Original Research

Complications of Pelvic Organ Prolapse Surgery in the 2015 Finnish Pelvic Organ Prolapse Surgery Survey Study

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OBJECTIVE: To describe the major complications of pelvic organ prolapse (POP) surgery in Finland.

METHODS: The Finnish Pelvic Organ Prolapse Surgery Survey 2015 study is a prospective cohort of POP surgeries performed in Finland in 2015. Perioperative, postoperative, and late complications during 1 year of follow-up were compared among native tissue repair, transvaginal mesh, and abdominal mesh surgery. Major complications were assessed using the Clavien-Dindo grading system. Predictive factors for major complications were studied with logistic regression analysis.

RESULTS: Within 1 year after POP surgery, 396 (11.2%) of 3,515 women had at least one complication: 10.9% after native tissue, 11.7% after transvaginal mesh, and 13.5% after abdominal mesh repair. The majority of complications occurred within 2 months after surgery and postoperative infection (4.3%) and bleeding or hematoma (2.6%) were the most frequent. The incidence of organ injuries was low. Mesh-augmented surgery was associated with significantly higher rates of bladder and bowel injuries than native tissue surgery. Complication-related reoperations occurred significantly more often after abdominal mesh repair than native tissue surgery (5.2% vs 1.8%, P=.001). Mesh-related complications were diagnosed more often after transvaginal mesh repair. The overall rate of major complications (Clavien-Dindo grades III–V) was 3.3%. Abdominal mesh surgery was associated with the highest rate of major adverse events (8.8% vs native tissue repair 2.6% and transvaginal mesh 4.9%). The incidence of Clavien-Dindo grade IV or V complications was rare (less than 0.6%). Mesh surgery (transvaginal mesh adjusted odds ratio [aOR] 2.23, 95% CI 1.31–3.80, and abdominal mesh aOR 3.02, 95% CI 1.67–5.46), longer operating time (aOR 2.84, 95% CI 1.78–4.53), prior POP surgery (aOR 1.68, 95% CI 1.00–2.81) and difficult surgery (aOR 2.75, 95% CI 1.63–4.62) were associated with an increased risk for occurrence of major complications.

CONCLUSION: Serious adverse events were rare regardless of the operative approach. However, mesh-augmented surgery was associated with higher risk for major complications.

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Pelvic organ prolapse (POP) is a common and often asymptomatic condition, affecting up to 50% of parous women when based on examination.[1] The estimated lifetime risk for prolapse surgery in the general female population is between 12% and 18%.[2–4] A variety of surgical procedures have been designed to reduce POP symptoms. There is, however, no consensus on the optimal approach, which is reflected by high reoperation rates due to recurrent prolapse, especially after native tissue repair.[1,5,6] Even though POP surgery is considered to be a relatively safe procedure, serious adverse events do occur and especially morbidity related to mesh procedures has raised concerns worldwide.[7]

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The rate of POP surgery-related complications varies depending on the route and the type of surgery and classification or grading used. Previous literature shows similar complication rates associated with native tissue repair and transvaginal mesh surgery, with a slightly higher incidence after abdominal mesh repair.[8] Higher rates of bladder injuries have been reported after transvaginal mesh repair[1] and higher rates of postoperative ileus, mesh or suture complications and thromboembolic phenomena after abdominal mesh repair when compared with native tissue repair.[8,9] Transvaginal mesh surgery has been associated with a higher rate of mesh-related complications and reoperations when compared with abdominal mesh surgery.[6,8] However, follow-up studies have shown mesh exposure rates after abdominal mesh repair to increase with time.[10] Nevertheless, previous studies consider the majority of complications as minor (Clavien-Dindo grades I and II) and serious adverse events leading to single- or multiorgan failure or even death as rare (0.2% or less).[8,11]

The highest reported complication rates have been related to simultaneous repair of multiple compartments, especially during transvaginal mesh repair.[12] Age, parity, surgeon experience, concomitant hysterectomy, previous prolapse repair, total vaginal mesh repair, mesh properties, sexual activity, smoking, and diabetes have been identified as risk factors for adverse events.[12,13] Operative technique used may also play a role in the complication rate.[14] Even though reporting surgical complications has become more standardized in prolapse surgery, many studies still provide insufficient data on complications and have short follow-up times.

In Finland, prolapse surgery is the second most common gynecologic procedure, with 4,200 procedures being performed annually.[4] The aim of this prospective study was to describe the complications related to POP surgery in a population-based cohort of POP surgeries performed in Finland during 2015. We studied whether the risk of major complications was different by type of surgery and aimed to identify predictors for major adverse events.

METHODS

This national, multicenter prospective cohort study (the Finnish Pelvic Organ Prolapse Surgery Survey) included data from 3,535 POP surgeries in Finland, representing 83% of POP surgeries performed nationwide between January 1, 2015, and December 31, 2015 (Fig. 1). Ninety-one percent of the Finnish hospitals performing POP surgery accepted the invitation to participate. This included each of five university hospitals, 15 central hospitals, 17 regional hospitals, and five private hospitals. Women older than age 18 years undergoing POP surgery, with the ability to communicate in oral and written Finnish or Swedish, were recruited. More detailed information on the surgical methods is given in a previous publication by Mattsson et al.[15]

Complications were collected from multiple sources: from surgeon questionnaires, patient questionnaires, and hospital discharge registers. Surgeons filled in questionnaires after surgery providing data on each patient's surgical history, preoperative assessment of the degree of prolapse using simplified POP quantification,[16] details of surgical procedure, subjective assessment of difficulty of the surgery, and

