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Efficacy and safety of the Calistar and Elevate anterior vaginal mesh procedures

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ABSTRACT

Objectives: The pelvic organ prolapse (POP) surgery with implantation of anterior transvaginal mesh (e.g. Elevate or Calistar) may provide objective and subjective improvement as compared to traditional POP repair without mesh. Given differences between the Elevate and the Calistar mesh and their different placement methods, some variation inlong-term clinical outcomes of these anterior vaginal mesh procedures can be expected.
Study design: The purpose of the study was to compare the 18-month operative success in patients who had undergone anterior POP surgery with either the Calistar (n = 54) or Elevate mesh (n = 50).
Results: There were no between-group differences in objective measures of operative efficacy, including POP-Q anterior stage 0 or I (94% for Calistar, 92% for Elevate) and "no descent beyond the hymen" (98% for Calistar, 94% for Elevate). The proportion of patients with subjective measure of operative efficacy (no vaginal bulge symptoms) did not differ between the groups (91% for Calistar, 78% for Elevate). There were no between-group differences in the proportion of women suffering from vaginal exposure, de novo stress urinary incontinence (SUI), de novo overactive bladder (OAB) symptoms, pelvic floor pain or dyspareunia. The operative cure of OAB symptoms was similar in the groups. The proportion of patients with the operative cure of SUI symptoms was significantly higher in the Calistar as compared to the Elevate group.
Conclusions: The results suggestthat the Calistar system offers similar efficacy in the treatment of anterior and both anterior and apical POP as compared to the Elevate. The use of anterior Calistar is associated with some additional benefits, i.e. SUI treatment in patients with concomitant anterior and both anterior and apical POP and SUI symptoms.

Introduction

The implantation of transvaginal mesh (TVM) in the treatment of pelvic organ prolapse (POP) may provide anatomical improvement as compared to traditional POP repair without mesh, particularly in anterior or both anterior and apical compartments [1,2]. Contemporary single-incision vaginal approach grafts (Calistar, Elevate) involve four-point fixation to the sacrospinous ligaments and the obturator internus muscles with the use of plastic fixation arms [3,4].

Self-fixating tips of the Elevate allow for mesh placement with only a small possibility to correct suburethral and bladder neck tension. In contrast to the Elevate system, the Calistar implant has self-anchoring arms with a multipoint fixation design anchored at the internal obturator muscle with loosening sutures to correct any interoperative tension underneath the bladder neck and urethra. In addition, Calistar implants have 6-millimeter diameter orifices in

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the central area of the mesh to improve tissue ingrowth and to provide additional flexibility [4].

Given these differences between the Elevate and the Calistar mesh and their different placement methods, some variation in long-term clinical outcomes of the Elevate and Calistar anterior vaginal mesh procedures can be expected. More specifically, one may hypothesize that the specially designed multipoint fixation arms and loosening sutures of the Calistar system will allow for a highly precise implantation of the suburethral and bladder neck portion of the implant and a lowering of incidence of stress urinary incontinence (SUI), overactive bladder (OAB), and vaginal pain symptoms.

Despite the clinical significance of the above hypothesis, there has been a paucity of data on guiding the selection of single-incision kits, especially in patients with concomitant OAB and/or SUI symptoms. Palma et al. [5] observed 97 women for 24 months following a Calistar anterior mesh placement. Most women (88.7%) were considered POP cured (POP-Q stage 0 or I). Concomitant SUI was confirmed in 43 of the patients (42.6%) before surgery. At the last follow-up of each patient, there were 32 negative stress tests (80.0%), and 8 positive stress tests (20%), indicating a significant improvement from baseline ($P < 0.0005$).

In a retrospective comparison of two vaginal mesh kits in the management of anterior and apical vaginal prolapse, Lamblin et al. [6] reported that the use of the Elevate anterior mesh was associated with significantly better correction at 2 years as compared to the Perigee system (92.9% vs. 66.7%). However, postoperative SUI symptoms tended to be greater in the Elevate anterior as compared to the Perigee anterior group (29.8% vs. 16.7%).

The primary purpose of the present study was to compare the 18-month operative success in patients who had undergone anterior POP surgery with either the Calistar or Elevate mesh. To the best of our knowledge this is the first study reporting a retrospective comparison between objective and subjective outcomes of Calistar and Elevate anterior single-incision mesh surgery in the treatment of anterior or both anterior and apical POP based on a comprehensive set of efficacy measures and taking account of complications addressed in line with international guidelines.

Material and methods

Study groups

The study was carried out in accordance with the Declaration of Helsinki of the World Medical Association. The study protocol was approved by the Ethics Committee for Human Studies at the Military Institute of Medicine, Warsaw, Poland. The study methods and definitions conformed to the standards jointly recommended by the International Urogynecological Association and the International Continence Society [7–9].

