HOW DOES A COMPLIANT AIR−FILLED INTRAVESICAL BALLOON INCREASE THE ABDOMINAL PRESSURE REQUIRED TO INDUCE STRESS URINARY INCONTINENCE (SUI) RELATED LEAKAGE?

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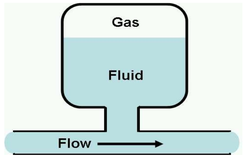
INTRODUCTION

- **Stress Urinary Incontinence (SUI)** related urine leakage occurs when intravesical pressure momentarily exceeds the urethral pressure, which commonly occurs during a cough, sneeze, or physical exertion.
- **Historically, most SUI treatments have focused on increasing urethral closure pressure** (i.e., improving the urethra's ability to remain closed during events with high intravesical pressure.)
- **Rovner et al[1] separately evaluated an air-filled intravesical balloon** as a means to reduce transient intravesical pressure and urinary leakage. Rovner reported a statistical difference in the number of patients that did not leak during a VLPP test with a balloon vs. control patients without a balloon.
- **An In-vitro experiment** was devised 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 clinical effect.

BACKGROUND

- **Air-based pressure attenuation is common** in many non-medical applications as a means to control pressure transients[2].

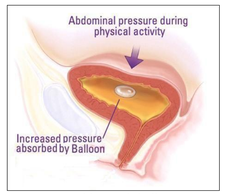
Gas-filled pulsation dampener for minimizing hydraulic shock in fluid-handling applications.[3]



Schematic drawing of a gas-filled hydropneumatic accumulator.[4]

- **Fluids are effectively non-compressible, but gases are compressible**. The behavior of a gas can be described by Boyle's Law: P1V1 = P2 V2. Using this derivative of the Ideal Gas Law as a reference, consider that in response to a pressure transient, P1→P2→P1, an air-filled balloon will momentarily contract to a new smaller volume, V2. This contraction has a time constant that is proportional to the volume of air within the balloon, thus slowing the rate of increase of pressure.
- **Abdominal pressure transients are strongly related to leakage** associated with stress urinary incontinence. When an incontinent patient laughs, coughs, or sneezes, for example, abdominal muscles tighten and cause an increase in abdominal pressure. This abdominal pressure in turn, presses down on the urinary bladder causing a corresponding increase in intravesical pressure. If the intravesical pressure exceeds the urethral closure pressure then leakage occurs.

Without balloon



With Vesair balloon

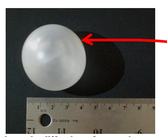
BACKGROUND (CONT'D)

- **Applying Pressure Attenuation 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. Micturition is driven by sustained pressure, it should not be affected by the presence of the balloon.

MATERIALS AND METHODOLOGY

The Vesair ®Balloon

- **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. A one-way valve seals the balloon after filling with air.
- **The buoyancy of the balloon makes it inherently non-occlusive**. Since it is free-floating and not anchored in any way, it will naturally float at the top of the bladder.
- **Insertion Device**. The balloon is inserted deflated, inside the tip of a lubricated catheter-like 18F inserter. It is inflated once it is inside the bladder, and released.

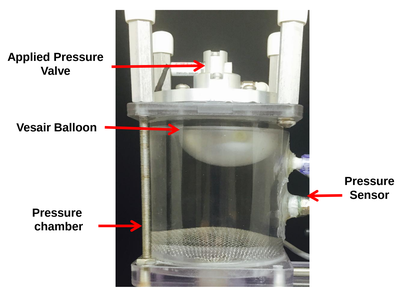


Thin, air-filled polyurethane balloon

Vesair Balloon delivery system

The In-Vitro Simulator

- **Pressure Chamber for In-Vitro Simulation**. In-vitro feasibility assessment of its pressure attenuation capability was made using a custom-built bench-top acrylic chamber. (Picture shown below).
- **Physiological Parameters** were generated in the chamber to simulate transient pressure events in the bladder which commonly induce leakage. Computer controlled valves, connected to an air source, were used to apply pressure to a 250cc chamber to various transient pressures in two experiments:
  1. Compare the Intravesical Pressure with and without the balloon with a fixed applied pressure on the chamber.
  2. Compare the applied pressure required to generate a fixed intravesical Pressure in the chamber, with and without the balloon.



RESULTS

Experiment 1:

The results of the in−vitro measurements using a 20 msec pulse in the acrylic chamber are shown in Figure 1. For a balloon volume of 30ml, the amplitude of a transient pressure pulse was reduced by 81% from 140cmH_2O to 27cmH_2O.

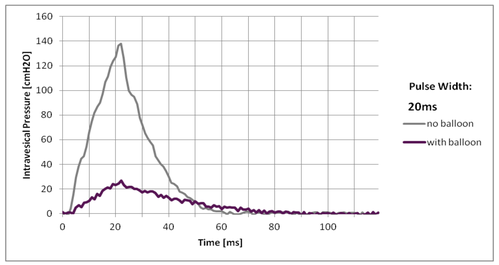


Figure 1: Reduction of Intravesical Pressure with Vesair Balloon, 20msec pulse.

