Assessment of Condoms as Probe Covers for Transvaginal Sonography

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ABSTRACT: Purpose. This prospective study assessed the incidence of transvaginal probe contamination and breakage of condoms used to cover those probes during transvaginal sonography.

Methods. Over a 9-month period, 214 women underwent transvaginal sonography with probes that had been coated with gel and then covered with a latex condom. Condom defects were detected after the scans by inspection, by adding hydrogen peroxide, and by filling the condoms with 500 ml of water. After the condoms were removed, the probe was either wiped with a dry tissue (during the first 18 weeks of the study) or wiped first with a dry tissue and then with a 70% isopropyl alcohol wipe. Probe head contamination was assessed by periodic swab sampling and culturing for bacteria and herpes simplex virus. Samples of the sonographic gel also were tested for bacterial contamination at approximately weekly intervals.

Results. A total of 217 condoms were used, 3 of which broke and were discarded while being applied to the probe. Two of the 214 condoms used (0.9%) were found upon visual inspection to have perforations. None of the other 212 condoms leaked upon being filled with water; none of the 204 condoms tested with hydrogen peroxide showed bubbles. Only 1 of the 46 probe swab samples was positive for bacteria (Acinetobacter species); none of the 26 probe swab samples cultured for viruses or the 25 gel samples cultured for bacteria were positive.


Keywords: ultrasonography, transvaginal; probe contamination; infection control

Transvaginal sonography (TVS) recently has become the method of choice for imaging the female pelvis, offering the advantages over transabdominal sonography of better image resolution of the pelvic organs and elimination of the need for a full bladder. Invasive procedures such as oocyte retrieval and drainage of simple cysts can also be performed transvaginally. Whereas transabdominal sonography is considered a low-risk procedure for the spread of infection, TVS is considered medium-risk because the probe is in contact with the vaginal mucous membrane, thereby posing a risk of contamination and cross-infection from organisms that are transmitted by genital secretions and menstrual blood.

The paucity of literature on the risk of TVS probe contamination and the broad range in the rate of condom perforation (0.6–7%)2,3 prompted us to prospectively study the incidence of condom cover breakage and subsequent probe contamination during TVS. To the best of our knowledge, this is the first study in which the incidence of transvaginal probe contamination was assessed directly by culturing swab samples taken from the probe head for the presence of bacteria and viruses. We also cultured the sonographic coupling gel, another potential source of infection, for bacteria. Finally, we also used not only visual inspection but 2 other methods for detecting condom leakage: adding hydrogen peroxide, which would cause any blood or cervical secretions in-
side the condom to bubble, and filling the condoms with 500 ml of water, which would reveal microscopic leaks.

PATIENTS AND METHODS

During the 9-month period from June 1996 through February 1997, 214 women referred to the Ovarian Cancer Screening Clinic underwent TVS. The women gave verbal consent to participate in this study after its objectives had been explained to them. For premenopausal women, a note was made of the day of their menstrual cycle on which scanning took place.

The probe used in this study was a 6-MHz endovaginal transducer (Toshiba Medical Systems, Crawley, United Kingdom). The total length of the probe and handle was 31.6 cm. The condoms used (Casmed UK, Banstead, United Kingdom) were latex without spermicide and were 3.5 cm wide at the base and 20 cm long. The composition of the latex and the powder coating were considered proprietary and were not provided to us. Quality-control tests of the condoms by the manufacturer were as follows. Every condom was tested by passing an electric current through it; those through which current passed were rejected. Samples were taken from each batch of 150,000–500,000 condoms for air-burst and tensile testing. The minimum acceptable air volume in air-burst testing was 40 l. Tensile testing involved stretching a 10-mm ring from the middle of the condom between 2 points until the condom broke; 8 times the original width was the minimum accepted distance.

