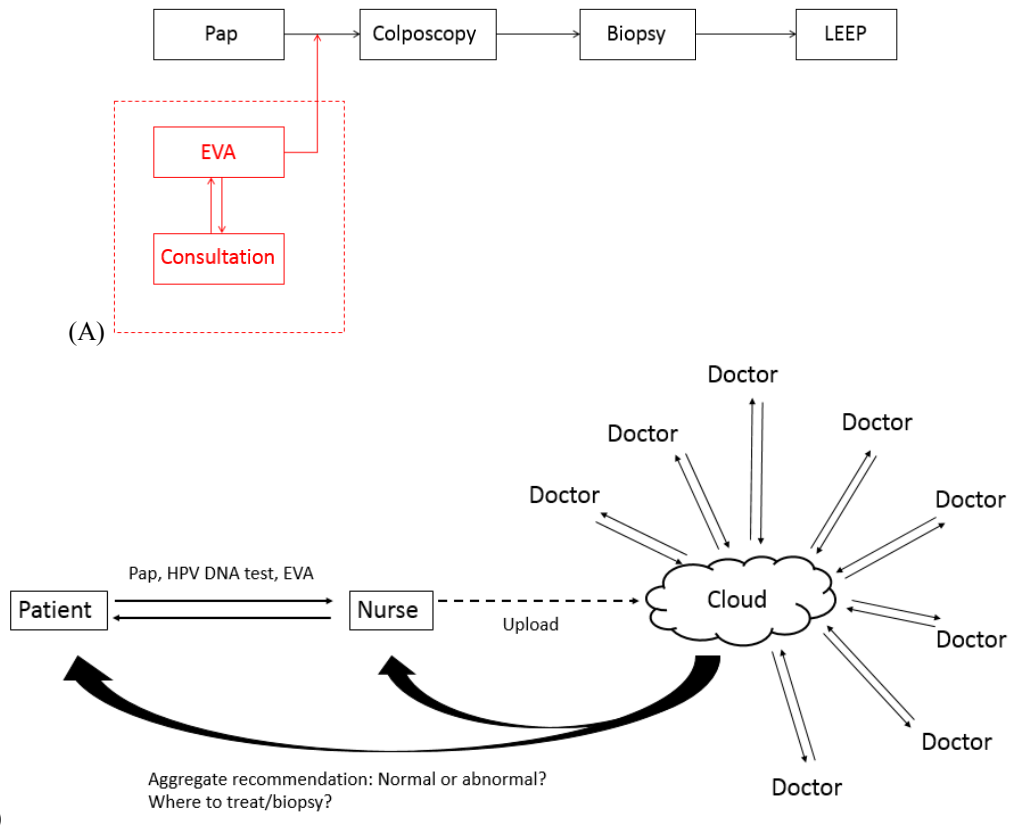

(A)

(B)

Fig. 4: (A) Proposed implementation of consultation feature at the primary screen. (B) Proposed new pathway of care integrating synchronous consultation features on the CervDx app.

4. CONCLUSION

In conclusion, initial testing of the EVA system at the point of primary screen yielded promising results. EVA images captured as a co-test together with Pap are beginning to provide valuable information to promote timely referrals and potentially catch false positives and false negative Pap results. This has the potential to yield savings to the clinician, patient, and health system as whole. Future developments will enable EVA review in real time at the point of care.

ACKNOWLEDGEMENTS

REFERENCES

[1] A Jemal, F Bray, MM Center, J Ferlay, E Ward, D Forman, "Global Cancer Statistics", *Ca Cancer J Clin* **61**, 69–90 (2011).

[2] P Holowaty, AB Miller, T Rohan, T To, "Natural History of Dysplasia of the Uterine Cervix", *J Natl Cancer Inst* **91**, 252-58 (1999).

[3] A Singer, JM Monaghan, and SC Quek. *Lower Genital Tract Precancer: Colposcopy, Pathology, and Treatment*, 2nd Ed. Blackwell, Oxford (2000).

[4] LS Palacio-Mejia, G Rangel-Gomez, M Hernandez-Avila, E Lazcano-Ponce. "Cervical cancer, a disease of poverty: mortality differences between urban and rural areas in Mexico" *Salud Publica Mex* **45**, S315-325 (2003).

[5] C Peterson, D Rose, J Mink, and D Levitz, "Real-Time Monitoring and Evaluation of a Visual-Based Cervical Cancer Screening Program Using a Clinical Decision Tree Algorithm". Submitted to *Diagnostics* (2016).