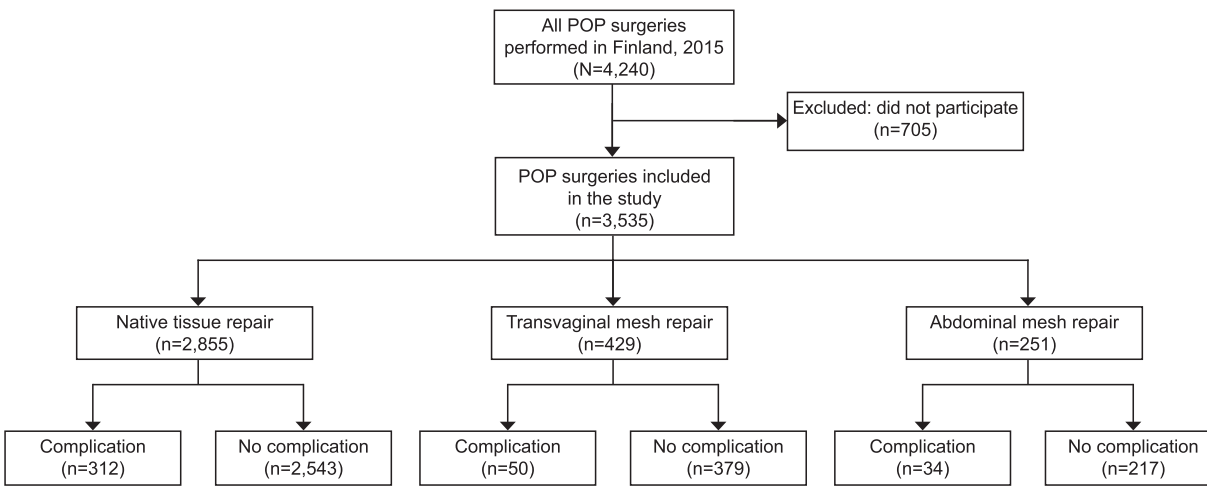

Fig. 1. Flow chart of study population and complication data availability. POP, pelvic organ prolapse.
Wihersaari. Complications of Prolapse Surgery. Obstet Gynecol 2020.

perioperative adverse events during surgery or before discharge. Additionally, surgeons were asked to complete online questionnaires at the event of a postoperative check-up or the occurrence of postoperative complication. Demographic data were recorded from preoperative patient questionnaires, including health status, smoking habits, and subjective symptoms. Six months after surgery, the patients received a questionnaire concerning recovery and complications. Recorded complications from the surgeons and patients included bowel, urinary tract, and vascular injuries, postoperative infections, hemorrhage, mesh-related complications, and organ dysfunctions.

International Classification of Diseases, Tenth Revision codes and Nordic Classification of Surgical Procedures codes (Appendix 1, available online at http://links.lww.com/AOG/C110) were used to screen possible complications from the Care Registers for Social Welfare and Health Care. This hospital discharge register contains inpatient and outpatient data from all hospitals nationwide, with reported coverage of more than 95%.[17] Registered data did not include possible outpatient visits to primary health care units.

After bringing together complication data from the surgeons, patients, and Care Registers for Social Welfare and Health Care, any serious adverse event reported by the patient or registered in the Care Registers for Social Welfare and Health Care that was not initially reported by the surgeon was confirmed from each hospital's patient records. In addition, the Finnish Population Register Center provided mortality data within 1 year of POP surgery and hospital patient records were examined to check for any complication-related deaths.

A nonsurgical complication was defined as any systemic or life-threatening infection, cardiovascular event or single- or multi-organ dysfunction. Surgical complications included any organ injuries, surgical site or wound infections, and vascular complications (intraoperative bleeding of at least 500 mL, abnormal intraoperative hemorrhage reported by surgeon, postoperative hematoma, and reoperations due to hemorrhage). Mesh complication was defined as mesh exposure or any mesh-related adverse event requiring surgical intervention with or without partial or total removal of mesh.

Adverse events were categorized based on the timing according to International Urogynecological Association/International Continence Society classification as perioperative (during surgery or within 48 hours), postoperative (within 2 months after hospital discharge), and late (2–12 months after surgery).[18] Owing to the differences in timely recording of available patient data, perioperative adverse event was redefined as an event taking place before hospital discharge. Nonsurgical complications occurring within 2 months of index surgery were recorded.

Clavien-Dindo classification was used to grade major complications (Clavien-Dindo grades IIIa-V): complications requiring surgical intervention under local (IIIa) and general (IIIb) anesthesia, single organ (IVa) and multi organ (IVb) dysfunction, and death of patient (V).[19] All other complications were regarded as minor. The reporting of multiple adverse events was discussed in publication by Clavien et al[20] in 2009, and no consensus was found on this matter. Therefore, in case of multiple adverse events occurring to one patient, each adverse event was graded separately.

For this study, we defined three surgical groups: native tissue repair, transvaginal mesh, and abdominal mesh. The data were analyzed using SPSS 25.0. Differences in categorical variables were tested with the χ^2 test or Fisher exact test. Bonferroni-corrected tests were used to assess pairwise differences among groups. Univariable logistic regression analysis was used to study predictive factors for major complications (Clavien-Dindo grade III and higher, Appendix 2 [available online at http://links.lww.com/AOG/C110] showing analysis within surgical groups). The association between major complication and surgical approach was modeled using multivariable logistic regression. Potential confounders were selected using previous literature and clinical experience. Spearman's rho was used to evaluate possible collinearity (with $r>0.4$ as a cutoff [Appendices 3 and 4, available online at http://links.lww.com/AOG/C110]). Owing to strong collinearity between type of surgery and operating time, operating time was categorized according to group median (at or above group median or below group median). Thus, the multivariable model was adjusted for type of surgery, age, body mass index (BMI, calculated as weight in kilograms divided by height in meters squared), diabetes, smoking, operating time, and most distal point of any compartment. Strong collinearity was also detected between multiple compartment repair and operating time, and therefore a reduced multivariable model (without operating time) was used when assessing the risk of multiple compartment repair. $P<.05$ was considered as statistically significant.