Before each sonographic examination, sono-graphic coupling gel (Henley’s Supplies, Welwyn-garden City, United Kingdom) was applied to the probe, which was then covered with a condom. The condom was secured by placing its base into the groove at the top of the handle. Then, K-Y lubricating jelly (Johnson & Johnson, Maidenhead, United Kingdom) was applied to the outside of the covered probe before the probe was inserted into the vagina. At the end of each examination, the condoms were visually inspected for microscopic defects while still applied to the probe. Then, the condoms were removed from the probe and tested for microscopic breaks, first by pouring 10 ml of 3% hydrogen peroxide into the condom and looking for bubbles and second by filling the condom with 500 ml of water and suspending it for 2 minutes. Fifty unused condoms were also inspected for defects and filled with water as described above.

During the first 18 weeks of the study, the transducer was uncovered and wiped with a dry tissue after each examination. Swab samples were taken from the probe head periodically between examinations by dipping the swabs in transport medium, wiping the swabs across the head of the probe, and culturing the swabs for the presence of routine bacteria and herpes simplex virus types 1 and 2 (HSV-1 and HSV-2).

During the second half of the study, after each examination the probe was uncovered and wiped first with a dry tissue and then with a 70% (v/v) isopropyl alcohol wipe (Alcowipe; Seton Prebbles, Bootle, United Kingdom). The probe head was allowed to dry, and swab samples were taken for bacterial and viral analyses as described below. A total of 25 samples of the coupling gel, collected approximately weekly, were examined for bacterial contamination as well.

For bacterial analysis, each swab or gel sample was spread onto 4 plates, incubated at 37°C, and analyzed as follows. Plates containing blood agar were incubated aerobically and assessed for vegetative bacterial or fungal growth at 24 and 48 hours. Plates containing blood agar with a 5-μg metronidazole-impregnated disc were incubated in Gaspak generated anaerobic jars (Oxoid, Basingstoke, United Kingdom) and assessed for growth after 5 days. Plates containing Sabouraud’s selective fungal medium were incubated aerobically for 48 hours. Plates containing New York City selective medium were incubated in 5–10% CO₂ and assessed for growth over 72 hours. For the viral tests, medium from each swab was inoculated into 2 tissue culture tubes containing human embryonic lung fibroblast cells. The tubes were incubated at 37°C without agitation and examined every other day for 7 days for the development of the herpes simplex virus cytopathic effect.

In the event of condom breakage during the scanning procedure, the probe head was cleaned with either a dry tissue or a dry tissue and an Alcowipe, depending on whether the break occurred during the first or second half of the study, and swab samples were collected from the probe head and cultured as described above.

RESULTS

Of the 214 patients who underwent TVS, 64 were scanned during the first 5 days of their menstrual cycle. A total of 217 condoms were used in the course of the 214 scans. Three condoms broke while they were being applied to the transvaginal probe and were discarded. Of the remaining 214 condoms, 2 were noted to be defective upon visual
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examination at the end of the scan (0.9%; 95% confidence interval, 0.1–3.3%). None of the other 212 condoms leaked upon being filled with water and suspended. Of these 212 condoms, 204 were tested with hydrogen peroxide, and none of them showed bubbling inside. On 2 occasions, no peroxide was available; on the other 6, the outside of the condom was so grossly contaminated with blood that contamination of the inside could not be excluded. However, these 6 condoms did not leak during water testing, and the probe was not visibly contaminated on these occasions. None of the 50 unused condoms had defects or leaked.

With regard to the swab samples taken from the probe head (24 bacterial and 11 viral during the first 18 weeks of the study and 22 bacterial and 15 viral during the second 18 weeks), only 1 swab, taken during the first period, was found to be positive, for *Acinetobacter* species. No growth was found in any of the other bacterial cultures of the probe head or gel, and no growth was found in any of the viral cultures.

