The Possibility of Transmitting Infections with Vaginal Ultrasound Probes: Why We Cannot Meet the Guidelines

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ABSTRACT: The use of ultrasound endovaginal probes is common practice in the fields of gynecology and obstetrics. The vagina serves as a host environment for many microorganisms, contributing greatly to its defensive mechanisms. It is not known whether the introduction of other microorganisms into the vaginal region are detrimental or require intensive preventive measures. Several national ultrasonography societies, as well as the Israel Ministry of Health, have addressed the proper and adequate handling of sonographic endovaginal probes, including the use of high-level disinfecting agents following cleansing and prior to using probe covers between patients. However, many obstetrics and gynecology ultrasound units in Israel find it difficult to adhere to these strict disinfecting requirements. While most of the guidelines are based on the theoretical risk of contaminations when ultrasound endovaginal probes are used, the rate of nosocomial infections linked to the use of these probes has yet to be verified. Based on the information available, there is an urgent need to find a solution that enables gynecological ultrasound users to properly disinfect endovaginal probes between patients. Currently, it is almost impossible to pragmatically adhere to the Israel Ministry of Health guidelines.

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Several medical fields utilize ultrasound technology, which is widely regarded as safe and sensitive diagnostic equipment. However, in recent years there is growing concern regarding the risk of transmitting infections, especially with internal probes such as endovaginal and endorectal ultrasound probes. The main concern is that these probes may enable contamination by pathogenic microorganisms and therefore act as vectors, transmitting pathogens among patients [1].

The U.S. Centers for Disease Control and Prevention defines ultrasound endovaginal probes as semi-critical devices in terms of their risk for transmitting infections

Among its varied applications in medicine, the endovaginal probe has an especially important role in the practices of obstetrics and gynecology [2]. The probe enables fetal surveillance during all stages of pregnancy [3] and facilitates the evaluation of different pathologic processes involving the female reproductive tract [2]. Therefore, it is considered an essential device for conducting clinical examinations in the field.

The increasing awareness of nosocomial infections in recent years, in addition to the few studies that detected contamination of the endovaginal probes by potentially pathogenic microorganism following their use [4-7], has led several national committees to publish guidelines addressing the optimal safe handling of endovaginal probes [8]. Likewise, the Israel Ministry of Health has responded by publishing its own guidelines on this matter (https://www.health.gov.il/hozer/mr03_2017.pdf).

Concomitantly, the vagina is known as a microorganism-rich environment, including species possessing pathogenic potential, all giving rise to the physiologic vaginal flora [9]. Due to the time needed for the endovaginal probe disinfection process and the heavy workloads of the staff, many obstetrics and gynecology ultrasound departments in Israel find it difficult to adhere to these strict disinfection requirements. In this review, we discuss the importance of the disinfection process as recommended by the Israel Ministry of Health.

THE VAGINAL MICROBIOTA

Many microorganisms are carried on the skin and mucosae of the human body, where they comprise part of our normal flora. As a result, healthy individuals serve as hosts for potentially pathogenic microbes. The well-known bacterium, *Staphylococcus aureus*, is a common example of this paradox [8].

The bacteria comprising a specific microbiota depend on their surrounding environment, which varies among different tissues throughout the body. In addition, the types of organisms occupying the female vagina vary among women and may change within short periods of time depending on specific factors. For example, days of menstruation or differences that occur in a woman's reproductive tract at premenstrual, reproductive, and menopausal states may differ [10].

The majority of microorganisms comprising the physiologic vaginal flora coexist in a mutual relationship with their surroundings, while the minority include opportunistic species [11]. In their landmark paper, Ravel et al. [12] studied the vaginal microbiome of reproductive-age women. Their hypothesis of a single bacterium core comprising the vaginal microbiota in all women was proven false. Nonetheless, species belonging to the group of *Lactobacillus* were found to dominate in most cases, and more than 20 of its subtypes have been isolated from the female genitalia. A logical explanation for the higher prevalence of these species is their ability to maintain an acidic environment. In up to 33% of healthy women, alternative acid-producing species prevail, such as *Atopobium vaginae*, *Megasphaera*, and sub-species of *Leptotrichia* [13]. Additional bacteria detected as part of the normal vaginal flora include groups of aerobic gram-positive bacilli (*Diphteroids*), gram-positive cocci (*Staphylococcus epidermidis*, *Staphylococcus aureus*, *Streptococcus* subspecies), and gram-negative bacilli (*Escherichia coli*, *Klebsiella, Proteus*). Anaerobic bacteria belonging to species of *Bacteroides*, *Clostridium*, *Fusobacterium*, and others were also found in varying prevalence [9].

