Summary and Methods

The authors discuss the need for a current study, testing the integrity of commonly utilized ultrasound probe barriers used in clinical practice for transvaginal ultrasound examinations. In this study, ten different commercial cover and condom brands with a sample of 500 each, both latex and non-latex, were tested (5,000 in total). All probe barriers were collected post-examination and subjected to a water leak test. Those broken upon application to the probe were recorded, as well as any breaks or micro-tears found during the water leak test. Photographs were also used as a form of documentation. Statistical analysis was then performed.

Discussion and Results

Many practices today use condoms as a barrier for transvaginal probes due to guidelines referencing studies published over two decades ago, which evaluated commercial covers and condoms no longer on the market. These studies relied on data with limited sample sizes and claimed condoms performed better and had fewer tears than commercial probe covers. There are a wide variety of commercial covers and condoms currently on the market. They range in quality as well as type, including latex and non-latex. Probe barriers can break in two ways: non-clinical, which occur while applying the cover to the probe; and clinical, which occur while the ultrasound examination is performed. A 1995 study reported a breakage rate of 81% for probe covers, and other outdated studies reported condoms had a lower breakage rate than probe covers. For this reason, many clinics and departments use condoms as a probe barrier during transvaginal ultrasound examinations. A new study was needed to evaluate the probe covers and condoms currently on the market and to provide current data for healthcare professionals. A multi-site study was performed using 5,000 commercial covers and condoms – 500 each of ten different brands. The probe barriers were collected after the ultrasound examination and subjected to a water leak test, which consisted of filling each cover or condom with water and assessing for micro-tears and leaks. Breaks that occurred during deployment onto the probe were also reported.

The breakage rate for latex condoms was 0.4%-2.6%, while latex commercial covers breakage rate was 0.6-5.0%. Interestingly, the non-latex commercial covers had a breakage rate of 0.0-1.0%, while non-latex condoms had a breakage rate of 13%. CIVCO NeoGuard™ non-latex covers had zero breaks in 500 samples (0.0%), and CIVCO latex covers had three breaks in 500 covers (0.6%).

Conclusions

Commercial probe covers have been vigorously tested for quality assurance and compatibility with substances such as ultrasound gel, while condoms are off label for use as a barrier for transvaginal ultrasound. This study, with its large sample size and variety of brands and types of barriers, is the first to conclude that non-latex commercial covers have a lower failure rate than condoms for transvaginal ultrasound exams. In a study published in 2017, 14% of transvaginal probes were contaminated with bacterial growth after the removal of a probe sheath. Therefore, per guidelines and recommendations, all transvaginal probes should be high-level disinfected when exposed to mucus membranes because of the potential for a commercial cover or condom to break.