

# 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 jednocześnie z korekcją zaburzeń statyki dna miednicy zwiększa częstość 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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**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 /**

## Streszczenie

**Cel pracy:** Około 20% kobiet uskarża się jednocześnie na zaburzenia statyki dna miednicy i nietrzymanie moczu. Wykazano również, że występowaniu objawów OAB towarzyszą istotne klinicznie zaburzenia statyki. Z drugiej strony zarówno slingi podcewkowe jak też operacje rekonstrukcyjne z użyciem siatek niosą ze sobą ryzyko wystąpienia de novo objawów OAB. Celem naszego badania było ustalenie, czy jednoczesowe 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 Prolift® Pelvic Floor Repair System), natomiast u pacjentek z objawowym bądź ukrytym nietrzymaniem moczu jednoczesowo zakładano sling podcewkowy. Obie grupy porównano wykorzystując test chi<sup>2</sup>.

**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%;  $p=0,0093$ ).

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

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

## Introduction

Overactive bladder is characterised by urgency with urgency incontinence (wet OAB) or without incontinence (dry OAB), together with frequency and nocturia [1]. The prevalence of overactive bladder symptoms reported by many authors differs and strictly depends on the methods used to identify affected individuals [2-5]. Nevertheless, the symptoms associated with OAB significantly decrease the patients' quality of life due to specific physical, social, psychological and sexual limitations. According to epidemiological studies, several risk factors for this condition in women have been recognised. The most commonly identified causative OAB factors are abdominal or vaginal hysterectomy, previous POP and SUI surgery, smoking, caffeine intake and alcohol consumption [6]. Preliminary data show that OAB symptoms might also be caused by bacterial biofilms lining the bladder epithelium. The symptoms are usually resistant to antimuscarinics; however, clinically meaningful improvement was observed after prolonged antibiotic treatment [7]. In the current literature, there is still little evidence regarding the potential importance of genetic factors for susceptibility to OAB. Results confirming the genetic impact on lower urinary tract symptoms (LUTS) including OAB have been reported in studies on familial susceptibility to disease, ethnic group diversity and twin studies [8, 9]. The largest cross-sectional survey of LUTS in a cohort of Swedish twins 20–46 yr of age ( $n=42582$ )

from the Swedish Twin Registry provides strong evidence of a genetic influence on susceptibility to UI, frequency and nocturia in women [10]. Taken together, the aetiology of OAB is multifactorial; however, the importance of both genetic and environmental factors is still poorly understood. Recently, it has been confirmed that POP alone is an independent risk factor for OAB symptoms [11]. On the other hand, pelvic organ prolapse and/or stress urinary incontinence surgery may also lead to the development of new lower urinary tract disorders, including *de novo* OAB symptoms, as it was reported in mentioned study, that *de novo* OAB symptoms were observed postoperatively in 21.6% patients with pelvic floor disorders. In the above-mentioned study, all of the women (except one where mesh was used) underwent classical anterior repair with the midline buttressing technique and classic posterior colporrhaphy with levator muscle plication [12]. On the other hand, the incidence of *de novo* OAB symptoms was approximately 5-6% in women who underwent surgery with mesh prostheses for POP [13]. Moreover, according to various reports, midurethral sling procedures used for the treatment of stress urinary incontinence (SUI) may also cause *de novo* OAB in 4,9% to 27% of women [14, 15]. In our previous study, *de novo* OAB symptoms were observed in 6.3% of patients after MUS placement [16]. It should be emphasised that *de novo* OAB symptoms after the placement of midurethral slings occurred more often among patients older than 70 years old when compared to

younger women (11.9% vs. 4.7%) [17]. The prevalence of *de novo* OAB symptoms varied between 15% and 29% in the short term (1–3 months postoperatively) and between 0% and 30% in the long term [18, 19]. Nevertheless, several studies confirmed that surgery for POP and SUI may lead to iatrogenic OAB. However, there is a relative lack of studies evaluating whether there is any additive influence of simultaneous surgical treatment of POP and SUI on the incidence of *de novo* OAB symptoms.

The aim of our study was to evaluate whether simultaneous MUS placement at the time of mesh prolapse surgery increases the risk of the postoperative incidence of *de novo* OAB.

## Materials and methods

Between August 2007 and October 2009, 427 women underwent surgery in the II Department of Gynecology 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 transobturator sling (IVS-04M, Covidien, 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. In 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 POPQ) were observed in 97 (85.1%) and 106 (88.4%) patients from group I and II, respectively ( $\chi^2 = 0.038$ ,  $p = 0.845$ ), 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

Table I. Demographic data of the patients from both study groups.

Parameters	Group I POP and SUI (n=114)	Group II POP (n= 120)	p value
Age (years)	61.7±10,3	64.2 ± 9.5	0.0509
BMI (kg/m <sup>2</sup> )	27.7± 3.8	27.3± 3.8	0.480
Parity (n)	2.8 ± 1.3	2.4 ± 0.9	0.027
POPQ - 0 and I	0	0	NS
POPQ - II	9	17	NS
POPQ - III	89	70	NS
POPQ - IV	16	33	0.04

Figure 1. Flow of participants through each stage of the trial.

