

HOW LONG SHOULD BE THE MINI-SLING? - PROSPECTIVE OBSERVATIONAL CASE-CONTROL STUDY

Hypothesis / aims of study

There is no reliable data what mini-sling length should actually be used for bilateral anchor to the obturator complex. There is evidence from cadaver and imaging studies of interpersonal variability in pelvis diameters, particular in the distance from the urethra to the obturator foramen(1) This may well imply that some mini-slings will not fit all patients. Obturator complex is desired structure for anchoring all single incision slings for the treatment of stress urinary incontinence. It has certainly been shown that not all of the mini-slings reach the desired anchoring structure. We know that in some mini-slings the efficacy is low.(2) But we do not know why.

We aim to use the mini-sling with adjustable length to measure and assess the variability of the inserted sling length in patients treated by this method. We also intend to establish whether there is a correlation with biometry parameters (height, BMI) or if tensioning the tape is affected. We will use the inside-out system (TVT Abbrevio) as a control group for tensioning comparison.

Study design, materials and methods

In all patients with urodynamic stress incontinence successfully treated with adjustable mini-sling (Ajust) we measured and calculated the exact sling length we really used. After the adjustment of the sling we are able to exactly assess the used length by measuring the distance of back pushed lock and subtract this from the original length of the sling. Secondly, we assess patients by introital ultrasound and we measure in the midsagittal plane the distance between the lower margin of symphysis and the sling: symphysis-sling gap. This establishes the tightness of the insertion. We use as a control group patients with successfully treated patients with transobturator sling (TVT Abbrevio) with similar in-out technique for controlling of the tightness of Ajust sling. We provide a descriptive statistical analysis of measured parameters and any correlation between them, using the Pearson correlation coefficient. For comparison of two methods, after normality testing we use the t-test for independent variables.

Results

In our prospective observational case study during the period from 1/2013 to 9/2014 we included 54 patients who had successfully undergone a procedure with the mini-sling Ajust, with adjustable length, and 45 patients with TVT Abbrevio. The average length of Ajust used was 9.6 cm (min 6, max 11.6; CI 95% 9.3-10.0) (Graph 1).

For these patients mean BMI was 26.6 (min 19.1 – max 42.5; CI 95%, 25,3-27.9), and mean height was 165.1 cm (min 154, max 178; CI 95% 164.2 – 167.2).

The mean gap between the tape and the lower margin of the symphysis during the Valsalva maneuver - was 12.3mm, (min 6; max 22; CI 95% 11.2-13.5),

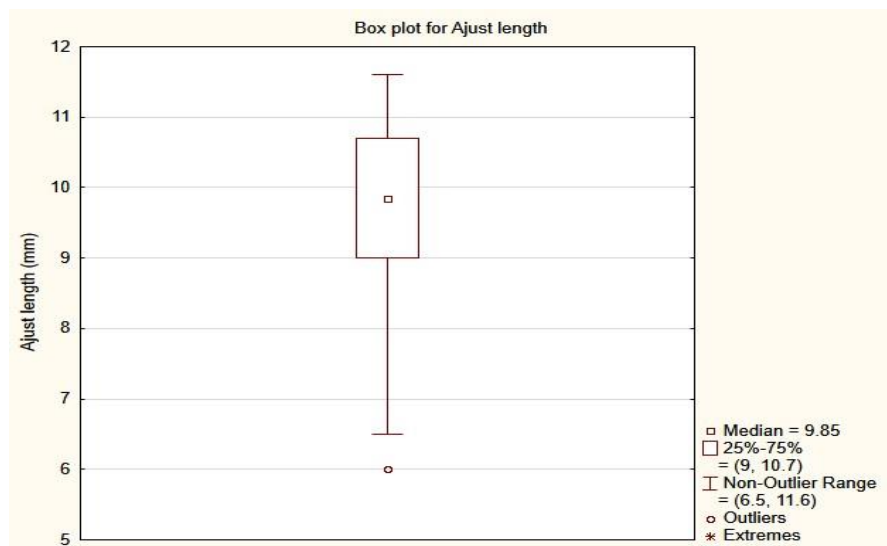
Correlation between the tape length and BMI was not statistically significant (Correlation coefficient 0.24; p=0.18), and this also applied to height (Correlation coefficient 0.20; p=0.26) (Graph 2)

In the TVT Abbrevio group the mean BMI was 25.8 (min 19.9 max 37.5; CI 95% 24.6-27.1).

