161

Lopez M[1], Snyder J[2]
1. *Hospital de Clinicas Caracas,* ***2.*** *Genitourinary Surgical Consultants , Denver*

CAN AN AIR-FILLED INTRAVESICAL BALLOON IN-VIVO ATTENUATE PRESSURE AND RAISE THE ABDOMINAL PRESSURE AT WHICH STRESS URINARY INCONTINENCE RELATED LEAKAGE OCCURS?

Hypothesis / aims of study

Stress Urinary Incontinence related urine leakage occurs when intravesical pressure momentarily exceeds the urethral pressure (the fluid pressure needed to just open a closed urethra). This commonly occurs, for example, during a cough, sneeze, or physical exertion. If the intravesical pressure change caused by such events can be reduced, there is the potential to reduce or eliminate this leakage. The authors have preliminarily assessed a novel intravesical balloon pressure attenuator device, both in-vitro and in-vivo, to determine its ability to reduce or suppress leakage by attenuating intravesical pressures due to short-duration transient pressure events.

Study design, materials and methods

A balloon was constructed of thin polyurethane material. A one-way valve permitted it to be filled with various volumes of air. In-vitro feasibility assessment of its pressure attenuation capability was made using a custom-built bench-top acrylic chamber. The chamber was designed to simulate a transient pressure event in the bladder similar to those which commonly induce leakage in patients with stress urinary incontinence. The chamber volume of 250 ml was chosen to simulate a typical functional capacity of a female bladder. Computer controlled valves, connected to a compressed air source, were used to pressurize the chamber to a pressure of 140 cm H_2O to simulate an intravesical pressure which might result in stress urinary incontinence leakage. Pressure in the chamber was recorded without the balloon, and then for a series of balloon air volumes ranging from 0 to 25 ml. Pressure pulse duration was chosen to be 80 milliseconds to represent a typical duration of a leakage-inducing transient pressure event, as estimated based on examination of conventional urodynamics charts chosen at random. In-vivo testing was performed under an approved clinical research protocol. Five female patients with stress urinary incontinence, having a mean age of 59.4 (range, 48-72) were enrolled into the study. Conventional urodynamic studies were conducted. Abdominal pressure was measured using a rectal catheter. These studies were conducted both immediately prior to balloon insertion and approximately 24 hours later.

Results

The results of the in-vitro measurements using the acrylic chamber are shown in Figure 1. For a balloon volume of 25 ml, which corresponds to the volume used in the in-vivo study, the amplitude of a transient pressure pulse was reduced by 48% from 144 cm H_2O to 74 cm H_2O. The in-vivo results are summarized in Figure 2. In 4 of the 5 patients an increase was noted in the lowest abdominal pressure at which leakage occurred. In patient #5, no leakage was observed up to the pressure shown.

Interpretation of results

The in-vitro test results are consistent with engineering and physics principles. Addition of a balloon attenuator to a fluid-filled chamber reliably attenuates the peak pressure observed in the chamber in response to a pressure stimulus. For volumes and pressures that approximate physiological values, very significant pressure attenuation (approx. 50%) can be obtained using a balloon volume that is just 10% of a typical functional bladder capacity. This in-vitro result predicts that in-vivo a higher abdominal pressure would be needed for leakage to occur *with* the balloon than *without* the balloon. It follows logically that if the balloon can have this effect, then a reduction in stress urinary incontinence leakage in some patients should occur. The in-vivo results support the in-vitro prediction, showing that either a higher abdominal pressure was needed for leakage to occur, or leakage was suppressed altogether. Review of other objective evidence (for example, flow rate and post-void residual both before and after the balloon insertion) supports a finding that the result is due to the device's pressure attenuation effect and not due to any obstructive phenomenon.

Concluding message

The findings are promising enough to warrant further investigation into the use of air-filled balloon attenuators as a means to reduce leakage associated with stress urinary incontinence.