Medical records of women with an anterior or anterior and apical prolapse admitted to the Department of Gynecology and Oncological Gynecology between January 2012 and December 2014 were reviewed. The study groups included patients with symptomatic anterior or both anterior and apical prolapse, stages III and IV, based on the POP-Q system [10,11], who had undergone standardized implantation of the Calistar anterior mesh (Calistar A, Promedon, Argentine) as described by Taner et al. [4] or the Elevate anterior mesh (American Medical Systems, Minnetonka, MN, USA) as described by Moore et al. [3]. The patients had undergone primary anterior prolapse surgery or an anterior repair following a previous posterior repair. No patient had undergone previous hysterectomy. A concomitant procedure was performed, if necessary, including a cervical amputation (7 patients), posterior vaginal repair without the use of mesh (11 patients), with no significant differences between the study groups. The procedures were performed by 3 gynecologists experienced in TVM surgery. Hysterectomy was not performed as an additional procedure in this groups of patients. Patients with medical conditions which might render the interpretation of results difficult (e.g. radiotherapy, severe neurological disorders) were excluded from the study. Women with prior anterior POP surgery were also excluded from the study. One hundred and twenty-eight records were initially identified for statistical analysis. Fifteen patients did not meet the inclusion criteria (and/or met the exclusion criteria). For all the patients included in the database, a clinical follow-up assessment was performed at 18 ± 1 months postoperatively. All participants gave written informed consent before the study began. Nine

Table 1
Basic sociodemographic and preoperative clinical characteristics of the study groups.

Patient characteristics	Calistar group n = 54	Elevate group n = 50	p value
Age (yrs.)	64.5 ± 7.1[a]	66.4 ± 7.2	0.10[b]
Height (cm)	161.9 ± 4.7	163.3 ± 6.4	0.22
Weight (kg)	73.3 ± 9.9	74.9 ± 9.0	0.38
Body Mass Index (BMI)	28.0 ± 3.2	28.1 ± 3.5	0.81
Gravidity	2.4 ± 1.5	2.3 ± 0.9	0.89
Vaginal deliveries	1.9 ± 1.3	1.8 ± 0.8	0.58
Postmenopausal status	51 (94%)	49 (98%)	0.66
Current smokers	3 (5.6%)	5 (10%)	0.63
Preoperative stress urinary incontinence	28 (52%)	23 (46%)	0.43
Preoperative overactive bladder	22 (41%)	18 (36%)	0.76
Prior posterior POP surgery	4 (7.4%)	7 (14%)	0.43
Prior SUI surgery	4 (7.4%)	9 (18%)	0.10
Preoperative pelvic floor pain	4 (7.4%)	3 (6%)	0.91
Preoperative dyspareunia	3 (5.6%)	3 (6%)	0.92
Preoperative POP-Q anterior	3.02 ± 0.2	3.1 ± 0.3	0.14
stage 0	0	0	0.41
stage I	0	0	
stage II	0	0	
stage III	49	43	
stage IV	1	4	
Preoperative anterior and apical prolapse POP-Q stage III	4 (7.4%)	3 (6%)	0.91
Preoperative POP-Q posterior	0.3 ± 0.8	0.3 ± 0.9	0.80
Interval from surgery to follow-up (months)	18.1 ± 1.1	18.0 ± 1.0	0.72

[a] mean±S.D.
[b] The *t*-test or χ^2-test.

patients were lost during follow-up. The final database contained pre- and postoperative records of 104 Caucasian women who fulfilled the inclusion criteria and did not meet the exclusion criteria and for whom full results of postoperative assessment were available.

Table 1 presents basic sociodemographic and clinical characteristics of the study groups.

Assessment of objective and subjective efficacy outcomes prior and following surgery

Efficacy outcomes (POP-Q anterior or apical stage 0-I vs. II-IV, presence vs. absence of the anterior or apical descent beyond the hymen, no re-treatment for POP recurrence) [7–9]were assessed using the patients' clinical records. Pelvic examination was performed with the patient in the dorsal lithotomy position. The POP-Q system was used to quantify the POP severity at a maximum Valsalva strain [10,11].

The vaginal bulge symptoms were assessed by asking a question selected from the Pelvic Floor Distress Inventory (PFDI) ("Do you usually have a bulge or something falling out that you can see or feel in your vaginal area?") [12]. Patients scoring ≥1 were considered as having bulge symptoms. Re-treatment for POP was defined as any repeat surgery for a prolapse arising from the same site [9,11] or the use of pessary for a recurrent anterior and/or apical descent [7].

