Author's response to reviews

Title: Transversal incision of the vagina favors the remaining of the tape in the middle-third urethra compared to longitudinal incision during transobturator sling procedures for stress urinary incontinence

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Version: 4
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Author's response to reviews: see over
Response to reviewers letter

Letter to the editor

Dear editor,

Thank you very much for taking the time to evaluate our manuscript. We consider the reviewers' comments very valuable and we revised the manuscript according to them. Please let us know if further modifications are required.

Best regards,
Laurentiu Pirtea

Reviewer's report

Title: Transversal incision of the vagina favors the remaining of the tape in the middle-third urethra compared to longitudinal incision during transobturator sling procedures for stress urinary incontinence

Version: 2 Date: 4 May 2015

Reviewer: Tarik Yonguc

Reviewer's report:

Dear Editor,

I reviewed the manuscript entitled "Transversal incision of the vagina favors the remaining of the tape in the middle-third urethra compared to longitudinal incision during transobturator sling procedures for stress urinary incontinence". It is an interesting study with a novel incision technique for the treatment of stress urinary incontinence. The authors described a new type of incision of the vagina during transobturator sling procedure and assessed the outcomes of the procedure at 1-year follow-up. The strength of the study is the prospective design and the weaknesses are no control group, no validated questionnaires for patient evaluation, not well documented outcomes except location of the tape.

Comments for the authors:

Minor Essential Revisions:
1. Abstract: Although in methods; it is written as “Tape position was evaluated by ultrasound at 6 and 12 months after surgery”, in Results location of the slings were documented at 3, 6 and 12 months.
L.Pirtea: You are right, we modified in the text

Major Compulsory Revisions
1. Background: Line 5 it is stated that “Tape position along the urethra after the mid-urethral sling procedures seems to play a role in the development of the de novo urgency and voiding difficulties” but the authors should also state that tension of the tape has an impact on voiding functions. Line 13 "We noticed that original technique describes a 2-2.5 cm longitudinal incision of the vaginal mucosa." This sentence should be revised because Delorme described technique as "A vertical midline vaginal incision is made in the middle third of the urethra passing through the whole thickness of the vaginal wall. Starting at the incision, the vagina is released laterally on either side of the urethra with Mayo scissors over a width of approximately 15 mm." (Transobturator tape (Uratape): a new minimally-invasive procedure to treat female urinary incontinence. Eur Urol. 2004 Feb;45(2):203-7).
L.Pirtea: You are absolutely right, thank you for this observation. Indeed Delorme describes a lateral opening of the vagina of about 15mm on each side, but in Williams Gynecology By Schorge J.O. 2008, Mc Graw Hill pg 984 the vaginal incision is described: “a midline incision made sharply in the vaginal epithelium beginning at 1cm proximal to the urethral meatus and extended 2-3 cm”. I think your observation is correct and we rephrased : “The length of the vertical vaginal incision varies from 1,5cm to 2-3cm according to different authors (Delorme.Transobturator tape (Uratape): a new minimally-invasive procedure to treat female urinary incontinence. Eur Urol. 2004 Feb;45(2):203-7); Schorge JO Williams Gynecology 2008 Mc Graw Hill pg 984)”

2. Materials and Methods: Line10 the sentence "We did not used stitches to suture the polypropylene tape to the vagina [6]." can be deleted.
L.Pirtea: We deleted the sentence;” we did not used stitches to suture the polypropylene tape to the vagina”

3. The authors performed urodynamic study to exclude detrusor instability but they did not state the number of patients with detrusor instability and how many of them were excluded. All?
All patients with detrusor instability were excluded. We inserted in the text: “Further urodynamic assessment was performed and all patients with detrusor instability were excluded “
4. The authors should describe the postoperative assessment of incontinence, CST?
L. Pirtea: Your observation is correct. We inserted in the text: “The rate of continence after surgery was assessed using the cough test.”

5. Results: If it is possible It would be better to show the outcomes of the study in a table.
L. Pirtea: 2 tables indicating the continence rate and sling position were inserted.

6. The complications are not well documented. There are no data about postoperative voiding dysfunction and leg/groin pain.
L. Pirtea: Your observation is correct. Regarding the leg/groin pain, we had no such complication but this is most likely linked to the limited number of cases (we expect the same incidence as the standard technique). We specified in the text. Regarding the postoperative voiding dysfunction: we had no cases of urine acute retention, and to show if using our technique is actually lowering the incidence of the novo urgency we need more cases (for power calculation). This is something we are working on and subject to some other report. In this article we want to assess mainly the position of the tape.

7. Discussion: Line 7 the sentence “the original technique…” should be revised.
L. Pirtea: The observation is correct. We revised the sentence and inserted the description of technique available in Williams Gynecology 2008 pg 984: “a midline incision of the vaginal mucosa between two Allis clamps, the first one placed 1 cm proximal to the external urethral meatus and the second one 2-3 cm cephalad.”

