RESULTS

INTRODUCTION

MATERIALS AND METHODOLOGY

This study evaluated a total of 642 balloons removed from patients from two separate clinical studies. The Vesair® Balloon

- The balloon is thin and has a low mass.
- The buoyancy of the balloon makes it inherently non-obstructive.
- With Vesair balloon, the balloons were inserted deflated, inside the bladder and released.

A one-way valve weekly balloon system. Balloons and catheters were analyzed after removal from the patient to evaluate the formation of calcium oxalate by SEM Analysis.

The Vesair® Balloon

- It is a seamed pressure-attenuation balloon with a valve welded into the seam (Figure 3A) that was filled with 15cc of air.

RESULTS

Study 1

- 462 (89.9%) of the balloons in Study 1 had no measurable sediment formation (Score <1).
- 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/beam interface.

Study 2

- 101 (86%) of the balloons in Study 2 had no measurable sediment formation (Score = 0).
- The remaining four balloons had a score of 1. None of these 4 balloons were associated with a UTI and all 4 met efficacy endpoints.

DISCUSSION

- The Vesair Balloon is unlike other urological devices that remain in the urinary tract for an extended period of time.
- Previous analysis demonstrated that the balloon is highly buoyant and floats at the top of the bladder, not at the base of the bladder where sediment resides. The balloon moves continually as the patient moves, and contracts and expands with changes in intravesical pressure.

CONCLUSION

- Sediment formation was much less than expected.
- There was no correlation between sediment formation and UTI.
- Resolution of UTI with the balloon indwelling was achieved.

Ten patients were diagnosed with a single UTI during Study 2. Eight resolved their UTI symptoms with the balloon in place. Two patients had the balloon removed prior to resolution. All 10 balloons had a sediment score of 0 when eventually removed.

Overall, in both studies:

- Any sediment formation that was measurable on the devices did not affect the device functionality and did not result in any obstructive issues.
- Representative samples of sediment from balloons were determined to be calcium oxalate by SEM Analysis.

REFERENCES


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