The importance of high-level disinfection of transvaginal ultrasound probes in OBGYN and MFM settings

Critical Summary

- The vaginal and uterine microbiome is important for establishing a favorable endometrial environment, for conception and during early pregnancy.
- Disruption of this microbiome, termed dysbiosis, is linked to infertility and adverse pregnancy outcomes.
- Preventing pathogen transmission into the vaginal and uterine microbiome is important to lower the risk of dysbiosis and associated infections.
- Transvaginal ultrasound probes should undergo high-level disinfection (HLD) and be used in conjunction with a sterile sheath, as per CSA guidance, to help prevent the risk of infection transmission.

The role of the vaginal microbiome in reproduction and pregnancy

The composition of the vaginal microbiome profoundly influences all stages of female reproduction from conception, throughout pregnancy, to birth.[1] A healthy microbiome helps establish a favorable endometrium environment, thereby improving the success of the reproductive process.[2-4] Furthermore, the continued balance of this microbiome aids the intricate process of sustaining the pregnancy to an adequate gestational age.[5]

It was once believed that the endometrium provided a sterile environment for fertilization and gestation.[6] Now, we know there are microbes present within the female genital tract that interact with and alter this environment.[3,7,8] A healthy vaginal microbiome includes both aerobic and anaerobic species, but is dominated by *Lactobacillus.*[1,5,9,10] Lactobacilli provide a front-line defense against pathogens through the production of hydrogen peroxide and lactic acid, as well as low-level immune system activation.[9,11] These processes help maintain a vaginal pH of <4.5 and create a hostile environment for colonization by other bacteria, viruses and fungi.[12]

An alteration or disruption of the composition of the vaginal microbiome is termed dysbiosis. Typically, this takes the form of a reduction in the prevalence of lactobacilli and an increase in competing species.[5] Dysbiosis can result from biological or hormonal changes, environmental factors like diet and nutrition, or infection.[5,13] It can have far-reaching effects on the uterine environment, leading to infection and adverse pregnancy outcomes.[4,5,9]

Dysbiosis increases infection risk

Dysbiosis can increase a patient's susceptibility to infections including bacterial vaginosis (BV), chronic endometritis (CE) and pelvic inflammatory disease (PID). These infections can lead to adverse maternal and neonatal outcomes[9], and diagnosis may be complicated as symptoms can vary and be mild, nonspecific or absent.[14]

Common infections of the female genital tract caused by dysbiosis

Bacterial vaginosis

BV is the most common cause of lower genital tract infections in women of reproductive age.[15] There is no single microorganism implicated in the diagnosis of BV, but rather a decrease in the prevalence of lactobacilli and overgrowth of competing bacteria.[5] BV can lead to an increased risk of many other infections of the reproductive tract.[9,16-19]

Chronic endometritis and pelvic inflammatory disease

When an infection, such as BV, ascends from the vagina, through the cervix, and into the endometrium or fallopian tubes, it can cause CE or PID.[5,9] CE is a persistent inflammation of the endometrial lining that commonly results from an altered endometrial microbiome.[20,21] PID can present with a variety of nonspecific symptoms and is associated with serious adverse health outcomes. Both CE and PID can develop secondary to BV, with more than 85% of cases of PID found to be caused by BV-related bacteria or sexually transmitted infections.[9]

Dysbiosis can lead to pregnancy complications

Dysbiosis has been linked to infections that disrupt the feto-placental complex[5], which may lead to preterm birth or pregnancy complications including pre-eclampsia, miscarriage, fetal growth restriction, stillbirth, low birth weight, and neonatal sepsis.[5,22]

Once within the uterine cavity, infectious agents induce the release of pro-inflammatory cytokines, prostaglandins and metalloproteases. These inflammatory agents trigger cervical ripening and weakening of membranes, potentially leading to prelabor rupture of membranes or preterm birth.[23-25] Intrauterine infection is implicated in up to 40% of cases of spontaneous preterm birth[26], and potentially preventable infections may account for up to 15% of early miscarriages and up to 66% of late miscarriages.[27]

Infections like PID can also cause adverse maternal outcomes including chronic pain, ectopic pregnancy and tubo-ovarian abscess.[28,29] The maternal microbiome also acts as a bacterial reservoir for microbial seeding of the newborn.[30] An initial exposure to a specific type of maternal microbiome has been shown to influence successive microbial patterns in the gut and can influence infant outcomes positively or negatively.[5] Microbes in the amniotic cavity can also trigger an inflammatory response, making neonates susceptible to adverse outcomes including early-onset neonatal sepsis, bronchopulmonary dysplasia and cerebral palsy.[5,26]

Epidemiological study finds patients undergoing transvaginal ultrasound were at a greater risk of infection

An epidemiological study commissioned by a national health authority revealed an unacceptable risk of infection associated with endocavitary ultrasound procedures including transvaginal (TV) ultrasound.[31] The longitudinal study followed 982,911 patient journeys retrospectively through linked national health databases over a period of six years. Gynecology patients undergoing TV scans were at a 41% greater risk of infection, and were 26% more likely to be prescribed antibiotics in the 30 days following the procedure, compared to those who did not receive TV scans.[27,31]

This heightened infection risk was attributed to clinically insufficient TV probe disinfection practices (low-level disinfection, LLD). The national health authority now mandates high-level disinfection (HLD) for all procedures utilizing a TV probe (Figure 1). The authors stated "failure to comply with [HLD] will continue to result in an unacceptable risk of harm to patients."[31]

