#264 Implantation of an intravesical balloon absorbs increases in intra-abdominal pressure and reduces complaints of stress urinary incontinence, a video urodynamic study

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Introduction

A novel therapeutic option for SUI patients utilizes the insertion of a small air-filled balloon into the bladder transurethrally. The air-filled balloon is proposed to serve as an efficient and minimally invasive treatment option for patients. Since gasses compress more easily than liquids, the balloon has been proposed to act as an absorber for increases in intravesical pressure in response to an increase in intra-abdominal pressure. We hypothesize that during coughing episodes the size and volume of the balloon, measured during video urodynamic investigation, will decrease as a result of successful transfer of abdominal pressure to the air-filled balloon. Absorbance of the increase in intra-abdominal pressure by the balloon is expected to cause a reduction in incontinence episodes or volume.

Methods

We recruited 10 female patients with SUI according to ICS criteria (mean age: 55.6, SD 7.8). The video urodynamic studies of 6 patients could be evaluated for this analysis after balloon implantation (4 patients had missing data due to technical difficulties).

After implantation of the balloon, participants were invited for a follow-up visit approximately 7-10 days after balloon placement and underwent a video urodynamic investigation at a sampling rate of 20 frames per second while participants were exposed to episodes of high intra-abdominal pressure using Valsalva maneuvers and coughing episodes during bladder filling with 100ml of saline with a contrast medium.

We designed a custom MATLAB (MathWorks, R2018b) script which enabled us to subtract information regarding the size of the balloon in an automated fashion. After optimizing the contrast of each frame of the video urodynamic assessment, we manually defined a cut-off gray value that would allow for the most optimal differentiation between the balloon and the rest of the image. Images were then converted to binary images where each pixel above our threshold was assigned the value 1 (white) and each other pixel 0 (black). The largest continuous object consisting of white pixels was considered to correspond to the balloon and was selected for further processing. The coordinates of the edge extremities (Fig. 1.A) of this object were computed and plotted over the original image grayscale image. Correspondence of the computed dimensions of the balloon with the original image were then visually verified by the researchers. The diameters of the balloon along the mediolateral axis (horizontal, or x direction) and cranio-caudal axis (vertical, or y direction) were then used for frame-by-frame computing of the size of an ellipse corresponding to the size of the balloon.

The difference between the maximal (rest) and minimal (high intra-abdominal pressure) size of the computed ellipse during the video urodynamic assessment was statistically assessed using an SPSS 26 (IBM, 2019) implementation of the Wilcoxon Signed-Rank non-parametric test. Since the abdominal pressure forces emerging from the coughing episodes travel in a cranio-caudal fashion we expect the dimensions of the balloon to mainly be affected in the vertical (y) direction. We tested this by statistically assessing the difference between the maximal and minimal diameters of the balloon along the y direction using a Wilcoxon Signed-Rank test.

