ORIGINAL ARTICLE

Surgical treatment of primary uterine prolapse: a comparison of vaginal native tissue surgical techniques

Karen Ruben Husby[1,2] · Michael Due Larsen[3,4] · Gunnar Lose[1,2] · Niels Klarskov[1,2]

Abstract

Introduction and hypothesis Uterine prolapse is a common diagnosis. Today no consensus exists on which operation technique is ideal to treat apical prolapse. Vaginal hysterectomy (VH) with suspension of the vaginal cuff is the most frequently used. The popularity of uterus-preserving techniques is increasing. The aim of this study was to compare the efficiency of vaginal native tissue operations to treat primary apical prolapse, evaluated on risk of relapse surgery.

Methods Data were obtained from the Danish National Patient Registry (NPR), which contains all operations performed in Denmark. Patients operated on for primary apical prolapse in Denmark 2010–2016 were included and followed until 2017. Clinical data were obtained from the Danish Urogynecological Database. Patients who were previously hysterectomized or operated on for prolapse in the apical compartment were excluded. Data were analyzed using Cox proportional hazard regression analysis and adjusted for age, BMI, smoking, preoperative prolapse stage and previous POP operations.

Results In total, 7247 operations were included. The hazard ratio (HR) for relapse operation in the apical compartment was significantly higher after sacrospinous hysteropexy (SH) compared with the Manchester-Fothergill procedure (MP) [40.2 confidence interval (CI) 21.6–74.7] and VH (8.5 CI: 6.0–12.1). Likewise, the HR was higher in the anterior compartment after SH compared with MP (4.3 CI: 2.9–6.4) and VH (2.8 CI: 2.0–4.0). No convincing difference was found in the posterior compartment. The 5-year reoperation rates were 30%, 7% and 11% after SH, MP, and VH, respectively.

Conclusions Sacrospinous hysteropexy has exceedingly high numbers of reoperations due to prolapse recurrence.

Keywords Pelvic organ prolapse (POP) · Apical prolapse · Manchester-Fothergill procedure · Vaginal hysterectomy · Sacrospinous hysteropexy

Abbreviations

ASA	The American Society of Anesthesiologists
BMI	Body mass index
DugaBase	The Danish Urogynecological Database
MP	Manchester-Fothergill procedure
SH	Sacrospinous hysteropexy
UI	Urinary incontinence
VH	Vaginal hysterectomy

✉ Karen Ruben Husby
Karen.ruben.husby.02@regionh.dk

1 Department of Obstetrics and Gynecology, Herlev and Gentofte University Hospital, Herlev Ringvej 75, 2730 Herlev, Denmark

2 University of Copenhagen, Copenhagen, Denmark

3 Center for Clinical Epidemiology, Odense University Hospital, Odense, Denmark

4 Research Unit of Clinical Epidemiology, University of Southern Denmark, Odense, Denmark

Introduction

The lifetime risk for prolapse surgery is 18.7% for Danish women [1] and the number of operations is continually growing [2]. Various surgical techniques are being performed to treat apical prolapse [3] with vaginal hysterectomy with suspension of the vaginal cuff as the most frequently used procedure. However, the popularity of uterus-preserving techniques is increasing. At the present time, there is still no consensus on the ideal operation technique.

Until now, no large high-quality study has compared vaginal hysterectomy, the Manchester-Fothergill procedure and sacrospinous hysteropexy in one study. The Danish National Patient Registry (NPR) includes information on all surgical procedures performed in Denmark since 1977. This database creates a unique setting to evaluate the efficiency of these operation types.

The aim of this study was to compare the efficiency of vaginal native tissue operation types to treat primary apical prolapse, evaluated on risk of relapse surgery.

Materials and methods

Study population and setting

This nationwide register-based study includes pelvic organ prolapse (POP) operations in the apical compartment during a 7-year period from 1 January 2010 to 31 December 2016. Data were retrieved from the Danish National Patient Registry (NPR) [4] and supplemented with clinical information from the Danish Urogynaecological Database (DugaBase) [5, 6].

The availability of nationwide Danish registries makes it possible to retrieve data from the NPR on all patients discharged from Danish hospitals since 1977 and on all outpatient visits since 1995 [4]. Because all citizens in Denmark have a unique civil registration number (CPR no.), it was possible to merge information from several databases. The NPR includes information on the patients' civil registration number, hospital, departments, date of admission and discharge, procedures performed and up to 20 discharge diagnoses. The diagnoses were based on the ICD 10th revision since 1994. Data on death and immigration were retrieved from the Danish Civil Registration System (CRS) for the entire Danish population, which comprises all data on death and immigration since 1968 and is very accurate [7]. For all patients, migration and comorbidity information was retrieved from the NPR. The DugaBase was established in 2006 to monitor, ensure and improve the quality of urogynecological operations for all urinary incontinence (UI) and POP operations in public and private hospitals in Denmark [6, 8]. The DugaBase contains information on > 45,000 UI and POP operations in an unselected nationwide cohort including full follow-up on migration, death, diagnosis and procedures. For all Danish hospital departments and private hospitals/clinics performing UI and POP procedures, it is mandatory according to Danish law to report data to the DugaBase via a national web-based input module with very high validity and completeness (> 90%) of the database [6, 8]. Pre- and postoperative questionnaires regarding POP and UI operations were systematically collected and contain information on five parts: (1) referral of patients, (2) a preoperative self-administrated patient questionnaire based on the International Consultation of Incontinence

Questionnaire scoring system, (3) a preoperative questionnaire completed by the gynecologists including information on preoperative examinations including POP-Q, BMI, smoking status and ASA score, (4) information on procedures and (5) a postoperation questionnaire consisting of the same self-administrated questionnaires used before operation.

