**INTRODUCTION**

Stress Urinary Incontinence (SUI) describes urine leakage when abdominal pressure suddenly increases, which commonly occurs during a cough, sneeze, or physical exertion.

**BACKGROUND**

- **Applying Pressure Ablation Penetration Technology to the Bladder:** With the addition of an air-filled balloon to the bladder, the intravesical pressure increase is dampened or attenuated. This limits the rate of pressure increase in the bladder, and for short events, limits the maximum pressure that will occur in the bladder associated with pressure events. Ablation is driven by sustained pressure, it should not be affected by the presence of the balloon.

**RESULTS (CONT’D)**

**MATERIALS AND METHODOLOGY**

**Introduction**

The balloon is thin and has a low mass. It is constructed of polyurethane film - a material with a long history of biocompatibility, including use in the urinary tract. With pressurization, the balloon is expected to remain closed during events with high intravesical pressure. When an incontinent patient is allowed to engage in physical exertion, a balloon will expand and press down on the urinary bladder causing a corresponding increase in abdominal pressure.

**Experimental Setup**

- **Pressure Chamber for In-vitro Experiment:** A 0.6 liter acrylic chamber built with a valve that seals the balloon. The In-vitro experiment was designed to evaluate its ability to attenuate intravesical pressures due to short-duration transient pressure events, and to aid in the understanding of the underlying mechanism of action of the observed circumferential effect.

**Results**

- **Figure 1:** Reduction of Intravesical Pressure with Vesair Balloon, 130cc pulse.
- **Figure 2:** Intravesical Pressure in the chamber, with and without the balloon.
- **Figure 3:** Applied Pressure to Generate a 70cmH2O Intravesical Pressure with the balloon in place.
- **Figure 4:** Applied Pressure to Generate a 70cmH2O Intravesical Pressure with balloon not in place.

**DISCUSSION**

The in-vitro simulation provides a demonstration of how the physics of an air-filled pressure attenuator system works. It verifies the magnitude of the attenuation obtained in an experiment that simulates physiological parameters, which help explain the statistically significant improvements in incontinence symptoms in two published multi-center randomized trials (Rovner et al., Wyndaele et al.).

**CONCLUSIONS**

For volumes and pressures that approximate physiological values, significant pressure attenuation can be obtained using a balloon volume less than 10% of typical functional bladder capacity. The findings warrant further investigation into the use of an air-filled balloon attenuator to reduce leakage associated with stress urinary incontinence.

**References**


**Figure 1:** Reduction of Intravesical Pressure with Vesair Balloon, 130cc pulse.

**Figure 2:** Intravesical Pressure in the chamber, with and without the balloon.

**Figure 3:** Applied Pressure to Generate a 70cmH2O Intravesical Pressure with the balloon in place.

**Figure 4:** Applied Pressure to Generate a 70cmH2O Intravesical Pressure with balloon not in place.

**Figure 5:** Applied Pressure to Generate a 140cmH2O Intravesical Pressure with balloon not in place.

**Figure 6:** Applied Pressure to Generate a 140cmH2O Intravesical Pressure with balloon not in place.

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