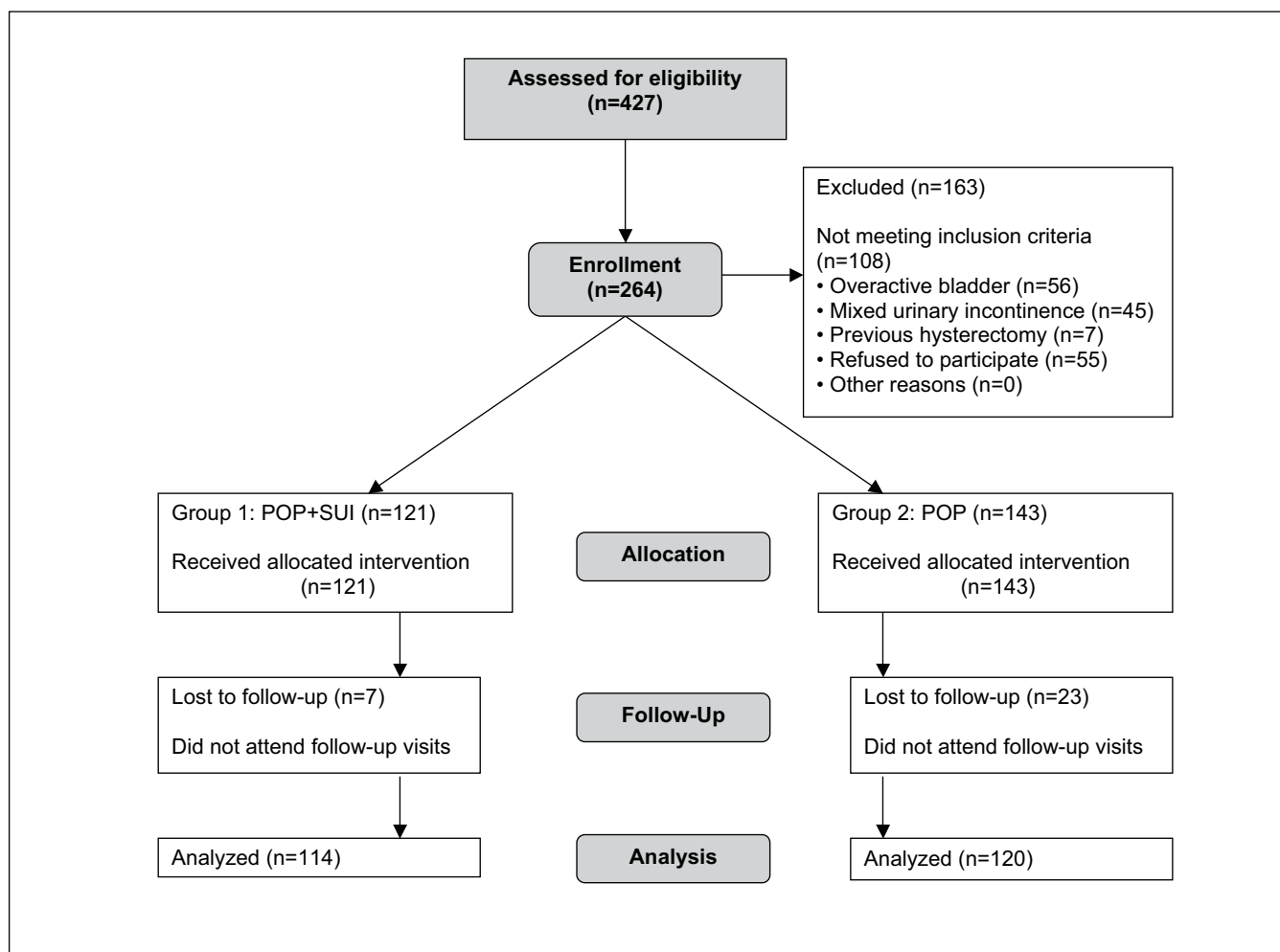


Table II. De novo OAB symptoms in relation to stress incontinence surgery outcome in patients with concomitant SUI – 12 months follow-up.

Procedure	Prolift® with IVS-04M (n=114)	
	OAB free	de novo OAB
Clinical outcome		
Failure	14 (12.3%)	9 (7.9%)
Improved	12 (10.5%)	3 (2.6%)
Cured	76 (66.7%)	0

group II, whereas recurrent SUI was observed in 14 (12.3%) cases in group I ( $\chi^2 = 0.805, p = 0.369$ ). Mesh erosions were observed in 6 patients (5.2%) in group I, whereas 5 (4.2%) erosions were found in group II ( $\chi^2 = 0.143, p = 0.705$ ). All these erosions were successfully treated by excision and suturing with local analgesia on an outpatient basis. *De novo* OAB symptoms were significantly more pronounced among women in the POP only surgery group (n=28; 23.3%) when compared to those who underwent Prolift® with simultaneous MUS placement (n=12; 10.5%;  $p=0.0093$ ). The incidence of *de novo* OAB symptoms stratified relative to the anatomical and functional clinical outcomes in both study groups is provided in tables II and III.

## 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

**Table III.** De novo OAB symptoms stratified against anatomical outcome after mesh reconstructive surgery as related to POP-Q scale.

Post-op POP-Q STAGE	POP + SUI n=114 (%)	POP n=120 (%)	de novo OAB as related to post-op POP-Q staging
Stage 0 (optimal)	16 (14.0)	14 (11.7)	16 (15.1%)
Stage 1 (satisfactory)	81 (71.1)	92 (76.7)	
Stage 2	14 (12.3)	8 (6,7)	6 (75%)
Stage 3	3 (2.6)	6 (5)	6 (100%)
Stage 4	0	0	

raised due to different pathophysiologies 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 therapeutical 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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