The importance of high-level disinfection of transvaginal ultrasound probes in fertility settings

Critical Summary

- The vaginal and uterine microbiome is important for establishing a favourable endometrial environment, successful implantation and for the conceptus during early pregnancy.
- Disruption of this microbiome, termed dysbiosis, is linked to infertility in prospective and retrospective trials.
- 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 Australian and New Zealand standards, to help prevent the risk of infection transmission.

The role of the vaginal microbiome in fertility

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 favourable endometrium environment, thereby improving the success of the reproductive process.[2-4]

It was once believed that the endometrium provided a sterile environment for fertilisation and gestation.[5] Now, we know there are microbes present within the female genital tract that interact with and alter this environment.[3,6,7] A healthy vaginal microbiome includes both aerobic and anaerobic species, but is dominated by *Lactobacillus*.[1,8-10] Lactobacilli provide a front-line defence against pathogens through the production of hydrogen peroxide and lactic acid, as well as low-level immune system activation.[8,11] These processes help maintain a vaginal pH of <4.5 and create a hostile environment for colonisation 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.[9] Dysbiosis can result from biological or hormonal changes, environmental factors like diet and nutrition, or infection.[9,13] It can have far-reaching effects on the uterine environment, leading to failed fertility cycles, infection, and adverse pregnancy outcomes.[4,8,9]

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). BV, CE and PID have all been linked to infertility[8], 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.[9] BV can lead to an increased risk of many other infections of the reproductive tract.[8,16-19]

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.[8,9] 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.[8]

Dysbiosis can cause failed fertility cycles

As well as having a role in susceptibility to infection, the uterine and vaginal microbiota also influence endometrial receptivity, and dysbiosis has been associated with implantation failure or pregnancy loss.[4]

The outcome of IVF is influenced by the composition of the vaginal microbiome on the day of embryo transfer.[22] Women with a lower prevalence of vaginal lactobacilli are less likely to have successful embryo implantations.[23] while other dysbiotic states are also associated with poor reproductive outcomes following IVF.[24]

Dysbiosis can also increase a woman's susceptibility to genital tract infections[9], which in turn can lead to failed fertility cycles. BV can decrease conception rates and may also increase early pregnancy losses.[25-27] Women with CE also have lower implantation rates[20], with one study identifying CE in 30.3% of women with repeated implantation failure at IVF.[28] Managing infections like BV and CE could reduce the number of treatment cycles needed, increase pregnancy rates, and have beneficial effects on couple well-being and healthcare costs.[1]

Dysbiosis can lead to pregnancy complications

Dysbiosis has also been linked to infections that disrupt the feto-placental complex[9], which may lead to preterm birth or pregnancy complications including pre-eclampsia, miscarriage, fetal growth restriction, stillbirth, low birth weight, and neonatal sepsis.[9,29] 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 prelabour rupture of membranes or preterm birth.[30-32]

Infections like PID can cause pregnancy complications including ectopic pregnancy and tubo-ovarian abscess.[33,34] Intrauterine infection is implicated in up to 40% of cases of spontaneous preterm birth[35], and potentially preventable infections may account for up to 15% of early miscarriages and up to 66% of late miscarriages.[36]

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.[37] The longitudinal study followed 982,911 patient journeys retrospectively through linked national health databases over a period of six years. Gynaecology 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.[36,37]

This heightened infection risk was attributed to clinically insufficient TV probe disinfection practices (low-level disinfection, LLD). The national health authority now mandates HLD for all procedures utilising 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."[37]

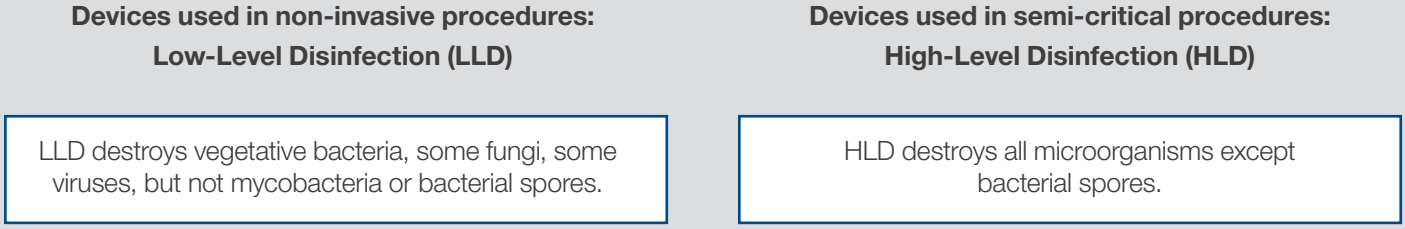

Figure 1. Levels of disinfection and criteria governing their use. Low-level and high-level disinfection have different spectrums of efficacy against microorganisms. An appropriate level of disinfection should be performed before reuse according to the intended use of the device.[38]

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.[39,40] 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.[39] 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.[39,40]

HPV infection has been linked to the development of BV[41] and is associated with 99.7% of cervical cancers.[42] Random surveillance has shown that 3-7% of endocavitary probes remain contaminated with HPV DNA following disinfection with wipes and sprays.[40,43,44] HPV is a stable virus able to survive on fomites for extended periods of time, and is available for non-sexual modes of transmission.[45,46] Common ultrasound probe LLD wipe and spray chemistries (e.g. quaternary ammonium compounds) are not effective against native HPV.[47]

National standards and guidelines require transvaginal probes undergo HLD

Transvaginal ultrasound probes contact mucous membranes and are classified as semi-critical devices according to the Spaulding Classification. Australian and New Zealand national standards and 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.[38,48]

National Standards

Semi-critical reusable medical devices require cleaning followed by high-level disinfection at a minimum. **-AS/NZS 4187:2014**[38]

Cleaning, disinfection or sterilization, as appropriate, of reusable medical devices shall be performed between uses even if a single use sheath/sleeve/protective barrier is used. **-AS/NZS 4187:2014**[38]

Items that come into contact with mucous membranes or non-intact skin … should be single use or sterilized after each use. If this is not possible, high-level disinfection is the minimum level of reprocessing that is acceptable. **-ACSQHC 2020**[49]

Professional Societies

Ultrasound transducers that come into contact with non-intact skin and/or mucous membranes and transducers that have had likely contact with blood/body fluids are considered as semi-critical medical devices due to the high risk of potential contamination. These transducers are reprocessed by cleaning followed by a high-level disinfection method. **-ACIPC / ASUM 2017**[48]

Conclusion

Preventing pathogen transmission into the vaginal and uterine microbiome and the subsequent induction of a biotic imbalance is critical for successful fertility treatment. Dysbiosis can cause infections that put patients at risk of failed fertility cycles and adverse pregnancy outcomes. Transvaginal ultrasound probes should undergo high-level disinfection and be used with a sterile sheath, per Australian and New Zealand 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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