Figure 1: In-Vitro Pressure Attenuation Due to an Air-Filled Balloon at a Range of Volumes

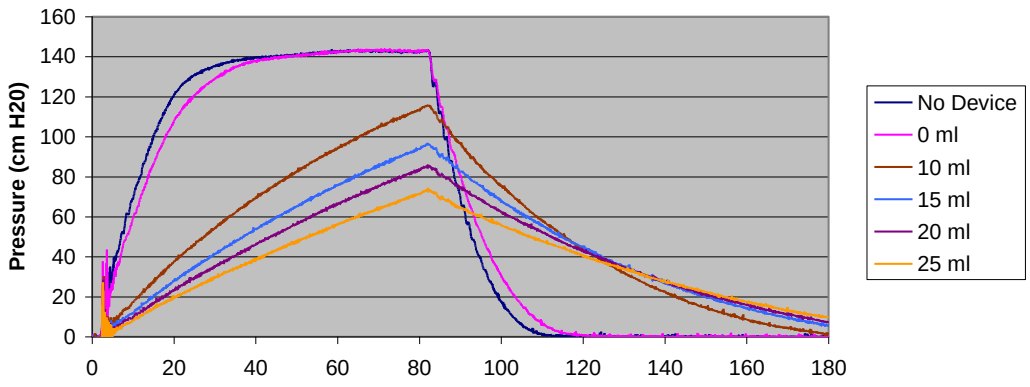
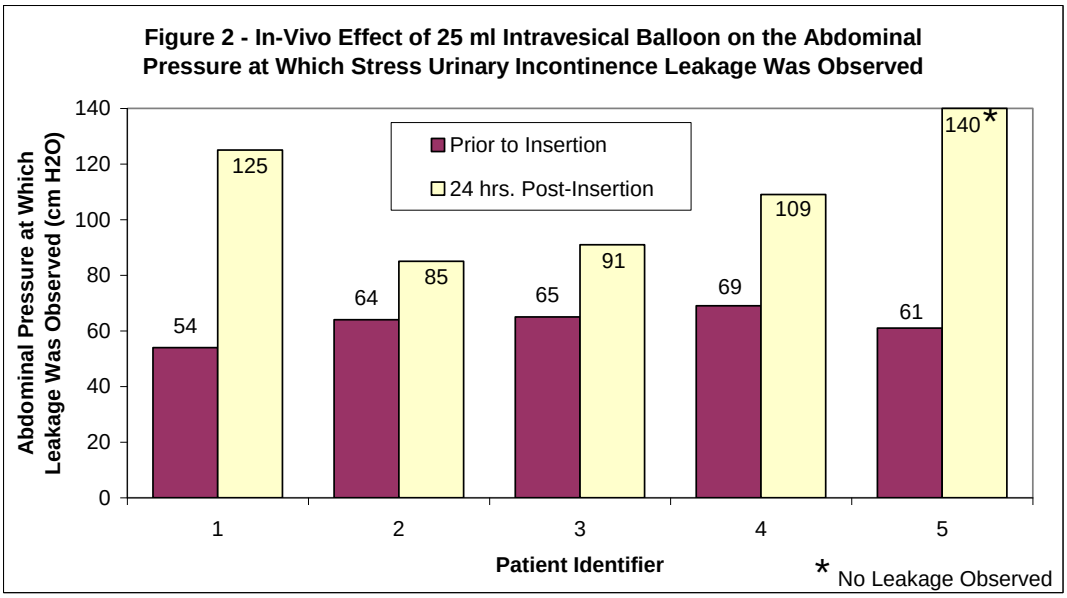


Figure 2 - In-Vivo Effect of 25 ml Intravesical Balloon on the Abdominal Pressure at Which Stress Urinary Incontinence Leakage Was Observed



Specify source of funding or grant	**Solace Therapeutics, Inc.**
Is this a clinical trial?	**Yes**
Is this study registered in a public clinical trials registry?	**No**
What were the subjects in the study?	**HUMAN**
Was this study approved by an ethics committee?	**Yes**
Specify Name of Ethics Committee	**Medical Ethics Committee of Hospital de Clinicas Caracas; Caracas, Venezuela**
Was the Declaration of Helsinki followed?	**Yes**
Was informed consent obtained from the patients?	**Yes**