The study was conducted by the Finnish Society for Gynecological surgery, a nonprofit organization. Written informed consent was acquired from each patient. Ethical approval was obtained from the Research Ethics Committee of the Northern Savo Hospital District

Table 1. Patient Characteristics

	NTR Group (n=2,855)	TVM Group (n=429)	AM Group (n=251)	*P*
Age at surgery (y)	63.3±11.0	68.6±7.7	64.0±9.7	<.001
BMI (kg/m^2)	26.9±4.1	26.9±3.8	26.1±3.7	.020
Cardiovascular disease	997 (34.9)	184 (42.9)	81 (32.3)	.003
Respiratory disease	257 (9.0)	47 (11.0)	19 (7.6)	.289
Diabetes	223 (7.8)	35 (8.2)	25 (10.0)	.481
Current smoker	206 (8.8)	28 (7.8)	21 (9.8)	.701
Parity	2.6±1.5	2.4±1.0	2.5±1.3	.001
History of cesarean delivery	215 (7.5)	26 (6.1)	16 (7.3)	.468
Estrogen therapy	406 (14.2)	86 (20.0)	47 (18.7)	.002
Local estrogen therapy	481 (16.8)	81 (18.9)	46 (18.3)	.520
Sexually active	877 (40.2)	93 (28.8)	84 (42.2)	<.001
Previous hysterectomy	656 (23.0)	339 (79.0)	191 (76.1)	<.001
Previous prolapse surgery	417 (14.6)	326 (76.0)	148 (59.0)	<.001
Prolapse stage II or higher	2,689 (95.4)	423 (99.1)	243 (97.2)	.001

NTR, native tissue repair; TVM, transvaginal mesh; AM, abdominal mesh; BMI, body mass index.
Data are mean±SD or n (%) unless otherwise specified.
Data presented in this table have previously been published by Mattsson et al 2019.[15]

(reference number 5/2014), the Ministry of Social Affairs and Health and from the institutional review board of each participating hospital.

RESULTS

Patient and perioperative characteristics are shown in Tables 1 and 2. There were 2,855 (80.7%) native tissue, 429 (12.1%) transvaginal mesh, and 251 (7.1%) abdominal mesh surgeries. The majority (91.0%) of abdominal mesh surgeries were laparoscopic. Perioperative data from surgeon questionnaires were available for all 3,535 operations.[15] The patient response rate to preoperative and 6-month postoperative questionnaires were 83.0% and 72.1%, respectively. Patients in the transvaginal mesh group were older and more likely to have cardiovascular disease, and they were less often sexually active. Patients in the abdominal mesh and transvaginal mesh groups had significantly higher rate of previous hysterectomy and prolapse surgery compared with those in the native tissue repair group. Prophylactic antibiotics were used in patients in the mesh group significantly more often than in those in the native tissue repair group. Prophylactic antithrombotic therapy was used more often in patients in the abdominal mesh group. Operating time and form of anesthesia differed among the surgical groups. Mean length of hospital stay including the day of surgery was 2.2 days (SD 1.3), and there was no significant difference among the surgical groups.

Table 2. Perioperative Characteristics

	NTR Group (n=2,855)	TVM Group (n=429)	AM Group (n=251)	*P*
Prophylactic antibiotics	2,031 (71.6)	426 (99.8)	251 (100)	<.001
Prophylactic antithrombotic therapy	1,093 (38.4)	194 (45.2)	133 (53.0)	<.001
Form of anesthesia				<.001
Local	327 (11.5)	1 (0.2)	0 (0)	
Regional	1,783 (62.8)	354 (82.9)	0 (0)	
General	701 (24.7)	68 (15.9)	247 (100)	
Other*	26 (0.9)	4 (0.9)	0 (0)	
Intraoperative blood loss (mL)	87±118.5	76±99.5	49±67.9	<.001
Operating time (min)	68±35.5	62±25.2	144±45.4	<.001
Hospital stay† (d)	2.1±1.3	2.3±0.9	2.7±1.8	<.001
Concomitant hysterectomy	1,329 (46.5)	23 (5.4)	45 (17.9)	<.001
Concomitant sling surgery	29 (1.0)	2 (0.5)	0 (0)	.201

NTR, native tissue repair; TVM, transvaginal mesh; AM, abdominal mesh.
Data are n (%) or mean±SD unless otherwise specified.
Data presented in this table have previously been published by Mattsson et al.[15]
* Epidural, combination of local and regional, conversion from regional to general anesthesia.
† Index surgery day included.

Table 3. Nonsurgical Complications Perioperatively and 30 Days Postoperatively

	All (N=3,535)	NTR Group (n=2,855)	TVM Group (n=429)	AM Group (n=251)	P
Myocardial infarction	3 (0.1)	2 (0.1)	0	1 (0.4)	.236
Stroke	4 (0.1)	2 (0.1)	2 (0.5)	0	.102
Pulmonary embolism	3 (0.1)	2 (0.1)	1 (0.1)	0	.473
Deep venous thrombosis	1 (<0.1)	1 (<0.1)	0	0	1.00
Acute renal failure	2 (0.1)	1 (<0.1)	0	1 (0.4)	.152
Ileus	3 (0.1)	2 (0.1)	0	1 (0.4)	.236
Pyelonephritis	9 (0.3)	7 (0.2)	0	2 (0.8)	.125
Sepsis	3 (<0.1)	1 (<0.1)	0	2 (0.8)	.019*
Pneumonia	2 (0.1)	1 (<0.1)	0	1 (0.4)	.152

NTR, native tissue repair; TVM, transvaginal mesh; AM, abdominal mesh.
Data are n (%) unless otherwise specified.
* Significant difference between native tissue repair and abdominal mesh (Bonferroni-corrected pairwise testing, *P*=.007).