**DISCUSSION**

Because TVS involves contact between the probe and the vaginal mucous membranes, it is important to minimize the risk of horizontal transmission of infectious agents by adequately covering the probe and by disinfecting the probe between patients. We found that the use of latex condoms as probe covers was associated with low rates of perforation (0.9%) and probe contamination (2%). Our perforation rate is similar to that of Rooks et al\(^3\) (0.6%) and is lower than the reported perforation rates of 3.1% for gloves and 1.7% for commercially available probe covers.\(^2,3\)

The risk of probe contamination from unavoidable breaks in probe covers during scanning had led to recommendations for chemical disinfection. Infection control policies on sterilization or decontamination of equipment are based on the invasiveness of the equipment, the likely organisms involved, the equipment itself, the workload of the department using it, and whether it is being used for high-, medium-, or low-risk procedures. According to these policies, transvaginal probes need decontamination rather than sterilization. Recommended procedures have included washing the probe with soap and water, which reduces the microbial load;\(^1\) using presoaked alcohol wipes, which kill bacteria, fungi, and certain enveloped viruses but not spores;\(^5\) or using 500 ppm sodium hypochlorite or 2% activated glutaraldehyde solutions.\(^6,7\) Disadvantages associated with sodium hypochlorite include the time required for soaking the probe (at least 2 minutes), its ineffectiveness against transmissible spongiform encephalopathic agents, its instability in solution, its corrosiveness to metal and textiles, and its poor wetting properties. Although 2% glutaraldehyde kills bacteria and viruses, including the human immunodeficiency and hepatitis B viruses, it is toxic to humans and may cause irritation of the eyes, skin, and mucous membranes. The use of glutaraldehyde requires adequate ventilation and protective equipment such as gloves and goggles to minimize exposure to it.

We chose to screen for HSV-1 and HSV-2 because of their role in genital herpes and because they are a surrogate indicator for the hepatitis and human immunodeficiency viruses. We found no evidence of viral contamination in this study; however, any conclusions are limited by the small number of samples collected (26 for viral analysis) and the lack of information as to how many of our subjects were infected. In developed countries, 20% of the general population is seropositive for HSV-2, and asymptomatic viral shedding occurs in about 5% of HSV-2–positive females. If these rates apply to the women in this study, only 1 or 2 of them may have been shedding the virus when they were scanned. Further studies with larger numbers of samples and patients, particularly those at high risk of infection, are required. More sensitive means of detecting viral transmission/protection could include DNA assays or an in vitro tissue culture. However, we believed that the expected low incidence (<1%) of HSV infection in the population we studied did not justify the use of such tests. We did not test directly for probe contamination with the human immunodeficiency virus for similar reasons.

With regard to bacterial contamination, no normal vaginal flora such as *Lactobacillus* species were found on the probe, providing evidence of protection against contamination by the condoms. The *Acinetobacter* species isolated from a swab sample of the probe head could have come from external contamination of the probe or from contamination in the laboratory. *Acinetobacter* species are ubiquitous saprophytic bacilli found in the environment and isolated from skin sites, including the groin and vagina, in up to 25% of healthy adults. Although *Acinetobacter* species typically cause nosocomial infections in immunocompromised patients, they have also been associated with a wide range of infections, including urinary tract infection and skin abscesses, in immunocompetent patients.

The incidence of pelvic infection after transvaginal sonographically directed follicle aspira-
tion is reportedly 0.6%.

Although no vaginal infections have been documented after routine TVS, conceivably infections could be transferred in the event of condom breakage and inadequate disinfection of the probe between scans of successive patients. However, the odds of such an event are very low (estimated incidence of 3.6 per 10,000 procedures). The only sure way of avoiding cross-infection at present is to sterilize the probe between examinations; this, however, can involve practical difficulties. Some new disinfectant agents (eg, Sterilox; Sterilox Medical Europe, Abingdon, United Kingdom) under evaluation may revolutionize the sterilization of invasive equipment. Until these agents are judged suitable for clinical use, simply wiping the probe with commercially available alcohol wipes between procedures will decrease the potential risk of cross-infection.

Results from this study confirm the slight possibility of condom perforation but are encouraging in that very little transmission of vaginal flora seems to occur despite the vagina being a rich source of microflora. Use of alcohol wipes cannot guarantee disinfection but does offer an additional level of protection that is of practical use in busy outpatient departments.

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