PATHOPHYSIOLOGY

Vaginitis is a common entity in gynecology with important clinical significance [14]. The microorganisms that have the ability to cause a vaginal infection may arise from endogenous or exogenous origin. The former results from intrusion of species integral to the human flora that are introduced through a cut or opening in the mucosa. These types of infections may occur during uptake of tissue biopsy from the genitalia, vagina, or cervix. In contrast, exogenous infections arise when organisms from outer sources are transmitted to a given individual [15].

As previously described, the normal flora presenting in different locations of the human body also involve bacteria with pathogenic potential. One of the leading theories suggests that individuals serving as a host for these species develop a type of immunity against them, preventing infections from constantly occurring. Thus, transmission of those organisms to another individual confers imminent risk for developing an infection. An example of this phenomenon is the famous outbreak of typhoid fever in the early 20th century [8].

The main physiologic role of the vaginal flora is to form, along with the innate immune system, the first line of defense for preventing infections in the genital area. The ability to produce lactic acid and maintain a low pH level is one of its major weapons in fighting this battle [10].

Certain conditions may alter and affect the balance of the vaginal microbiota. These situations include contamination with exogenous parasites such as *Trichomonas vaginalis*, colonization of bacteria that are not part of the normal vaginal inhabitants, and situations involving proliferation or transformation of endogenous organisms. However, these circumstances do not necessarily imply the development of infections or symptoms. A combination of several factors is required for this to occur. These conditions involve a quantitative dominance of the given microbe, its level of virulence, and the host's immune system response [13]. A commonly accepted example for such disorders resulting from alteration in the balance of the vaginal flora is the condition of bacterial vaginosis [16].

PREVENTING NOSOCOMIAL INFECTIONS

The various methods available for the prevention of nosocomial infections arising from medical instruments distinguish between sterilization and disinfection techniques. Sterilization eradicates all living microorganisms and is performed using chemical and physical methods such as steam pressure, dry heat, and chemical preparations. In contrast, disinfection enables the disintegration of most of the pathogenic organisms, with the exception of spore-forming bacteria, mainly by using chemical liquids. The disinfectants are further categorized into high-level, mid-level, and low-level, based on their efficacy. The U.S. Food and Drug Administration has defined high-level disinfectants as sterilants used for a shorter contact time to achieve a 6-log$_{10}$ kill of an appropriate *Mycobacterium* species [17]. These sterilants have the ability to destroy most microorganisms, except for those capable of forming endospores; whereas low-level disinfectants are effective against vegetative bacteria, viruses, and a majority of parasites [18].

Several associations and committees worldwide, including in Israel, recommend using high-level disinfectants in addition to probe coverings for safer handling of endovaginal probes

Spaulding [19] proposed a classification, based on the potential for transmitting infections, which divides medical equipment into three main categories. The critical group includes those instruments with the highest risk for transmitting infections due to their ability to penetrate the skin or mucosae. This group of instruments must undergo sterilization prior to their use. The second group, in terms of risk for infections, is termed semi-critical and includes medical instruments that come into contact with the mucosae, such as fibro-optic endoscopes. They require high-level disinfectants. The non-critical category involves the lowest risk and consists of devices that do not come into contact with mucosae [20].

A commonly accepted safety recommendation involving the endovaginal probes is the use of probe covers, which prevent contact with the mucosa. Condoms made from polyurethane or other materials were found to be superior to other available probe covers [4]. Based on Spaulding's classification [19], one could conclude that the endovaginal probes covered with

condoms do not have contact with the vaginal mucosa and thus should be classified as non-critical instruments. However, the U.S. Centers for Disease Control and Prevention (CDC) categorize them as semi-critical devices based on the slight chance of failure or rupture of the probe covers during or prior to the examination [17]. The CDC therefore recommends disinfecting the probes using high-level disinfectants in addition to the use of probe covers after each patient. In response, the American [18], Canadian [21], Australian [15], and Scottish [22] national medical societies published guidelines with similar recommendations.

However, based on the existing drawbacks of exposure to high-level disinfectants, medical guidelines in other countries, such as France, recommend the use of low-level disinfectants. Drawbacks of using high-level disinfectants include risks of harming the patient's mucosa or the skin of the examiner, damaging the quality of the probes and, most importantly, requiring long periods of time to complete this procedure [23].