A total of 396 (11.2%) women had at least one nonsurgical or surgical complication during the follow-up period of 1 year: 312 (10.9%) in native tissue group, 50 (11.7%) in transvaginal mesh group, and 34 (13.5%) in abdominal mesh group (Fig. 1; *P* for between-group difference .430). The majority of complications occurred during the postoperative follow-up period of 2 months. The most common complication during this period was surgical site and wound infection (152 cases, 4.3%), followed by vascular complication (92 cases, 2.6%). All nonsurgical complications occurred within 30 days of surgery (Table 3).

Surgical complications are listed in Table 4: 17 bladder (0.5%), seven bowel (0.2%), and three ureteral (0.1%) injuries were diagnosed. No urethral injuries were recorded. The rate of perioperative bowel and ureteral injuries were significantly higher in the abdominal mesh group. Perioperative bladder injuries occurred significantly more often in both mesh groups compared with the native tissue repair group (0.2% vs 1.4% in the transvaginal mesh group, *P*=.002, and 1.6% in the abdominal mesh group, *P*=.006), with no difference between the mesh groups.

The overall rate of complication-related reoperations within 1 year after surgery was highest in the abdominal mesh group (5.2%) in comparison with other surgical groups (native tissue repair 1.8%, *P*=.001, and transvaginal mesh 3.0%, *P*=.213). Reoperations related to causes other than bleeding, infection, or mesh-related adverse events, such as ureteral injury, diagnostic laparoscopy, and suture complications were also significantly more common after abdominal mesh repair.

Nine deaths occurred during the first year after surgery, two within postoperative follow-up period of 2 months. The first death occurred 1 day after vaginal native tissue surgery performed under spinal anesthesia. The patient was a 63-year-old woman who was a smoker and had a medical history of coronary heart disease, high blood pressure, and diabetes. Forensic autopsy confirmed acute myocardial infarction as the cause of death. The second death occurred in a 78-year-old woman 27 days after open sacrocolpopexy performed under general anesthesia. She had a medical history of asthma, high blood pressure, and diabetes. The cause of death was acute respiratory distress syndrome after aspiration of food 2 days after surgery. Postmortem patient record assessment revealed fibrotic lung disease that also contributed to her death. These two deaths were recorded as major complications. The remaining seven deaths were not related to POP surgery.

Within 1 year after POP surgery, 19 (0.5%) women were diagnosed with a mesh-related complication–15 (3.5%) in the transvaginal mesh group, three (1.2%) in the abdominal mesh group, and one (less than 0.1%) in the native tissue repair group. One patient in the transvaginal mesh group was treated twice for mesh complication and one patient in the native tissue repair group had a transobturator tape sling removed owing to pain (inserted during posterior colporrhaphy operation). Eight women (1.2%) had a reoperation due to mesh complication. Five of these women had a partial or total removal of mesh, of which one was due to a ureteral injury and infection (abdominal mesh group), one mesh erosion into bladder (transvaginal mesh group), one transobturator tape sling removal (native tissue repair, as mentioned previously), and two vaginal wall exposures (transvaginal mesh group). One patient in the abdominal mesh group was diagnosed with a mesh-related fistula, which was treated conservatively. Mesh exposure was diagnosed and treated conservatively in the remaining 10 cases. The occurrence of mesh-related complications and reoperations due to mesh-related complications was highest in the

Table 4. Perioperative, Postoperative, and Late Surgical Complications and Complication-Related Reoperations

	Perioperative				Postoperative (2 mo)			
	NTR (n=2,855)	TVM (n=429)	AM (n=251)	*P*	NTR (n=2,855)	TVM (n=429)	AM (n=251)	*P*
Bowel injury	2 (0.1)	0	4 (1.6)	.001[b]	1 (<0.1)	0	1 (0.4)	.152
Bladder injury	6 (0.2)	6 (1.4)	4 (1.6)	<.001[d]	0	1 (0.2)	0	.192
Ureteral injury	0	0	2 (0.8)	.005[f]	0	0	0	NA
Vascular, bleeding	80 (2.8)	10 (2.3)	2 (0.8)	.149	74 (2.6)	14 (3.3)	4 (1.6)	.426
Wound infection	5 (0.2)	1 (0.2)	2 (0.8)	.126	130 (4.6)	16 (3.7)	6 (2.4)	.218
Peritonitis	2 (0.1)	0	2 (0.8)	.044[h]	0	0	0	NA
Mesh complication	0	0	0	NA	1[j] (<0.1)	5 (1.2)	1 (0.4)	<.001
Fistula	0	0	0	NA	0	0	0	NA
Reoperation								
Bleeding	15 (0.5)	1 (0.2)	1 (0.4)	.892	9[k] (0.3)	0	0	.802
Infection	2 (0.1)	0	1 (0.4)	.236	6 (0.2)	0	0	1.00
Mesh	0	0	0	NA	0	1 (0.2)	0	.192
Other[l]	6 (0.2)	0	4 (1.6)	.003[m]	10 (0.4)	1 (0.2)	7 (2.8)	<.001[n]

