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HOW DOES A COMPLAINT AIR FILLED INTRAVESICAL BALLOON DECREASE INTRAVESICAL PRESSURE CHANGES TO REDUCE LEAKAGE ASSOCIATED WITH STRESS URINIARY INCONTINENCE?

Hypothesis / aims of study

Stress Urinary Incontinence related urine leakage occurs when intravesical pressure momentarily exceeds the urethral pressure, which commonly occurs during a cough, sneeze, or physical exertion. A recent published study[i] clinically evaluated an air-filled intravesical balloon as a means to reduce transient intravesical pressure and urinary leakage. The study reported a statistical difference in the number of patients with the Vesair® intravesical balloon that did not leak during a VLPP test vs. control patients without a balloon. The authors have assessed an attenuator device in-vitro to evaluate its ability to reduce or suppress leakage by attenuating intravesical pressures due to short-duration transient pressure events. The authors have also assessed the increase in abdominal pressure required to generate a defined intravesical pressure when the balloon is in place in an in-vitro model.

Study design, materials and methods

A Vesair balloon was constructed of thin polyurethane material with a one-way valve to permit filling with air. In-vitro feasibility assessment was made using a custom-built bench-top acrylic chamber. Computer controlled valves, connected to a compressed air source, were used to pressurize a 250cc chamber to transient pressure of 70 and 140 cm H_2O to simulate an intravesical pressure which may result in stress urinary incontinence leakage. Pressure in the chamber was recorded without the balloon, and then with a 30ml balloon. Pressure pulse duration was 20 msec, 40 msec, 80 msec and 120 msec to represent a typical duration of a leakage-inducing transient pressure event. In a separate test, the intravesical pressure in the chamber with the balloon was set to both 70 and 140cmH20 at the pulse widths mentioned above and the external pressure exerted on the chamber was then recorded (simulated abdominal pressure).

Results

The results of the in-vitro measurements using a 20 and 40msec pulse in the acrylic chamber are shown in Figures 1 and 2. For a 20msec pulse, the amplitude of a transient pressure pulse was reduced by 80% from 140 cm H_2O to 28 cm H_2O when a balloon is placed in the chamber. For a 40msec pulse, the amplitude of a transient pressure pulse was reduced by 65% from 140 cm H_2O to 49 cm H_2O. The required simulated abdominal pressure increased 238% to 334cm H20 to generate a 140cmH20 intravesical pressure (at 80msec) when the balloon was placed in the chamber (Figure 3).

Interpretation of results

The in-vitro test results are consistent with engineering and physics principles. For volumes and pressures that approximate physiological values, very significant pressure attenuation can be obtained using a balloon volume that is approximately 10-15% of a typical functional bladder capacity.

Concluding message

The findings warrant further investigation into the use of air-filled balloon attenuators as a means 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 No. 6: 2243-50

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

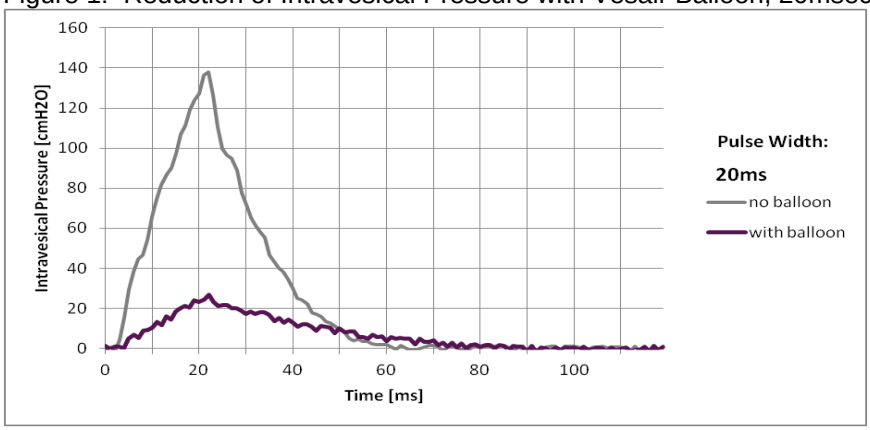

Figure 2: Reduction of Intravesical Pressure with Vesair Balloon, 40msec pulse.

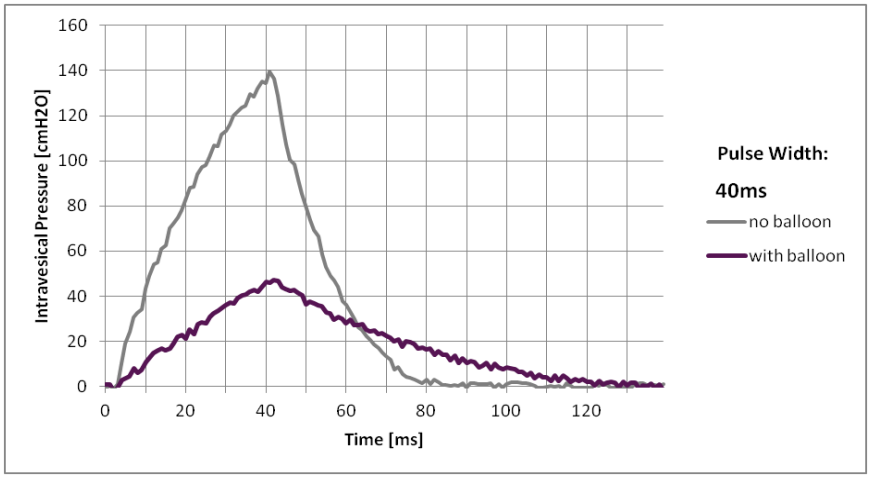

Figure 3: Increase in Abdominal Pressure required to generate 140cmH20 Intravesical Pressure Pulse with Vesair Balloon.