Does a midurethral sling inserted at the time of pelvic organ prolapse mesh surgery increase the rate of de novo OAB? A prospective longitudinal study

Czy założenie taśmy podcewkowej jednoczasowo z korekcją zaburzeń statyki dna miednicy zwiększa częstotliwość występowania de novo OAB? – prospektywne badanie obserwacyjne

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Abstract

Objectives: Approximately 20% of women suffer from pelvic organ prolapse (POP) and stress urinary incontinence (SUI). Furthermore, POP and overactive bladder (OAB) symptoms often coexist. Midurethral slings and mesh surgeries are both considered to be risk factors for de novo OAB symptoms. The aim of our study was to determine whether simultaneous midurethral sling insertion at the time of pelvic organ prolapse mesh surgery further increases the risk of de novo OAB.

Materials and methods: The study group consisted of 234 women who underwent surgery in our department between August 2007 and October 2009 (114 patients underwent surgery because of coexisting POP and SUI, and 120 underwent surgery because POP alone). The patients were evaluated at follow-up visits scheduled after 6-8 weeks and after 12 months. All women underwent surgery using the Gynecare Prolift® Pelvic Floor Repair System, whereas in women with additional overt or occult SUI after restoration of the pelvic anatomy, monofilament midurethral slings were simultaneously inserted. The chi-squared test was used to compare the study groups.

Results: De novo OAB symptoms were significantly more pronounced among women in the Prolift® only surgery group (23.3%) compared to the Prolift® with IVS04M group (10.5%; p=0.0093).

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**Streszczenie**

*Introduction* Około 20% kobiet uskarża się jednocześnie na zaburzenia statyki dna miednicy i nietrzymanie moczu. Wykazano również, że występowaniu objawów OAB towarzyszą istotnie klinicznie zaburzenia statyki. Z drugiej strony zarówno slingu podcewkowego jak też operacje rekonstrukcyjne z użyciem siatek noszącą ze sobą ryzyko wystąpienia de novo objawów OAB. Celem naszego badania było ustalenie, czy jednoczesne zakładanie slingu podcewkowego podczas operacji rekonstrukcyjnej niesie ze sobą podwyższenie ryzyka wystąpienia de novo pooperacyjnych objawów OAB.

*Materiał i metody:* Grupa badana obejmowała 234 pacjentki leczone w klinice pomiędzy sierpniem 2007 a październikiem 2009 (u 114 pacjentek wykonano operację korygującą statykę dna miednicy oraz wysiłkowe nietrzymanie moczu, a u 120 kobiet korygowano jedynie zaburzenia statyki). Pacjentki były oceniane 6-8 tygodni oraz 12 miesięcy po zabiegu. Wszystkie pacjentki operowano z użyciem monofilamentowych siatek polipropylenowych (Gynecare Profill® Pelvic Floor Repair System), natomiast u pacjentek z objawowym bądź ukrytym nietrzymaniem moczu jednoczasowo zakładano sling podcewkowy. Obie grupy porównywano wykorzystując test chi2.

*Wyniki:* De novo objawy OAB wystąpiły częściej u pacjentek, u których korygowano jedynie statykę dna miednicy (23.3%) w porównaniu do pacjentek, u których dodatkowo zakładano sling podcewkowy (10,5%; p=0,0093).

*Niniejszy:* Jednoczesne zakładanie slingu podcewkowego podczas operacji rekonstrukcyjnej dna miednicy nie zwiększa ryzyka wystąpienia pooperacyjnych objawów nadreaktywności miejsiienia wypieracza. Jednocześnie niepowodzenie anatomiczne operacji rekonstrukcyjnej jest czynnikiem ryzyka wystąpienia de novo pooperacyjnych objawów OAB.

*Słowa kluczowe:* chirurgia rekonstrukcyjna dna miednicy / siatki polipropylenowe / pecherz nadreaktywny / wysiłkowe nietrzymanie moczu /

**Conclusions:** Midurethral sling insertion at the time of pelvic organ prolapse surgery significantly decreases the rate of postoperative de novo OAB symptoms. The lack of anatomical success of the mesh-based reconstructive surgery is a risk factor for the development of de novo OAB symptoms.

**Key words:** anti-incontinence surgery / lower urinary tract symptoms / mesh surgery / overactive bladder / pelvic organ prolapse / urinary incontinence /
Does a midurethral sling inserted at the time of pelvic organ prolapse mesh surgery increase the rate of de novo OAB?