NTR, native tissue repair; TVM, transvaginal mesh repair; AM, abdominal mesh repair; NA, not available.
Data are n (%) unless otherwise specified.
[a] Cumulative number of patients with a surgical complication within surgical groups.
[b] Significant difference between NTR and AM (Bonferroni-corrected pairwise testing, *P*=.005). Significant difference between TVM and AM (Bonferroni-corrected pairwise testing, *P*=.050).
[c] Significant difference between NTR and AM (Bonferroni-corrected pairwise testing, *P*=.001). Significant difference between TVM and AM (Bonferroni-corrected pairwise testing, *P*=.028).
[d] Significant difference between NTR and TVM (Bonferroni-corrected pairwise testing, *P*=.002). Significant difference between NTR and AM (Bonferroni-corrected pairwise testing, *P*=.006).
[e] Significant difference between NTR and TVM (Bonferroni-corrected pairwise testing, *P*=.001). Significant difference between NTR and AM (Bonferroni-corrected pairwise testing, *P*=.006).
[f] Significant difference between NTR and AM (Bonferroni-corrected pairwise testing, *P*=.007).
[g] Significant difference between NTR and AM (Bonferroni-corrected pairwise testing, *P*=.018).
[h] Significant difference between NTR and AM (Bonferroni-corrected pairwise testing, *P*=.035).
[i] Significant difference between NTR and AM (Bonferroni-corrected pairwise testing, *P*=.035).
[j] Posterior colporrhaphy with transvaginal tape.
[k] One patient in the NTR group had reoperation due to bleeding and infection.
[l] Resuturing of vaginal wound, suture complication, diagnostic laparoscopy, ureteral operation, surgical operation of peritoneal adhesions.
[m] Significant difference between NTR and AM (Bonferroni-corrected pairwise testing, *P*=.006). Significant difference between TVM and AM (Bonferroni-corrected pairwise testing, *P*=.018).
[n] Significant difference between NTR and AM (Bonferroni-corrected pairwise testing, *P*<.001). Significant difference between TVM and AM (Bonferroni-corrected pairwise testing, *P*=.005).
[o] Significant difference between NTR and AM (Bonferroni-corrected pairwise testing, *P*<.001). Significant difference between TVM and AM (Bonferroni-corrected pairwise testing, *P*=.027).

transvaginal mesh group, but no significant difference was found between the two mesh groups (*P*=.085 and *P*=.269, respectively).

A total of 141 major complications (Clavien-Dindo grades III–V) were reported in 118 women (3.3%) (Table 5). We observed one major complication in 97 patients (63 in the native tissue repair group, 18 in the transvaginal mesh group, and 16 in the abdominal mesh group), two in 19 patients (11 in the native tissue repair group, three in the transvaginal mesh group, and five in the abdominal mesh group), and three in two patients (one in the native tissue repair group and one in the abdominal mesh group). Major adverse events occurred significantly more often after abdominal mesh repair compared with both native tissue repair and transvaginal mesh surgeries.

Women in the transvaginal mesh group had significantly higher rate of complications requiring surgical intervention under local anesthesia (grade IIIa) compared with native tissue repair (*P*=.002). Sixteen women (6.4%) in the abdominal mesh group required surgical treatment of complication under general anesthesia (grade IIIb), which was significantly higher than in the native tissue repair (1.3%, *P*<.001) or transvaginal mesh (1.2%, *P*<.001) groups. The highest rate of single-organ dysfunction (grade IVa) occurred in the abdominal mesh group, with statistically significant difference only to the native tissue repair group.

In univariable analyses, surgical approach, operating time, prior POP surgery, previous vaginal hysterectomy, and difficult surgery were associated

Late (2–12 mo)				Cumulative 1-y frequency[a]			
NTR (n=2,855)	TVM (n=429)	AM (n=251)	*P*	NTR (n=2,855)	TVM (n=429)	AM (n=251)	*P*
0	0	0	NA	2 (0.1)	0	5 (2.0)	<.001[c]
0	0	1 (0.4)	.071	6 (0.2)	7 (1.6)	4 (1.6)	<.001[e]
1 (<0.1)	0	1 (0.4)	.152	1 (<0.1)	0	2 (0.8)	.016[g]
15 (0.5)	2 (0.5)	2 (0.8)	.820	159 (5.6)	21 (4.9)	6 (2.4)	.090
22 (0.8)	2 (0.5)	4 (1.6)	.227	143 (5.0)	18 (4.2)	9 (3.6)	.506
0	0	0	NA	2 (0.1)	0	2 (0.8)	.044[i]
0	11 (2.6)	2 (0.8)	<.001	0	15 (3.5)	3 (1.2)	<.001
0	0	1 (0.4)	.071	0	0	1 (0.4)	.071
0	0	0	NA	24 (0.8)	1 (0.2)	1 (0.4)	.313
1 (<0.1)	1 (0.2)	0	.348	9 (0.3)	1 (0.2)	1 (0.4)	1.00
0	6 (1.4)	1 (0.4)	<.001	0	7 (1.6)	1 (0.4)	<.001
3 (0.1)	4 (0.9)	2 (0.8)	.003	19 (0.7)	5 (1.2)	10 (4.0)	<.001[o]

with higher risk of major complications (Table 6). In the multivariable model, the associations of surgical approach, operating time, and prior POP surgery remained. Both mesh groups were independently associated with increased risk for major complication compared with native tissue repair.

DISCUSSION

We observed similar overall complication rates between native tissue and mesh-augmented repair surgeries. Low rates of individual surgical and nonsurgical complications occurred, with a moderate complication rate of 11.2% when all three approaches were combined. This study provides extensive data on major adverse events in the vast majority of POP surgeries performed in Finland over 1 year.