The results of the in−vitro measurements using a 40 msec pulse in the acrylic chamber are shown in Figure 2. For a balloon volume of 30 ml, the amplitude of a transient pressure pulse was reduced by 65% from 140 cm H_2O to 49 cm H_2O.

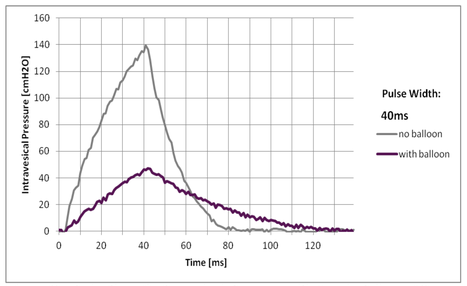


Figure 2: Reduction of Intravesical Pressure with Vesair Balloon, 40msec pulse

The results of the in−vitro measurements using a 80 msec pulse in the acrylic chamber are shown in Figure 3. For a balloon volume of 30 ml, the amplitude of a transient pressure pulse was reduced by 40% from 140cmH_2O to 84cmH_2O.

RESULTS (CONT'D)

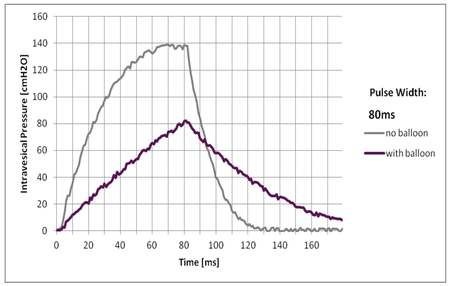


Figure 3: Reduction of Intravesical Pressure with Vesair Balloon, 80msec pulse.

Experiment 2:

The results of the in-vitro measurements of the applied pressure required to generate a 70cmH_2O Intravesical Pressure are shown in Figure 4. 269cmH_2O of applied pressure was required to generate a 70cmH_2O Intravesical Pressure with the balloon in place.

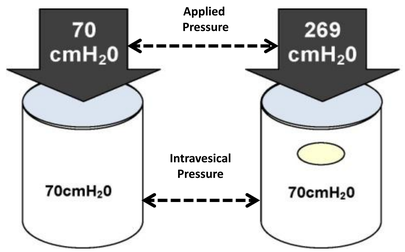


Figure 4: Applied Pressure to Generate a 70cmH_2O Intravesical Pressure with/without Balloon (40 msec pulse)

The results of the in-vitro measurements of the applied pressure required to generate a 140 cmH_2O Intravesical Pressure are shown in Figure 5. >350cmH_2O of applied pressure was required to generate a 140cmH_2O Intravesical Pressure with the balloon in place.

RESULTS (CONT'D)

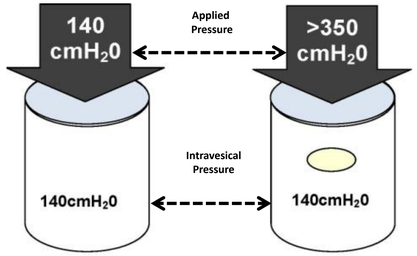
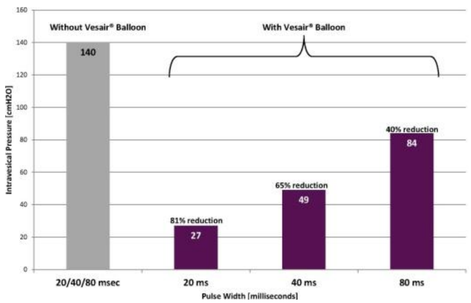


Figure 5: Applied Pressure to Generate a 140cmH_2O Intravesical Pressure with/without Balloon (40 msec pulse)

DISCUSSION

The in-vitro simulation provides a demonstration of how the physics of an air-based pressure attenuator system works. It verifies the magnitude of the attenuation obtained in an experiment that simulates physiological parameters, which helps explain the statistically significant improvements in incontinence symptoms in two published multi-center randomized trials (Rovner et at[1], Wyndaele et al[5]).



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 air−filled balloon attenuator to reduce leakage associated with stress urinary incontinence.

References

1.Rovner et al, A Randomized, Controlled Clinical Trial of a Novel Intravesical Pressure Attenuation Device for the Treatment of Stress Urinary Incontinence. J Urol. 2013; 190: 2243-50

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3.Thomas M. Walski et al. Advanced Water Distribution Modeling and Management (Waterbury CT USA. Haested Press 2003) 607-609

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5.Wyndaele et al, A Randomized, Controlled Clinical Trial of an Intravesical Pressure Attenuation Balloon System for the Treatment of Stress Urinary Incontinence in Females. Neurourol Urodyn. 2015 Jan 16. DOI: 10.1002/nau.22708

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