Assessment of additional efficacy and safety outcomes prior and following surgery

The assessment of secondary outcomes was a part of standard follow-up. The OAB symptoms were assessed using questions selected from the PFDI [11,13,14] ("Do you usually experience frequent urination?", "Do you usually experience a strong feeling of urgency to empty your bladder?", "Do you usually experience urine leakage associated with feeling of urgency, that is, a strong sensation of needing to go to the bathroom?"). The patients who answered "yes" to any of these questions were considered to have OAB [13,14].

The patients were interviewed about SUI symptoms using the Stamey Incontinence Score [15]. The patients with grade ≥1 or showing a positive cough stress test were considered to have SUI. The number of SUI and OAB symptom reductions were calculated respectively for both groups. The patients were interviewed about postoperative pelvic floor pain and dyspareunia. The postoperative pain severity was estimated by the patient using a five-point scale based on the IUGA/ICS grading system for the assessment of mesh-related pain. The severity of pain might vary from 1 (asymptomatic, no pain), through 2 (provoked pain only during vaginal examination), 3 (pain during intercourse), 4 (pain during physical activities) to 5 (spontaneous pain) [16]. Patients were considered to experience postoperative pain if they rated the pain severity ≥2. Dyspareunia was assessed with the question "Do you have pain with intercourse?" [11,17].

Vaginal exposure following surgery was defined as a condition of a vaginal mesh visualized through a separated vaginal epithelium [16].

Statistics

Sociodemographic and clinical parameters were expressed as means (±S.D.) or proportions (n/N). The Calistar and Elevate groups were compared using the Student's *t*-test or the χ^2 test. A probability level (p) less than 0.05 was considered significant. All statistical analyses were performed using the Statistica 5.0 software package (StatSoft, Tulsa, OK, USA).

Results

The two groups did not differ in age, height, weight, body mass index (BMI), gravidity, vaginal deliveries, postmenopausal status, and smoking habits. Neither were there any differences between the two groups with reference to their preoperative SUI and OAB symptoms (all p values >0.05). The two groups did not differ in the anterior, apical and posterior POP-Q stages and the proportions of patients reporting preoperative pelvic floor pain and/or dyspareunia. Similarly, the proportions of women, who had undergone a prior posterior POP and/or SUI surgery, did not differ between the Calistar and Elevate groups (Table 1).

Table 2
Operative success rates and pelvic floor symptoms following the Calistar or Elevate vaginal mesh procedure.

		Calistar group n = 54		Elevate group n = 50	P value
Operative success rates					
Postoperative POP-Q anterior or apical		0.35 ± 0.65[a]		0.52 ± 0.7	0.21[b]
stage 0		39		29	
stage I		12		17	
stage II		2		3	
stage III		1		1	
stage IV		0		0	
Postoperative POP-Q anterior or apical stage 0 or I		51 (94%)		46 (92%)	0.91
No descent beyond the hymen		53 (98%)		47 (94%)	0.59
Subjective cure / no vaginal bulge symptoms		50 (91%)		39 (78%)	0.07
No re-treatment for POP recurrence		51 (94%)		60 (92%)	0.91
Vaginal exposure		2 (3.7%)		0 (0%)	0.09
Stress urinary incontinence symptoms					
de novo Stress urinary incontinence	4/26 (15.4%)			5/27 (18.5%)	0.95
Operative cure of stress urinary incontinence	18/28 (64.4%)		6/23 (26%)		0.02*
Total postoperative stress urinary incontinence	14/54 (25.9%)		22/50 (44%)		0.08
Overactive bladder symptoms					
de novo Overactive bladder		3/32 (9%)		4/32 (12%)	0.92
Operative cure of overactive bladder		14/22 (66.6%)		6/18 (33.3%)	0.40
Total postoperative overactive bladder		11/54 (20.4%)		16/50 (32%)	0.25
Other pelvic floor symptoms					
Postoperative pelvic floor pain		4 (7%)		4 (8%)	0.78
Postoperative dyspareunia		3 (5.6%)		4 (8%)	0.80
Postoperative POP-Q posterior		0.48 ± 0.42		0.44 ± 0.83	0.83

[a] mean±S.D.
[b] The *t*-test or χ^2-test.
* P<0.05.

Table 2 shows the operative success rates in the Calistar and Elevate groups assessed 18 ± 1 months following surgery. There were no between-group differences in objective measures of operative efficacy (POP-Q anterior or apical stage 0 or I, Calistar: 94%, Elevate: 92%; absence of anterior or apical descent beyond the hymen, Calistar: 98%, Elevate: 94%, no re-treatment for POP recurrence, Calistar: 94%, Elevate: 92%). In line with the above, the mean anterior or apical POP-Q stage assessed on the follow-up evaluation did not differ between the groups (p values >0.05). The proportion of patients with subjective measure of operative efficacy (no vaginal bulge symptoms) did not differ between the study groups (see Table 2 for details).