A systematic review of 124 studies of apical prolapse repair reported slightly higher complication rates for native tissue repair, transvaginal mesh kits, and abdominal sacrocolpopexy: 15.3%, 14.5%, and 17.1% respectively.[8] The lower complication rates of our study might be a result of the inability to track minor complications such as postoperative urinary tract and wound infections treated in primary

Table 5. Clavien-Dindo Grading of Perioperative and Postoperative Adverse Events

Grade*	All (N=3,535)	NTR Group (n=2,855)	TVM Group (n=429)	AM Group (n=251)	*P*
IIIa	66 (1.9)	42 (1.5)	16 (3.7)	8 (3.2)	.003[†]
IIIb	57 (1.6)	36 (1.3)	5 (1.2)	16 (6.4)	<.001[‡]
IVa	16 (0.5)	9 (0.3)	3 (0.7)	4 (1.6)	.014[§]
IVb	0	0	0	0	NA
V	2 (0.1)	1 (<0.1)	0	1 (0.4)	.152
Total	141	75 (2.6)	21 (4.9)	22 (8.8)	<.001[‖]

NTR, native tissue repair; TVM, transvaginal mesh; AM, abdominal mesh; NA, not available.
Data are n (%) unless otherwise specified.
Differences were assessed using either χ^2 or Fisher exact test.
* Grade III adverse events are defined as requiring surgical, endoscopic, or radiologic intervention under local anesthesia (IIIa) or general anesthesia (IIIb). Grade IV is defined as a life-threatening complication (including central nervous system complications) requiring intensive care unit management, with either single-organ dysfunction (including dialysis) (IVa) or multi-organ dysfunction (IVb). Grade V is defined as death of patient.
† Significant difference between NTR and TVM (pairwise testing, *P*=.001).
‡ Significant difference between NTR and AM (Bonferroni-corrected pairwise testing, *P*<.001). Significant difference between TVM and AM (Bonferroni-corrected pairwise testing, *P*<.001).
§ Significant difference between NTR and AM (Bonferroni-corrected pairwise testing, *P*<.017).
‖ Significant difference between NTR and AM (Bonferroni-corrected pairwise testing, *P*<.001). Significant difference between TVM and AM (Bonferroni-corrected pairwise testing, *P*=.045).

Table 6. Predictive Factors for the Occurrence of Clavien-Dindo Grades III–V Complications

Characteristic	Crude OR (95% CI)	Adjusted OR (95% CI)*
Type of surgery		
Native tissue repair	1	1
Transvaginal mesh	**1.91** (1.16–3.13)	**2.23** (1.31–3.80)
Abdominal mesh	**3.56** (2.17–5.84)	**3.02** (1.67–5.46)
Age, per year	1.00 (0.98–1.02)	1.00 (0.98–1.02)
BMI, per unit	0.96 (0.92–1.02)	0.97 (0.92–1.02)
Diabetes	1.07 (0.55–2.06)	0.99 (0.48–2.03)
Smoking	1.30 (0.69–2.47)	1.37 (0.71–2.64)
Operating time at or above group median	**2.66** (1.75–4.05)	**2.84** (1.78–4.53)
Most distal point of any compartment	1.11 (1.00–1.23)	0.97 (0.85–1.11)
Multiple compartment repair	1.21 (0.83–1.75)	0.97 (0.64–1.47)†
Parity (total)	1.06 (0.93–1.20)	1.07 (0.94–1.22)
History of cesarean delivery	1.02 (0.51–2.06)	1.02 (0.50–2.07)
Prior POP surgery	**2.17** (1.49–3.16)	**1.68** (1.00–2.81)
Prior hysterectomy		
No prior hysterectomy	1	1
For other reason than POP	1.41 (0.90–2.20)	1.26 (0.71–2.22)
Vaginal POP surgery	**1.72** (1.06–2.79)	1.13 (0.58–2.19)
Concomitant hysterectomy	0.94 (0.65–1.37)	0.66 (0.40–1.10)
Difficult surgery‡	**4.91** (3.22–7.49)	**2.75** (1.63–4.62)
Supervised gynecology trainee as surgeon	0.82 (0.53–1.29)	1.11 (0.66–1.89)
Hospital type		
University hospital	1	1
Central hospital	0.81 (0.54–1.22)	0.68 (0.43–1.09)
Regional hospital	0.76 (0.45–1.28)	0.84 (0.48–1.47)
Private hospital	0.82 (0.28–5.07)	1.41 (0.32–6.25)

OR, odds ratio; BMI, body mass index; POP, pelvic organ prolapse.
Statistically significant associations bolded.
* Multivariable model adjusted for type of surgery, age, BMI, diabetes, smoking, operating time, and most distal point of any compartment.
† Calculated using reduced multivariable model (including type of surgery, age, BMI, diabetes, smoking, and most distal point of any compartment) due to strong collinearity between operating time.
‡ Surgeon's subjective assessment on a three-level scale: easy, average, difficult.

care centers. The rate of nonsurgical complications was low in all surgical groups (less than 0.5%), which is comparable with our results.[8]

In previous studies, native tissue repair has been associated with low rates of surgical complications.[1,5,9,21] The occurrence of bowel, bladder, and ureteral injuries after native tissue repair were also low in our study. As for transvaginal mesh repair, bladder injuries occurred significantly more often compared with native tissue repair, which corresponds to the results of recent Cochrane Review.[1] We detected significantly higher rates of bladder and bowel injuries after abdominal mesh repair compared with native tissue repair, which differs from previous studies.[8,9] Also, our results show a significantly higher rate of complication-related reoperations (5.2%) in the abdominal mesh group compared with the native tissue repair group. Wu et al[11] reported no reoperations for serious complications within 90 days after abdominal sacrocolpopexy in a population of 43,458 women, whereas a systematic review estimated a 4.8% reoperation rate for other reasons than prolapse recurrence.[8]