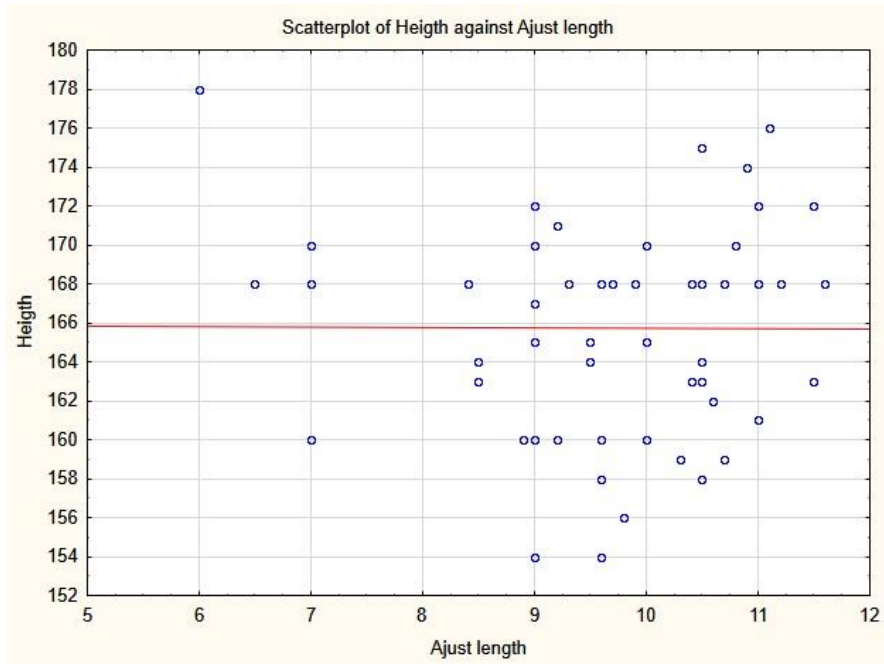
The mean gap between the tape and lower margin of the symphysis was 11.6 mm (min 7 max 18, CI 95% 10.8-12.5).

There was no statistically significant difference in tightness in comparison of both tapes. 12.3mm vs 11.6 mm (t-test; p=0.13)

Bearing in mind the data gained from measuring the Ajust length (max 11.6), it appears that our reference tape TVT Abbrevio, with a length of 12cm, should be sufficient to reach the obturator complex in all patients.



Graph 1 – Used Ajust length



Graph 2 – Correlation between Ajust used length and height.

Interpretation of results

We firstly provide real clinical data about the variability of the length of sling required in order to reach the designed fixing structures. More important than the mean used length (9.6 cm) are the limits. The variability is large, from 6 cm to 11.6 cm, which is a difference of 98%. We are not able to predict the desired length using the most common biometrical parameters such as height or BMI. Single incision sling Ajust is tensioned as same as TVT Abbrevio.

Concluding message

Our study shows the limits of single incision slings for reaching desired anchoring structure and gives reference data for further comparison with unsuccessfully treated patients.

References

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2. Masata, J., K. Svabik, K. Zvara, P. Drahoradova, R. El Haddad, P. Hubka, and A. Martan, Randomized trial of a comparison of the efficacy of TVT-O and single-incision tape TVT SECUR systems in the treatment of stress urinary incontinent women-2-year follow-up. *Int Urogynecol J.* 2012.

Disclosures

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