**Materials and methods**

Between August 2007 and October 2009, 427 women underwent surgery in the II Department of Gynecological Medical University of Lublin, Poland either for POP or SUI coexisting with POP. The study was approved by Bioethics Committee at the Medical University of Lublin, and patients signed informed consent. We strictly followed the STROBE guidelines of reporting the observational studies [20]. The criteria for enrolment in this study were as follows: group I - patients with SUI and POP, as indicated by a full clinical examination, including the medical history, a complete gynaecologic examination and the cough provocation test performed in the supine and standing positions with a comfortably full bladder, always after prolapse reposition with a Kallmorgen speculum; group II - patients suffering from POP symptoms only. Additionally, all patients enrolled in the study were free of any other gynaecological diseases, and they did not have any OAB symptoms (daytime frequency or urgency incontinence confirmed by a 3-day bladder diary). Based on these criteria, 121 patients with POP and SUI (group I) and 143 with POP alone (group II) were enrolled in the study. The patient flow chart is shown in Figure 1. In total, 234 women were available for evaluation throughout the complete follow-up period. All women underwent surgery with the Gynecare Prolift® Pelvic Floor Repair System (Ethicon, Johnson & Johnson, Sommerville, NJ, USA), whereas women with additional overt or occult SUI after restoration of the pelvic anatomy received a simultaneously inserted midurethral monofilament transobturateur sling (IVS-04M, Coviden, France). All women were evaluated after 6-8 weeks and 12 months postoperatively. The patients were considered completely cured when they were free of all subjective POP and SUI symptoms as confirmed by the medical history, a full clinical examination and the cough and pad tests. The operation was considered a failure in terms of continence restoration if the patient still reported urine leakage during increased intra-abdominal pressure or if the cough test or pad test was positive.

The group of patients who experienced improvement, the cough test was negative but the patients still reported occasional urinary leakage, or the pad test was negative, but the increase in pad weight was less than 1g but not 0g. Patients were also asked to record all micturitions and any urgency episode for 3 consecutive days before the follow-up visit. Traditionally, the occurrence of seven episodes of micturition during waking hours has been taken as the upper limit of normal bladder condition. Eight or more micturitions accompanied by urgency and more than one episode of nocturia are the criteria for diagnosing de novo OAB. The chi-squared test was used to compare the difference between the study groups. To achieve a power of 80% with a p value of less than 5% in our trial, based on the literature, we assumed a 20% rate of de novo OAB after mesh surgery and an additional 6.5% risk of de novo OAB symptoms after simultaneous MUS placement. Based on these assumptions, our calculations showed that the study groups should consist of at least 93 patients each to enable proper statistical analysis. Because there are no published data on the incidence of de novo OAB after simultaneous POP mesh restoration supplemented with MUS, we also calculated the power of our study after receiving the results. Post hoc calculation showed that the power of this study reached 100% because the difference between de novo OAB incidence in study groups was higher than we expected. All statistical tests were 2-sided. The level of significance was set at p<0.05. Statistical analysis was performed using Statistical package version 8.0 (StatSoft®, Poland).

**Results**

The patients’ demographic data are provided in Table I. Optimal and/or satisfactory anatomical correction (0 and I according to POPOP) were observed in 97 (85.1%) and 106 (88.4%) patients from group I and II, respectively ($\chi^2 = 0.838, p = 0.845$), whereas in 3 (2.6%) and 6 (5%) women, recurrent POP was observed ($\chi^2 = 0.822, p = 0.364$). All anatomical recurrences occurred within the first 6-8 weeks and were found at the first follow-up visit. All of these women who had stage II prolapse without any additional symptoms did not require any additional surgical procedure. De novo SUI occurred in 10 patients (8.3%) in Group II.
Figure 1. Flow of participants through each stage of the trial.

Table II. De novo OAB symptoms in relation to stress incontinence surgery outcome in patients with concomitant SUI – 12 months follow-up.

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Prolift® with IVS-04M (n=114)</th>
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<tbody>
<tr>
<td></td>
<td>Clinical outcome</td>
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<tr>
<td></td>
<td>Failure</td>
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<tr>
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<td>Improved</td>
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Discussion

There are many possible theories regarding the underlying mechanism of OAB in relation to POP, and it is likely that bladder obstruction itself also plays an important role [11]. POP can cause bladder outlet obstruction (BOO) because of urethral kinking leading to decreased urine flow [21]. Other possible mechanisms responsible for OAB symptoms are changes in the spinal micturition reflexes caused by BOO [22]. Overactive bladder symptoms are among the most common functional complications after surgical treatment of POP and stress urinary incontinence. These symptoms can occur after any type of incontinence or mesh reconstructive surgery, and they may significantly impair the patient’s quality of life. It should also be stressed that even after successful surgical correction of prolapse, women still have a risk of developing OAB symptoms. This risk may also be increased due to the relatively old age of this population and irreversible changes in the muscle, nerves and supportive connective tissue. The mechanisms that are responsible for de novo OAB symptoms after POP surgery are still poorly understood; however, several hypotheses are currently being considered.

