ANALYSIS OF SEDIMENT FORMATION ON LONG-TERM INDWELLING FREE-FLOATING INTRAVESICAL BALLOONS FOR THE TREATMENT OF SUI FROM TWO MULTICENTER RANDOMIZED CONTROLLED CLINICAL STUDIES

Stefan De Wachter1, JJ Wyndaele1, Eric Ravner2, Karrey Jacob3, Roger Dmochowski4, Giovanni Tommaselli5, 6, Susan Kalota6, Gommert van Koeveringe7


Introduction

• A novel free floating, non-occlusive, compliant intravesical balloon filled with compressible gas has been evaluated in US and European multi-center randomized controlled clinical trials for the treatment of SUI. The balloon aims to reduce transient spikes in intravesical pressure that are common to all forms of SUI, regardless of their etiology.

• 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 associated with stress related to leakage then leakage occurs.

• Fluids are effectively non-compressible, but gases are compressible. The behavior of a gas can be described by Boyle’s Law: P1V1=P2V2. Using this derivative of the Ideal Gas Law as a reference, consider that in response to a pressure transient, P1+P2+P3, 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.

• 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. Mitigation is driven by sustained pressure. It should not be affected by the presence of the balloon.

• Encrustation is a concern with any intravesical device, as the chemical constituents of the urine combine with the device to produce a matrix for the growth of stones. This formation may impact the efficacy of the device or result in stones dislodging from the device and becoming obstructive.

Materials and Methodology

This study evaluated a total of 635 balloons removed from patients from two separate clinical studies.

Methods and Materials (cont’d)

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 inflated, inside the tip of a lubricated catheter-like 18F inserter. It is inflated once it is inside the bladder, and released.

Results (cont’d)

Study 1

482 (89.4%) of the balloons in Study 1 had no measurable sediment formation (Score = 0). 33 had a score of 1, 15 had a score of 2, four had a score of 3 and three had a score of 4. All sediment for balloons with a score greater than 1 was located at the valve/seam interface.

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Discussion

The Vesair Balloon is unlike other urological devices that remain in the urinary tract for extended periods of time. It is highly buoyant and floats at the top of the bladder, and moves continually as the patient moves, and contracts and expands with changes in intravesical pressure. Sediment formation was much less than expected, and the balloon design changes implemented in Study 2 further reduced sediment formation.

The Vesair Balloon is remarkably free of significant mineral deposit. Further study is required to better understand which of these factors resulted in the reduction of sediment formation.

Conclusion

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References

2. Rovner et al., A Randomized, Controlled Clinical Trial of a Novel Intravesical Pressure-Attenuation Device for the Treatment of Stress Urinary Incontinence. Urology. 2013, 83, 2243-50