The χ^2 test showed no between-group differences in the proportion of women suffering from vaginal exposure (Calistar: 3.7%, Elevate: 0.0%), de novo SUI, de novo OAB symptoms, pelvic floor pain or dyspareunia (see Table 2 for other details). The operative cure of OAB symptoms was similar in the Calistar and Elevate groups. Postoperative POP-Q posterior staging did not show any between-group differences (p values >0.05).

The proportion of patients with the operative cure of SUI symptoms was significantly higher in the Calistar (18/28, 64.4%) as compared to the Elevate group (6/23, 26%; p = 0.02; Table 2).

Comment

Our study showed high and comparable operative success rates of the POP surgery with both the anterior Calistar and Elevate mesh. Notably, neither objective nor subjective efficacy parameters showed any significant differences between the study groups. In general, the present results provide further support for studies showing high objective and subjective success rates following both anterior Elevate [6,18–21] and anterior Calistar mesh repair [5]. For example, the recently published study with follow-up ranging from 15 to 45 months showed that the Elevate system was an effective procedure for prolapse repair with an objective success rate in the anterior and apical compartment exceeding 90% [18]. In another retrospective study, Palma et al. [5] found 88.7% women POP cured (POP-Q stage 0 or I) after the anterior Calistar implantation.

Given the differences between the Elevate and Calistar mesh and in their placement methods (for details, see Introduction), differences in some long-term safety outcomes were expected. We hypothesized that specially designed multipoint fixation arms and loosening sutures of the Calistar system allowing a more precise implantation of the suburethral and bladder neck portion of the mesh could be associated with a lower incidence of de novo SUI, OAB, and vaginal pain symptoms. The results of the present study provided only partial support for our hypothesis. There were no major differences between the Elevate and Calistar system in terms of the rate of de novo SUI, OAB, and pelvic floor pain. On the other hand, although the Calistar and Elevate implants were associated with the appearance of de novo SUI symptoms in a similar proportion of patients, the Calistar system cured preoperative SUI symptoms in a significantly greater proportion of women (64.4%) that the Elevate mesh (26%).

Previous studies provide some indirect support for this latter finding. Palma et al. [5] reported significant improvement in SUI symptoms following Calistar anterior mesh placement. Lo et al. [19] found that Elevate mesh caused a significantly higher rate of de novo SUI postoperatively than the Perigee device. It is worth noting that in some studies the assessment of SUI symptom reduction after anterior TVM was not possible as women with positive SUI symptoms with anterior POP defect underwent concomitant anti-incontinence intervention during POP surgery [20].

Taking into account the present and previous findings [5,19], one may postulate that the precise bladder neck adjustment during the anterior Calistar implantation offers a higher chance of a cure for preoperative SUI symptoms as compared to the Elevate. It is possible that more tension applied by the anterior Elevate under the bladder and its neck promotes both treatment and harm in patients with concomitant POP and SUI. More tension applied below the bladder neck may fix the urethra and reduce SUI symptoms, while more tension applied below the bladder may promote urinary leaks. The latter mechanism is less likely to be evident in the case of the anterior Calistar system, resulting in the better functional outcome found in the present study.

There were no between-group differences in the rate of vaginal exposure. This finding is consistent with our previous report [11] showing a low rate of vaginal exposure in case of Elevate and Prolift procedures. Our result is also in agreement with the findings of Lo et al. [19] who reported vaginal mesh exposure in 3 (4.9%) women out of 61 after Perigee and in 0 women out of 57 after Elevate. Moreover, there were no between-group differences in the rate of postoperative pelvic floor pain and dyspareunia. The latter finding supports our previous report [11] showing no differences between the Elevate and Prolift in terms of postoperative pelvic floor pain which was present in 11.3% of patients treated with the Elevate and in 11.5% of patients treated with the Prolift. Our result is also consistent with the findings of McLennan et al. [22] who reported no differences in pain scores during the immediate postoperative period between the Elevate and Prolift.

Some limitations of the present study should be noted. We retrospectively analyzed a relatively small group of patients treated in one tertiary-care urogynecological center. In future studies, other single-incision mesh systems (e.g. Ingynious) should be taken into account as the Elevate system has already been withdrawn from the market. Nevertheless, our findings may be of direct practical importance because patients implanted with the Elevate are still in follow-up.

In conclusion, our results suggest that: i) the anterior Calistar system offers similar efficacy in the treatment of anterior and both anterior and apical POP as compared to the anterior Elevate, ii) the use of anterior Calistar is associated with some additional benefits, i.e. SUI treatment in patients with concomitant anterior POP and SUI symptoms. The latter conclusion, however, should be treated with caution and validated in longitudinal studies on larger samples of POP women treated with single-incision vaginal approach grafts.

Conflict of interest

Artur Rogowski, Tomasz Kluz, and Wlodzimierz Baranowski acted as consultants for UniTech (a Polish representative of Promedon group).

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