8. Discussion: The authors stated that the position of the tape is associated with postoperative voiding dysfunction but they did not assess postoperative voiding functions in their study.
L. Pirtea: Your observation is correct. We will use citation only, as this is not a result of our study: "Tape location at proximal urethra and at the level of the bladder neck is considered a possible cause of de novo urgency and voiding dysfunction after TOT [4]". 4. Yuan-Hong Jiang, Chung-Cheng Wang, Fei-Chi Chuang, Qian-Sheng Ke, Hann-Chorng Kuo (2013) Positioning of a Suburethral Sling at the Bladder Neck Is Associated With a Higher Recurrence Rate of Stress Urinary Incontinence. J Ultrasound Med; 32:239–245

9. The authors should write a limitation paragraph.
L. Pirtea: This is fair. We inserted a limitation paragraph: "The main limitation of our study is represented by the lack of a control group including patients operated by the same team using the
vertical incision. We considered that the data available for the vertical incision are very consistent and we used them for comparison”.

10. The most important point about the transversal incision type is the long suture line parallel to the tape which can lead to more mesh exposures. Although the authors did not encounter mesh exposure, presumably the reason may be due to small sample size.

L.Pirtea: You are correct. We inserted in the text: “Using the transversal incision we create a suture line parallel to the sling which can lead to mesh exposure. We had no such cases but we need to validate that on a larger group of patients”

Level of interest: An article of importance in its field
Quality of written English: Acceptable
Statistical review: No, the manuscript does not need to be seen by a statistician.
Declaration of competing interests:
I declare that I have no competing interests

Letter to the reviewer 3 (Tarik Yonguc)

Dear Sir,

Thank you very much for evaluating our manuscript.
Thank you for your valuable comments; we revised our manuscript according to them.

Thank you very much for considering our manuscript of importance in its field.
Best regards,
Laurentiu Pirtea

Reviewer's report
Title: Transversal incision of the vagina favors the remaining of the tape in the middle-third urethra compared to longitudinal incision during transobturator sling procedures for stress urinary incontinence
The Authors describe very well the surgical technique, which has been applied in 51 consecutive patients, but the results lack of statistical comparison with a group of patients treated by traditional TOT technique.

L. Pirtea: We agree that the lack of a control group of patients operated by the same surgeon using the standard technique is the main limitation of our study. But on the other hand there is a lot of data available in literature in terms of sling position after surgery and we choose to use that for comparison. I think that using the standard technique our results in the control group should have been the same as described in literature. But for sure having a control group would add strength to our study.

References are up to date. Major revision of English language is needed.

L. Pirtea: We had our article revised a native English speaker in order to improve the quality of the written English.

Level of interest: An article of importance in its field
Quality of written English: Not suitable for publication unless extensively edited
Statistical review: No, the manuscript does not need to be seen by a statistician.
Declaration of competing interests:
I declare that I have no conflict of interest.

Letter to reviewer 1 (Eva Intagliata)

Dear reviewer,

Thank you very much for taking time to evaluate our manuscript
We consider your comments valuable in order to improve our paper.
Thank you very much for considering our article as one of interest in its field.

Best regards,
Laurentiu Pirtea
Reviewer's report

Title: Transversal incision of the vagina favors the remaining of the tape in the middle-third urethra compared to longitudinal incision during transobturator sling procedures for stress urinary incontinence

Version: 2
Date: 30 April 2015
Reviewer: Osman As&quest;e;oglu

Reviewer's report:

1) In material-method part, of the article, they expressed that they used sample size calculation but in the article number of samples were calculated and determined by power analysis. Also, the success rate mesh localization is given as 54%, but there isn't such un exact data in the sample article and the urethral range that is considered to be succesful isn't as 40-60% in the sample article.

L. Pirtea: We used for comparison the study of Bogusiewicz et al 2014. They found that the percentage of slings that remained at the level of mid urethra was 54%. You are right: we defined midurethral area as 40-60% of urethral length and the sample article uses 50-70%, but we considered that middle third of urethral lenght is better represented by our percentage.

2) In power analysis, in the sample article measured time was given as 24 months. In this article measures were done after 6 months. There isn't any exact daha with 24 month.

L. Pirtea: We agree that the sample article evaluated the position of the sling at 24 moths. Our study evaluated the position of sling at 3, 6 and 12 months. And at 12 months the results were the same as 6 months. We belive that the process of fibrosis is completed after 12 months and the probability to have significat differences at 24 months is low. But in terms of statistics you are absolutely right and we will continue to monitor our cases.

3) In the study, why the midurethral area was defined as 40-60%, should be explained, because in the sample article this defined as 50-70%

L. Pirtea: You are correct. We agree that we defined midurethral area as 40-60% of urethral length and the sample article uses 50-70%, but we considered that middle third of urethral lenght is better represented by our percentage.

4) In this article, the number of patients and duration of six month is not seem to be sufficient to arrive to a definite conclusion.

L. Pirtea: We agree that number of patients (51) is not very high but according to our calculation the power of our study is over 90 %. The duration of our study is 12 months.
5) In the article, discussed references and highlighter spots are inadequate.

Level of interest: An article whose findings are important to those with closely related research interests

Quality of written English: Needs some language corrections before being published

Statistical review: Yes, but I do not feel adequately qualified to assess the statistics.

Letter to reviewer 2 (Osman As....)

Dear sir,

Thank you very much for taking time to evaluate our manuscript.

We consider your observation valuable in order to improve our paper.

Thank you very much.

Best regards,

Laurentiu Pirtea