In January 2017, the Israel Ministry of Health published guidelines addressing precautions required prior to an endovaginal probe examination (https://www.health.gov.il/hozer/mr03_2017.pdf). These recommendations were based mainly on the published guidelines from the CDC [17] and the American Institute of Ultrasound in Medicine (AIUM) [18]. According to these guidelines, the process of disinfecting endovaginal probes should be performed in the following order: (i) remove the probe cover, (ii) change gloves after adequate hand hygiene/preliminary hand disinfection, (iii) clean the probe using special pads or wipes, and (iv) clean with a high-level disinfectant including a chemical or physical method (e.g., ultraviolet light). A certain length of time is required for the disinfectant to dry or dissipate before the examination of the next patient can begin. This entire procedure can take several minutes, which should be considered when scheduling patients.

The rate of nosocomial infections linked to the use of endovaginal probes has yet to be verified. Currently, it is almost impossible to pragmatically adhere to the Israeli guidelines

STUDIES IN THE FIELD

The risk of perforation of the endovaginal probe cover is the main reason this device was characterized as semi-critical. A study by Rooks and colleagues [24] compared the risk for perforation when using condoms versus probe covers. In their study, in 15 of 180 examinations using probe covers perforation occurred, compared to only three events with probe condoms (8.3 vs. 1.7%, $P < 0.05$, relative risk 5.4, 95% confidence interval 1.4–18.5). The researchers further concluded that the use of condoms was superior and less expensive than other probe covers. We tried to replicate the results of this study and examined latex lubricated probe covers (ECOFUNDA CE0318, Novico Medica S.A. Barcelona, Spain) after 80 consecutive vaginal ultrasound examinations. We did not detect any probe perforation.

Table 1. Studies evaluating the risk for contamination of endovaginal probes

Study	Method	Type of probes	Bacterial contamination, n (%)	Viral contamination, n (%)
Leroy [4]	Meta-analysis	Endovaginal	4/408 (0.98%)	77/596 (12.9%)
Kac et al. [5]	Prospective	Endorectal, endovaginal	15/440 (3.4%)	5/336 (1.5%)
Casalegno et al. [6]	Prospective	Endovaginal	Not tested	7/197 (3.5)
Westerway et al. [7]	Blinded	Transabdominal, endovaginal	Not tested	9/63 (14.2%)

Several studies evaluated the risk for contamination of endovaginal ultrasound probes, despite the use of probe covers [4,7] [Table 1]. The first, by Kac et al. [5], investigated the risk for contamination of endovaginal and endorectal ultrasound probes following their use. They found that 15 of 440 probes examined had been contaminated with pathogenic bacteria (3.4%). In 5 of 336 probes (1.5%), they detected viral nucleic acids, including human papillomavirus (HPV). A second study, which was conducted in France, showed that despite using endovaginal probe covers, which remained complete and intact during the entire examination, 7/197 probes tested were contaminated with HPV (3.5%) [6]. A third study from Sydney, Australia, evaluated the risk that women were exposed to during a transabdominal or transvaginal sonographic examination. They also compared the efficacy of low-level and high-level disinfectants. Their results showed that 14% of the endovaginal probes were contaminated during the procedure. The use of low-level disinfectants displayed partial response, with 4% of the probes contaminated with endospore-forming bacteria, in contrast to complete disintegration with the use of high-level disinfectants [7]. Leroy [4] conducted a meta-analysis of 32 studies that reviewed the risk for contamination of endovaginal and endorectal probes using probe covers and low-level disinfectants. She found that 13% were contaminated with pathogenic bacteria and 1% with common viruses, such as herpes simplex virus, HPV, and cytomegalovirus.

Despite existing evidence for the risk of endovaginal probe contamination during examinations, there have been surprisingly few reports in the literature describing nosocomial infections that occurred subsequent to the use of this device [23] [Table 2]. Moreover, the previous studies, which successfully isolated microbes from those probes, declared that they were not able to predict their risk of producing an infection [7]. According to published reports, the endovaginal probe examination was identified as the source for a nosocomial infection outbreak in two cases. The first was presented in Paris, where an outbreak of nosocomial infection induced by the pathogenic bacterium *Klebsiella pneumoniae* erupted among eight women in a local obstetrics and gynecology department after they underwent an endovaginal sonographic examination.

Table 2. Case reports of nosocomial infections suspected to arise from endovaginal probe examination

Study	Year	Number of cases	Procedure	Pathogen	Type of infection	Identified source
Gaillot et al. [25]	1993	6 adult women and 2 neonates	TVS examination	*Klebsiella pneumoniae*	UTI, fever, RDS, colonization	Ultrasound gel
Lesourd et al. [27]	1997	2 adult women	Oocyte retrieval during ART	Hepatitis C virus	Acute hepatitis, contamination	Medical staff

ART = assisted reproductive therapy, RDS = respiratory distress syndrome, TVS = transvaginal sonography, UTI = urinary tract infection

Following thorough investigations, the ultrasound gel used in that facility was detected as the source for contamination [25]. Further studies showed that ultrasound gel carries a major risk for contaminations and infections in several cases [26]. The second report, by Lesourd and co-workers [27], published two cases of women infected with hepatitis C virus during assisted reproductive treatments at the same institution. In these cases, despite early suspicions the source of infections was not the endovaginal probes but rather the local medical staff. In addition to the medical staff and ultrasound gel, evidence suggests that another common source for contamination includes the ultrasound handles [28]. To overcome those multiple sources, automated machines capable of performing the process of disinfection have been developed in recent years and show promising results [29].