We have to admit that there is a theoretical possibility that the observed differences in OAB symptoms might have been
raised due to different pathophysiology in these two groups and not due to the presence or absence of a sling, but such clinical scenario is, in our opinion, very questionable. For women with POP and concomitant overt or occult SUI, many urologists or gynecologists would perform a sling at the time of POP surgery. However, in some hospitals incontinence surgery is not performed at the time of vaginal repair but at later date, only if clinically necessary. This approach is based on the observation that around 1/3 of SUI sufferers were cured after prolapse surgery alone [23]. Of course our study was not aimed to answer very important clinical question if women with POP and no SUI should have a prophylactic sling? On the other hand the results of our study clearly show that concomitant POP and incontinence surgery could improve final functional outcome in terms of de novo post-op OAB symptoms.

In the present study, we demonstrated that the rate of de novo OAB symptoms among patients after mesh surgery for advanced POP was as high as 23.3%. This is in contrast with data showing that the prevalence of de novo OAB after mesh reconstructive surgery was only 2% [24]. On the other hand, the majority of authors reported that surgery for POP reduced the symptoms of OAB if they were present before the surgery. The postoperative symptoms of OAB, namely frequency, urgency and urgency incontinence, were completely resolved in 60, 70 and 82% of women, respectively [25]. Additionally, a causative relationship between OAB and POP, clearly indicating that the POP surgery often improves or even completely cures OAB symptoms was suggested [11]. In fact, in our study, the post-operative OAB symptoms were present in 100% of patients with anatomical failure of reconstructive surgery (POP-Q stage III). The same was reported by others, who found that the transvaginal mesh surgery for anterior vaginal wall prolapse was associated with an overall resolution of most symptoms associated with overactive bladder syndrome and bladder outlet obstruction [26]. Additionally, some authors clearly indicated a strict relationship between anterior and posterior vaginal wall prolapse and OAB symptoms. In their report, surgical repair of POP resulted in a significant improvement in urgency and frequency, whereas anterior repair alone provided an improvement in the urgency incontinence rate [27]. Contrary to these findings, some investigators did not observe any such correlations [28]. On the other hand, it was reported that OAB symptoms decreased after POP surgery, with frequency and urgency being more likely to improve compared to urgency incontinence and nocturia.

However, de novo OAB symptoms appeared in 5-6% of women [6]. Similar to our results, it was found that approximately 20% of women who underwent surgery for POP developed OAB soon after the surgery. De novo OAB was diagnosed in 19.8% patients, and the median time of onset of de novo OAB symptoms after surgery was 3 months, which might suggest that excessive fibrosis caused by the prostheses might be involved as an etiological factor [29]. In our study, the incidence of de novo OAB symptoms among patients who underwent surgery for POP and concomitant SUI was 10.5%. The reported rate of de novo postoperative OAB after sling surgery according to various studies ranges from 6% to 33% [16, 30]. On the other hand the estimated risk for de novo OAB symptoms after concomitant prolapse repair and sling procedures was 10%, which is in accordance with our findings [31]. It should be mentioned that currently there is no consensus regarding the indications for concomitant anti-incontinence surgery among patients who underwent surgery for POP. Most likely, the outcome of the CUPIDO trial will provide the definitive answer for this extremely important clinical question. But we have to remember that, if the patient is suffering from SUI along with pelvic organ prolapse and we did not add a sling during primary procedure, patient is at much higher risk of developing de novo OAB. As a professionals we perfectly know that if patients suffers from OAB symptoms the last therapeutic option we will think of, to cure it, will be the midurethral sling. Our results show that we can decrease this risk by half simply by adding sling during primary procedure.

Conclusions

We can conclude that concomitant anti-incontinence surgery in patients who undergo surgery for advanced POP does not cause an increase of de novo OAB symptoms. Instead, the procedure significantly decreases this possibility. Furthermore, the lack of anatomical success of mesh-based reconstructive surgery is a risk factor for the development of de novo OAB symptoms.
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References