The reported incidence of mesh-related complications after abdominal mesh and transvaginal mesh repair varies in literature. Transvaginal mesh repair has been associated with higher rates of mesh removal and revision compared with abdominal mesh surgery, especially with concomitant sling surgery.[6] Our results show a higher rate of mesh-related complications associated with transvaginal mesh surgery, with significantly higher occurrence of reoperations related to mesh complications. However, the relatively short follow-up period of 1 year in our study should be considered in the assessment of mesh complications in these two surgical groups, because studies with longer follow-up periods indicate an increase in mesh exposure rates over time.[10] In fact, a retrospective population-based study reported no difference in mesh removal or revision rates between abdominal and transvaginal mesh repair during an average follow-up time of 7 years.[11]

Out of the three surgical groups, native tissue repair was associated with the lowest rate of major adverse events (2.6% vs transvaginal mesh 4.9% and abdominal

mesh 8.8%). Several other studies have reported similar results of serious adverse events between native tissue repair and mesh- and graft-augmented repair.[21–24] In comparison, Mothes et al[25] reported a slightly lower rate of grades III–V complications after native tissue repair (0.9%), which might be a result of different methods of collecting complication data (retrospective patient chart view). In our study, the difference was driven by Clavien-Dindo grade III complications (any adverse event requiring surgical intervention), with a significantly higher rate of Clavien-Dindo grade IIIb complications (surgical intervention under general anesthesia) related to abdominal mesh surgery. No difference was observed with the more severe complications.

Mesh surgery, longer operating time, previous POP surgery, and difficult surgery were associated with higher risk of major adverse events in our study. Tobacco use or obesity were not associated with increased risk of major complication (including mesh complications), which is consistent with the results of the Swedish national register study.[21] Also, contrary to other previous studies, we did not find multiple compartment repair, stage of prolapse, concomitant hysterectomy, or diabetes to be associated with increased risk for major complication.[26] An Israeli study comparing native tissue repair with transvaginal mesh repair, however, reported a similar finding on association between occurrence of major adverse events and surgical duration.[27]

One of the main strengths of this study is the comprehensive collection of postoperative complication data, using information from surgeon and patient questionnaires as well as International Classification of Diseases, Tenth Revision and Nordic Classification of Surgical Procedures codes from national health care registers. The response rates from surgeons and patients were extensive, 100% and 72.1%, respectively. A previously published comparative study of determining complications after vaginal hysterectomy concluded that accurate assessment of postoperative complications requires combined use of code classification and chart review data. Of all identified complications, 98.1% were identified through chart review and 29.8% through coded data. Hence, reliance on data from either source only might be misleading, and combined methods should be used to maximize validity.[28]

There is no national POP surgery register in Finland. Patients are commonly treated postoperatively in local outpatient clinics for minor events in their postoperative course. Owing to uncertainty of comprehensive data regarding minor complications, such as postoperative urinary tract infections, we chose to focus on major complications of POP surgery. This, of course, should be taken into consideration when interpreting the relatively low complication rates presented in this study. In addition, the overall low rate of adverse events might have reduced the power to detect differences among surgical groups.

In current literature, assessing complications related to gynecologic POP surgery varies widely, and standardized reporting of postoperative complications is infrequent. Few studies have reported serious adverse events after POP repair using standardized classification comparing native tissue repair with mesh surgery.[8,9,27] The use of the standardized Clavien-Dindo grading system increases the value and comparability of this study. Several women in our study population had multiple Clavien-Dindo grades III–V adverse events; because there was no standard way to decide on concurrence of different complications, we reported and graded each adverse event separately.

Rogers et al[24] compared serious adverse events after open abdominal sacrocolpopexy and vaginal prolapse repair using data from three multicenter randomized trials. The overall rate of serious adverse events during a 1-year follow-up period was 26% after abdominal and 13% after vaginal surgery. In both groups, the rates of maximum reported Dindo score were highest for Clavien-Dindo grade III complications, 16% for abdominal and 8% for vaginal repair, respectively. Although the overall rates of serious adverse events are much higher than in our study, the trend between abdominal and vaginal repair remain similar. Also, the rates of prior prolapse surgery were significantly higher in the abdominal surgery group, which highlights the association between prior prolapse surgery and the occurrence of a major adverse event.

We conclude that POP surgery is a procedure associated with a low rate of serious complications. The main priority of POP surgery should be in improving the woman's quality of life by reducing the symptoms and providing the best possible anatomic durability with minimal risks. Even though long-term success rates of abdominal mesh procedures are quite promising, the higher risk of serious adverse events and surgical complications, such as bowel and bladder injuries associated with mesh procedures, should be carefully considered and discussed with the patient when planning POP surgery. Abdominal mesh surgery was associated with higher risk of major complications than transvaginal mesh, which should be taken into consideration when dealing with

multimorbid elderly patients. Unlike previous studies, multiple compartment repair did not raise the risk for complications. In further studies, a longer follow-up period will show whether further risk factors, especially associated with mesh complications, will appear.