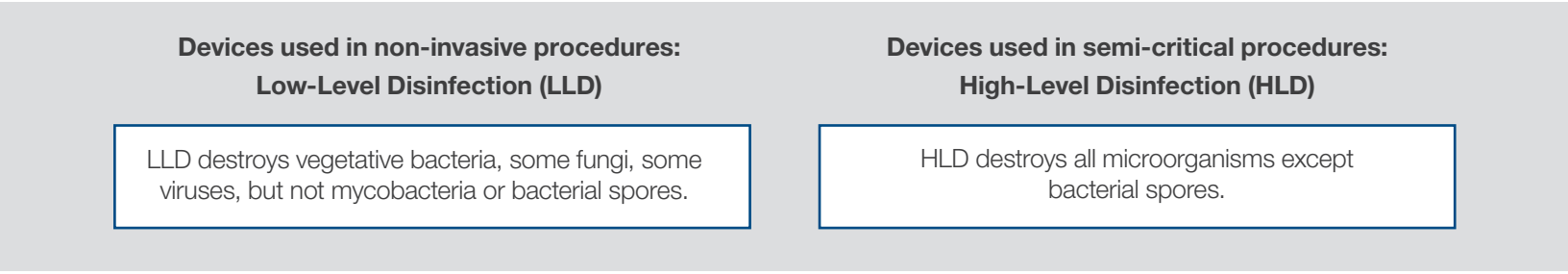

Figure 1. Levels of disinfection and criteria governing their use. Low-level and high-level disinfection have different spectrums of efficacy against microorganisms. An appropriate level of disinfection should be performed before reuse according to the intended use of the device.[32]

Ultrasound probes are contaminated even after LLD

Studies demonstrate that LLD wipes and sprays can fail to eliminate bacteria and viruses from covered TV probes after patient use.[33,34] A meta-analysis found a prevalence of 12.9% for frequently occurring bacteria and 1% for viruses on TV & transrectal probes after LLD wipes and sprays.[33] TV probes have also been found contaminated with pathogens that cause sexually transmitted infections like *Chlamydia trachomatis*, hepatitis C virus (HCV) and human papillomavirus (HPV), after LLD.[33,34]

HPV infection has been linked to the development of BV[35] and is associated with 99.7% of cervical cancers.[36] Random surveillance has shown that 3-7% of endocavitary probes remain contaminated with HPV DNA following disinfection with wipes and sprays.[34,37,38] HPV is a stable virus able to survive on fomites for extended periods of time, and is available for non-sexual modes of transmission.[39,40] Common ultrasound probe LLD wipe and spray chemistries (e.g. quaternary ammonium compounds) are not effective against native HPV.[41]

National standards and US Federal guidelines require transvaginal probes undergo HLD

Transvaginal ultrasound probes contact mucous membranes and are classified as semi-critical devices according to the Spaulding Classification. Canadian national standards, as well as US Federal guidelines, require TV ultrasound probes undergo a minimum of high-level disinfection, and be used in combination with a sheath, to help protect patients from infection risk.[32,42,43]

National standards

Ultrasound transducer probes that will come in contact with mucous membranes shall, at a minimum, be cleaned and undergo high-level disinfection according to the MIFUs. A clean or sterile sheath shall be applied to the probe before use as a semi-critical item. **-CAN/CSA 2018**[32]

Federal guidelines

Probes used in semi-critical applications should undergo sterilization between uses whenever feasible, but high level disinfection is minimally acceptable. In addition, the use of a sterile sheath is recommended for every semi-critical use of the probe. **-FDA 2019**[42]

For clinical applications of a semi-critical or critical nature (e.g., intraoperative, transrectal, transvaginal, transesophageal, or biopsy procedures), labeling should recommend, when appropriate, the use of sterile, legally marketed probe sheaths. **-FDA 2019**[42]

A vaginal probe and all endocavitary probes without a probe cover are semicritical devices because they have direct contact with mucous membranes (e.g., vagina, rectum, pharynx). While use of the probe cover could be considered as changing the category, this guideline proposes use of a new condom/probe cover for the probe for each patient, and because condoms/probe covers can fail, the probe also should be high-level disinfected. **-CDC 2008**[43]

Professional societies

Ultrasound transducers which come in contact with mucous membranes (transesophageal, transvaginal probes, etc.) and non-intact skin should be covered in a single-use clean/sterile probe cover just prior to the scan and removed prior to cleaning and sterilization or high-level disinfection. **– Sonography Canada 2018**[44]

All semi-critical equipment/devices that can be sterilized, will be sterilized according to the MIFU. If a semi-critical device cannot be sterilized, then it shall, at a minimum, be high-level disinfected according to the MIFU between patient uses (e.g. transvaginal probe). **– Infection Prevention and Control Canada (IPAC) 2019**[45]

Transvaginal ultrasound transducers always should be covered with a single-use disposable cover when used. However, disposable protective covers are not without risk of rupture or defect, and it is recommended that transvaginal ultrasound transducers undergo high-level disinfection between each use. **–ACOG 2016**[46]

After each use, transvaginal ultrasound probes should be cleaned and then treated with high-level disinfection. Wipe down and spray are low-level disinfection procedures and are not sufficient for transvaginal probes. **–SMFM 2020**[47]

Conclusion

Preventing pathogen transmission into the vaginal and uterine microbiome and the subsequent induction of a biotic imbalance is critical in OBGYN and MFM settings. Dysbiosis can cause infections that put patients at risk of pregnancy complications and adverse outcomes. Transvaginal ultrasound probes should undergo high-level disinfection and be used with a sterile sheath, per Canadian national standards, to help lower the risk of pathogen transmission and dysbiosis.

Contact us today to discuss your specific needs on when to HLD at your facility.

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