DISCUSSION

As we have shown in this review, the vaginal physiologic flora host many different microorganisms, with some possessing virulence capability. One of the functions of the vaginal microbiota, which explains its mutualistic relationship with the human body, is its ability to protect against exogenous and endogenous infections [30].

Despite reported risks for contamination of endovaginal ultrasound probes and their frequent use in daily practice, there are few published reports regarding infections arising subsequent to those examinations [23]. Furthermore, the few published reports ultimately concluded that the ultrasound probes were not the source of contamination. On the other hand, strict adherence to the guidelines of vaginal ultrasound probe disinfection may prevent transmission of viruses such as hepatitis A, hepatitis B, hepatitis C, HIV, and HPV, which may be undetected for years.

Due to the risks described, and despite a limited number of studies on the risks of vaginal infections transmitted by the use of endovaginal ultrasound probes, the Israel Ministry of Health guidelines, which correlate with those of the American, Canadian and Australian societies [2], require strict maintenance for handling these probes, including the use of high-level disinfectants. The majority of these guidelines rely on the CDC standards [17], which categorize endovaginal probes as semi-critical devices. However, those extreme precautions were based mainly on the risk of perforating the probe covers, which in recent studies were found to be of low incidence [6].

Finally, the difference in the risk of infection after examinations using vaginal probes with a sterile cover compared to digital examination using a non-sterile or sterile glove as performed routinely, is not clear. No similar guidelines for hand disinfection before and after digital vaginal examination have been issued. Although the risk of contamination is greatly reduced when disinfecting with high-level disinfectants [7], this procedure is not harmless and has several disadvantages that can endanger the patient's or the examiner's health and damage the quality of the transducers [23]. Therefore, we must consider whether to invest time, effort, and resources to prevent disease transmission even though the incidence and existence remain an unsolved mystery.

The pioneers of hygiene in obstetrics, Ignaz Philipp Semmelweis and Olivier Holmes, taught us the importance of preventing infections in the field of gynecology in general, and in obstetrics specifically [31,32]. We therefore emphasize the importance of maintaining a clean environment in a clinic, disinfecting hands, and changing gloves prior to the use of medically approved probe covers during a physical examination.

CONCLUSIONS

Future research should focus on defining the actual incidence of infections transmitted through endovaginal probes as these occurrences may be under-reported. This research may help to accurately define the risks of infection associated with endovaginal ultrasound examination, thereby determining the optimal methods for ultrasound probe disinfection.

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Capsule

Association of changes in effusion-synovitis with progression of cartilage damage over 18 months in patients with osteoarthritis and meniscal tear

Synovitis is a feature of knee osteoarthritis (OA) and meniscal tear and has been associated with articular cartilage damage. This study examined the associations between baseline effusion-synovitis and changes in effusion-synovitis with changes in cartilage damage in a cohort with OA and meniscal tear. **MacFarlane** and co-authors analyzed data from the Meniscal Tear in Osteoarthritis Research (MeTeOR) and analyzed 221 participants. Over 18 months, effusion-synovitis was persistently minimal in 45.3% and persistently extensive in 21.3% of the patients. The remaining 33.5% of the patients had minimal synovitis on one occasion and extensive synovitis on another. In adjusted analyses, patients with extensive effusion-synovitis at baseline had a relative risk (RR) of progression of cartilage damage depth of 1.7 (95% confidence interval [95%CI] 1.0–2.7). Compared to those with persistently minimal effusion-synovitis, those with persistently extensive effusion-synovitis had a significantly increased risk of progression of cartilage damage depth (RR 2.0, 95%CI 1.1–3.4). These findings indicate that the presence of extensive effusion-synovitis is associated with subsequent progression of cartilage damage over 18 months. The persistence of extensive effusion-synovitis over time is associated with the greatest risk of concurrent cartilage damage progression.

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Eitan Israeli

"Gratitude is a quality similar to electricity: it must be produced and discharged and used up in order to exist at all"

William Faulkner (1897–1962), American writer and Nobel Prize laureate