REFERENCES

1. Maher C, Feiner B, Baessler K, Christmann-Schmid C, Haya N, Marjoribanks J. Transvaginal mesh or grafts compared with native tissue repair for vaginal prolapse. The Cochrane Database of Systematic Reviews 2016, Issue 2. Art. No.: CD012079. DOI: 10.1002/14651858.CD012079.
2. Smith FJ, Holman CDAJ, Moorin RE, Tsokos N. Lifetime risk of undergoing surgery for pelvic organ prolapse. Obstet Gynecol 2010;116:1096–100.
3. Wu JM, Matthews CA, Conover MM, Pate V, Jonsson Funk M. Lifetime risk of stress urinary incontinence or pelvic organ prolapse surgery. Obstet Gynecol 2014;123:1201–6.
4. Kurkijärvi K, Aaltonen R, Gissler M, Mäkinen J. Pelvic organ prolapse surgery in Finland from 1987 to 2009: a national register based study. Eur J Obstet Gynecol Reprod Biol 2017;214:71–7.
5. Altman D, Väyrynen T, Engh ME, Axelsen S, Falconer C. Anterior colporrhaphy versus transvaginal mesh for pelvic-organ prolapse. N Engl J Med 2011;364:1826–36.
6. Dandolu V, Akiyama M, Allenback G, Pathak P. Mesh complications and failure rates after transvaginal mesh repair compared with abdominal or laparoscopic sacrocolpopexy and to native tissue repair in treating apical prolapse. Int Urogynecol J 2017;28:215–22.
7. Pelvic organ prolapse. ACOG Practice Bulletin No. 214. American College of Obstetricians and Gynecologists. Obstet Gynecol 2019;134:e126–42.
8. Diwadkar GB, Barber MD, Feiner B, Maher C, Jelovsek JE. Complication and reoperation rates after apical vaginal prolapse surgical repair: a systematic review. Obstet Gynecol 2009;113:367–73.
9. Siddiqui NY, Grimes CL, Casiano ER, Abed HT, Jeppson PC, Olivera CK, et al. Mesh sacrocolpopexy compared with native tissue vaginal repair: a systematic review and meta-analysis. Obstet Gynecol 2015;125:44–55.
10. Nygaard I, Brubaker L, Zyczynski HM, Cundiff G, Richter H, Gantz M, et al. Long-term outcomes following abdominal sacrocolpopexy for pelvic organ prolapse. JAMA 2013;309:2016–24.
11. WuMaria Y, Reid J, Chou Q, MacMillan B, Leong Y, Welk B. Association between method of pelvic organ prolapse repair involving the vaginal apex and re-operation: a population-based, retrospective cohort study. Int Urogynecol J 2019;30:537–544.
12. Barski D, Otto T, Gerullis H. Systematic review and classification of complications after anterior, posterior, apical, and total vaginal mesh implantation for prolapse repair. Surg Technol Int 2014;24:217–24.
13. Nguyen JN, Jakus-Waldman SM, Walter AJ, White T, Menefee SA. Perioperative complications and reoperations after incontinence and prolapse surgeries using prosthetic implants. Obstet Gynecol 2012;119:539–46.
14. Nieminen K, Hiltunen R, Takala T, Heiskanen E, Merikari M, Niemi K, et al. Outcomes after anterior vaginal wall repair with mesh: a randomized, controlled trial with a 3 year follow-up. Am J Obstet Gynecol 2010;203:235.e1–8.
15. Mattsson NK, Karjalainen P, Tolppanen AM, Heikkinen AM, Jalkanen J, Härkki P, et al. Methods of surgery for pelvic organ prolapse in a nationwide cohort (FINPOP 2015). Acta Obstet Gynecol Scand 2019;98:451–9.
16. Haylen BT, Maher CF, Barber MD, Camargo S, Dandolu V, Digesu A, et al. An International Urogynecological Association (IUGA)/International Continence Society (ICS) joint report on the terminology for female pelvic organ prolapse (POP). Neurourol Urodyn 2016;27:655–84.
17. Sund R. Quality of the Finnish hospital discharge register: a systematic review. Scand J Public Health 2012;40:505–15.
18. Haylen BT, Freeman RM, Lee J, Swift SE, Cosson M, Deprest J, et al. An International Urogynecological Association (IUGA)/International Continence Society (ICS) joint terminology and classification of the complications related to native tissue female pelvic floor surgery. Int Urogynecol J 2012;23:515–26.
19. Dindo D, Demartines N, Clavien PA. Classification of surgical complications. Ann Surg 2004;240:205–13.
20. Clavien PA, Barkun J, De Oliveira ML, Vauthey JN, Dindo D, Schulick RD, et al. The Clavien-Dindo classification of surgical complications: five-year experience. Ann Surg 2009;250:187–96.
21. Bohlin KS, Ankardal M, Nüssler E, Lindkvist H, Milsom I. Factors influencing the outcome of surgery for pelvic organ prolapse. Int Urogynecol J 2018;29:81–9.
22. Morling JR, McAllister DA, Agur W, Fischbacher CM, Glazener CM, Guerrero K, et al. Adverse events after first, single, mesh and non-mesh surgical procedures for stress urinary incontinence and pelvic organ prolapse in Scotland, 1997–2016: a population-based cohort study. Lancet 2017;389:629–40.
23. Glazener CM, Breeman S, Elders A, Hemming C, Cooper KG, Freeman RM, et al. Mesh, graft, or standard repair for women having primary transvaginal anterior or posterior compartment prolapse surgery: two parallel-group, multicentre, randomised, controlled trials (PROSPECT). Lancet 2017;389:381–92.
24. Rogers RG, Nolen TL, Weidner AC, Richter HE, Jelovsek JE, Shepherd JP, et al. Open sacrocolpopexy and vaginal apical repair: retrospective comparison of success and serious complications. Int Urogynecol J 2018;29:1101–10.
25. Mothes AR, Mothes HK, Radosa MP, Runnebaum IB. Systematic assessment of surgical complications in 438 cases of vaginal native tissue repair for pelvic organ prolapse adopting Clavien–Dindo classification. Arch Gynecol Obstet 2015;291:1297–301.
26. Parkes IL, Shveiky D. Sacrocolpopexy for treatment of vaginal apical prolapse: evidence-based surgery. J Minim Invasive Gynecol 2014;21:546–57.
27. Besser L, Schwarzman P, Mastrolia SA, Rotem R, Leron E, Yohay D, et al. Comparative analysis of early adverse events of pelvic organ prolapse repair with or without transvaginal mesh using Clavien-Dindo classification. Int J Gynecol Obstet 2018;142:108–113.
28. Heisler CA, Melton LJ, Weaver AL, Gebhart JB. Determining perioperative complications associated with vaginal hysterectomy: code classification versus chart review. J Am Coll Surg 2009;209:119–22.

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