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Effect of topical vaginal products on the detection of prostate-specific antigen, a biomarker of semen exposure, using ABAcards☆,☆☆

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Abstract

Background: Prostate-specific antigen (PSA) is a biomarker of recent semen exposure. There is currently only limited information on whether topical vaginal products affect PSA assays. We investigated this question using various dilutions of several vaginal products (lubricants and spermicides) and the Abacus ABAcard for PSA detection.
Study Design: Pooled semen controls and various dilutions of nonoxynol-9 (N9), carboxymethyl cellulose (CMC), Replens, Gynol 2, K-Y jelly, Astroglide, Surgilube, combined with pooled semen dilutions, were tested for PSA using the Abacus ABAcard.
Results: N9 (2% with saline) and CMC did not appear to affect the results of testing with the ABAcard, but not all semen dilutions were tested. The other products (including Replens and Gynol, which is 2% N9 with propylene glycol, K-Y, Astroglide and Surgilube) at some of the dilutions tested either affected or gave invalid results with PSA testing using the ABAcard. Both Gynol 2 and K-Y at 1:10 dilution gave false-positive results.
Conclusions: Some vaginal products affect PSA results obtained by using the semiquantitative ABAcard. In vivo confirmation is necessary to further optimize PSA detection when topical vaginal products are present.

Keywords: Vaginal products; PSA; Semen; Biomarker; ABAcard; Lubricants; Spermicide

1. Introduction

Prostate-specific antigen (PSA) is a biomarker used to indicate recent vaginal semen exposure [1,2]. It is a sensitive and specific method for semen detection in women, originally developed for forensic purposes [3] and more recently adapted and utilized in reproductive health studies as an indicator of recent exposure to semen from unprotected sex or incorrect condom use [1,4–6]. PSA can be used as a marker to assess self-reported condom use as well as condom effectiveness [4] and, in clinical trials of contraception or sexually transmitted infections (STIs) and HIV prevention, as an indicator of adherence to study procedures (such as avoiding recent unprotected sex).

It is important to know whether spermicides or other vaginal products can affect the detection of PSA. In a clinical study of a new contraceptive diaphragm in which PSA was measured using the Abbott AXSYM® Microparticle Enzyme Immunoassay (Abbott Laboratories, Abbott Park, IL, USA), it appeared that nonoxynol-9 (N9) may have interfered with PSA detection [5]. There are other methods

☆ The findings and conclusions in this article are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention.

☆☆ Use of trade names is for identification only and does not imply endorsement by the US Department of Health and Human Services.

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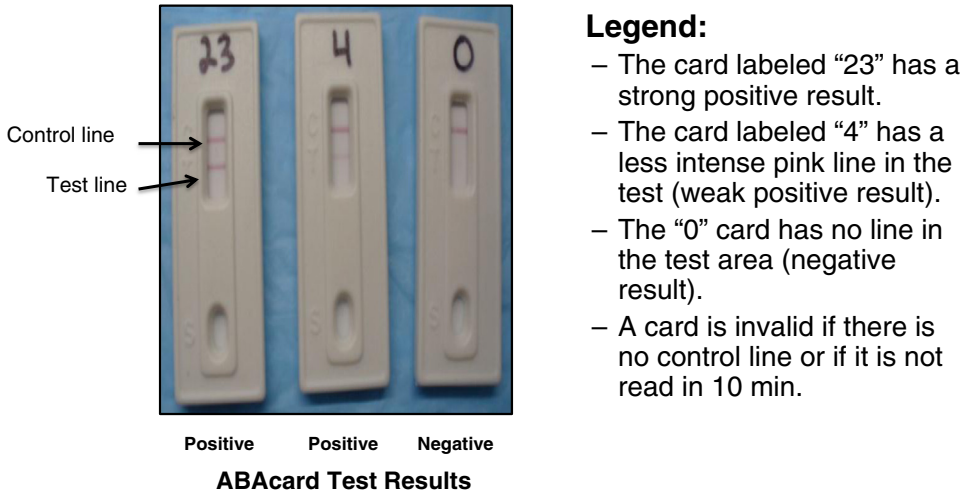

Fig. 1. ABAcard.

available for PSA detection. One is the Abacus OneStep ABAcard (Abacus Diagnostics, West Hills, CA, USA) [6–8]. The card yields rapid and straightforward qualitative or semiquantitative results [9] and is relatively inexpensive.

Abacus OneStep ABAcard is an antigen-specific monoclonal antibody membrane assay that has a lower limit of PSA detection of 4-ng PSA/mL vaginal swab eluent [7]. Although the card was originally developed as a qualitative assay, it has been used semiquantitatively [9] (Fig. 1), and its semiquantitative results correlated well with results of the quantitative Abbott IMX assay [9]. There is only limited evidence on the effect of vaginal products on PSA testing using ABAcards. Given the lack of available information on this topic, as well as the important role that biomarkers of semen exposure can play in microbicide, HIV/STI prevention and contraception research, we undertook laboratory investigations to determine whether specific vaginal products affect PSA detection by ABAcards.

2. Methods

2.1. In vitro experiments

Table 1 describes the vaginal products (lubricants and spermicides) that were tested: N9 (formulated at Eastern Virginia Medical School laboratory as 2% N9 in saline), carboxymethyl cellulose (CMC), Replens, Gynol (2% N9 with propylene glycol), K-Y, Astroglide and Surgilube.

First, positive controls (semen alone) were prepared by serially diluting [with phosphate buffer saline (PBS)] pooled semen stock, which had been stored at −80°C at a 1:50 dilution and then thawed. PBS was used as the diluting medium rather than what is supplied by the manufacturer as it is a commonly used diluting medium. Twofold dilutions were created and tested (without vaginal products) by the ABAcard starting with1:1600 through 1:1,638,400. Semen alone was also tested with the Abbott Architect chemiluminescent quantitative immunoassay [10], in order to quantify the PSA concentration range for each dilution and correlate with the semiquantitative results obtained from ABAcard.

Next, each of the vaginal products was mixed with semen. Each was diluted in PBS at 1:10 and 1:40 dilutions (Surgilube was also diluted at 1:20) and then added to the series of semen dilutions in equal volumes so that the final semen dilutions were twofold, ranging from 1:1600 through 1:1,638,400. For each of the samples tested with the ABAcard, 200 μL of an extract was placed in the test device, and all test results read at 10 min. Results were considered invalid if there was no control line visible within 10 min.

Table 1
Vaginal products included in the experiments of PSA detection by ABAcards

Product	Brand name (manufacturer)	Main ingredient	Type	Date tested
N9	N/A (formulated @ EVMS)	N9 2% in saline	Spermicide	June 2009
CMC	N/A (formulated @ EVMS)	CMC	Main ingredient for lubricants	June 2009
Replens	Replens (LDS Consumer Products)	Polycarbofil	Vaginal lubricant	September 2009
K-Y	K-Y Brand Jelly (Johnson & Johnson)	CMC	Vaginal lubricant	September 2009
Astro	Astroglide (BioFilm, Inc)	Glycerin and propylene glycol	Vaginal lubricant	September 2009
Gynol	Gynol 2 (Ortho)	N9 2% in propylene glycol	Spermicide	September 2009
Surgi	Surgilube (Fougera)	Chlorexidine gluconate and natural water soluble gums	Surgical sterile lubricant	March 2010

N/A: not applicable; EVMS: Eastern Virginia Medical School.