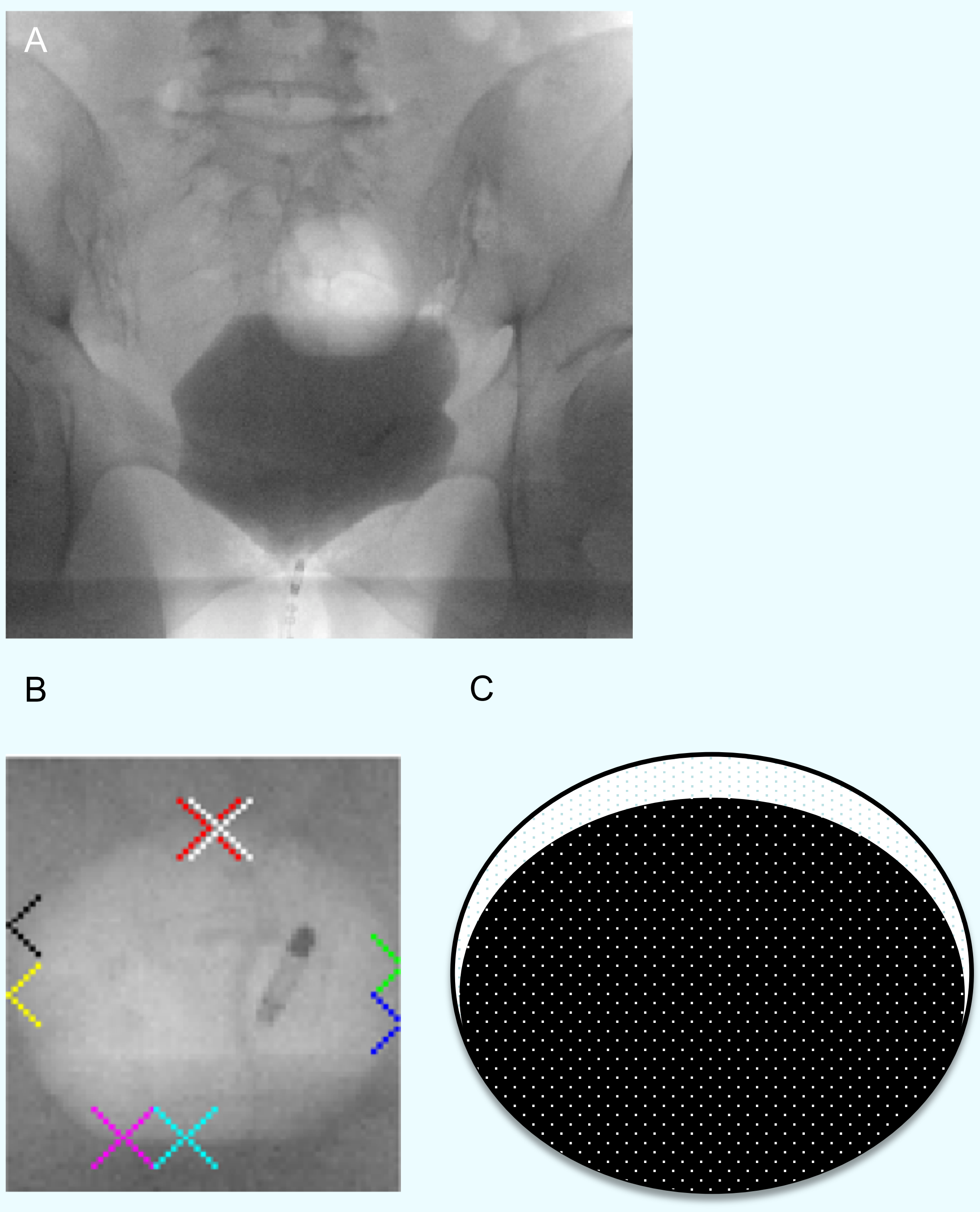

*Figure 1: **A)** Gross overview of the intravesical balloon inside the bladder. **B)** Example of a projection of the extremities of the balloon as determined by the script projected over the original grayscale image. **C)** Illustration of the change in size and cranio-caudal diameter of the intravesical balloon as seen in the frontal plane. Maximal size is indicated by the dotted pattern and minimal size is indicated by the dark patterned area. The surface area of the ellipse based on diameters of the balloon along the mediolateral and cranio-caudal axis significantly decreased during coughing ($p = 0.028$). Mean decrease = 9.26%, SD = 2.44, mean minimal ellipse = 3485.34 pixels, SD = 1558.53, mean maximal ellipse = 3945.58 pixels, SD = 1804.63. Additionally, the decrease of the cranio-caudal diameter of the balloon also proved to be significant ($p = 0.028$). Mean decrease = 11.5%, SD = 3.61, mean minimal vertical diameter = 59 pixels, SD = 12.92, mean maximal vertical diameter = 65 pixels, SD = 13.93.*

Results

The surface area of an ellipse based on the dimensions of the balloon in the frontal plane was found to significantly decrease in size during coughing episodes ($p = 0.028$, mean decrease = 9.26%, SD: 2.44) (Fig. 1.B). Because abdominal pressure forces due to coughing mainly travel in cranio-caudal (vertical) direction we, additionally, assessed changes in the diameter of the balloon along the vertical axis and found a significant decrease of the diameter of the balloon during coughing ($p = 0.028$, mean decrease = 11.5%, SD: 3.61, $n = 6$) (Fig. 1.B).

Conclusion

The dimensions of the balloon in the frontal view show a significant decrease during episodes of high abdominal pressure, mainly along the cranio-caudal axis. We argue that the decrease in size of the balloon is a direct result of compression of the air inside the balloon. This indicates that the balloon is successful in absorbing at least part of the intra-abdominal pressure which is transferred to the bladder. Thereby decreasing the extent to which the intravesical pressure increases in response to episodes of high intra-abdominal pressure.

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