Demographic characteristics and comorbidity of participants

From the NPR information on the surgical procedures for POP was included (according to the 'Nordic Classification of Surgical Procedures'). In this study, succeeding primary POP operations in the apical compartment were included: Manchester-Fothergill procedure (MP) (KLEF00B and KLDC10), vaginal hysterectomy (VH) (KLEF53 + KLCD10) and sacrospinous hysteropexy (SH) (KLEF53B). Patients who were previously hysterectomized or operated on for prolapse in the apical compartment were excluded. Likewise, women registered with a POP procedure in combination with a UI procedure were excluded. Finally, women with a hospital contact for a malignant disease within 5 years before the operation [9] were excluded, and only Danish citizens were included to ensure a full history of comorbidity and migration.

Outcome measures

Primary outcome was a new POP operation in the apical compartment. Secondary outcome was a new POP operation in any compartment. Patients were followed until 30 June 2017.

Statistical analysis

All results are reported using descriptive statistics in exact numbers and means with 95% confidence intervals (CI). Data were analyzed using a Cox proportional hazard regression analysis and adjusted for age, preoperative prolapse stage in the apical compartment, smoking, BMI and previous POP surgery in the anterior and posterior compartment.

All calculations were performed using STATA release 14.2 (StataCorp, College Station, TX, USA).

Ethics and approvals

The DugaBase operates under Danish law on data protection, with a license granted by the Danish Data Protection Agency and the Danish Health and Medicines Authority. This specific study was approved by the Region of Southern Denmark no. 17.444 45. According to Danish law, ethical approval is not required for non-intervention registry-based studies.

Table 1 Characteristics of women undergoing vaginal native tissue surgery for primary uterine prolapse in Denmark, 2010–2016

	Total	Manchester-Fothergill procedure	Vaginal hysterectomy	Sacrospinous hysteropexy
All	7247	2786	4045	416
Age, mean (SD)	62.4 (12.0)	61.9 (12.3)	63.2 (11.4) §	58.2 (14.2) §#
Age < 50 (%)	3674 (50.7)	1468 (52.7)	1960 (48.5)	246 (59.1)
Age 50–75 (%)	2508 (34.6)	923 (33.1)	1459 (36.1)	126 (30.3)
Age > 75 (%)	1065 (14.7)	395 (14.2)	626 (15.5)	44 (10.6)
BMI			§	§
< 25 (%)	2787 (38.5)	1092 (39.2)	1502 (37.1)	193 (46.4)
25–29 (%)	2200 (30.4)	816 (29.3)	1259 (31.1)	125 (30.1)
30–35 (%)	772 (10.7)	299 (10.7)	438 (10.8)	35 (8.4)
> 35 (%)	176 (2.4)	79 (2.8)	83 (2.0)	14 (3.4)
Smoking			§	§
No (%)	5101 (70.4)	1982 (71.1)	2794 (69.1)	325 (78.1)
Yes (%)	747 (10.3)	286 (10.3)	427 (10.6)	34 (8.2)
Previous prolapse surgery				
Anterior compartment (%)	320 (4.4)	125 (4.5)	134 (3.3) §	61 (14.7)
Posterior compartment (%)	198 (2.7)	78 (2.8)	93 (2.3) §	27 (6.5)
Cesarean section (%)	360 (6.3)	150 (6.8)	182 (5.7) §	28 (8.1) §#
Parity			§	§#
0 (%)	84 (1.2)	28 (1.0)	54 (1.3)	2 (0.5)
1 (%)	650 (9.0)	248 (8.9)	369 (9.1)	33 (7.9)
> 1 (%)	5329 (73.5)	2074 (74.4)	2924 (72.3)	331 (79.6)
Preoperative POP stage in apical compartment				
0 (%)	218 (3.0)	102 (3.7)	101 (2.5)	15 (3.6)
1 (%)	616 (8.5)	337 (12.1)	211 (5.2)	68 (16.4)
2 (%)	3471 (47.9)	1498 (53.8)	1734 (42.9)	239 (57.5)
3 (%)	1600 (22.1)	422 (15.2)	1123 (27.8)	55 (13.2)
4 (%)	342 (4.7)	48 (1.7)	277 (6.9)	17 (4.1)
Preoperative POP stage in anterior compartment				
0 (%)	621 (8.6)	158 (5.7)	434 (10.7)	29 (7.0)
1 (%)	648 (8.9)	216 (7.8)	393 (9.7)	39 (9.4)
2 (%)	2370 (32.7)	1029 (36.9)	1119 (27.7)	222 (53.4)
3 (%)	2324 (32.1)	945 (33.9)	1294 (32.0)	85 (20.4)
4 (%)	267 (3.7)	69 (2.5)	179 (4.4)	19 (4.6)
Preoperative POP stage in posterior compartment				
0 (%)	2337 (32.3)	884 (31.7)	1295 (32.0)	158 (38.0)
1 (%)	2027 (28.0)	828 (29.7)	1050 (26.0)	149 (35.8)
2 (%)	1232 (17.0)	493 (17.7)	685 (16.9)	54 (13.0)
3 (%)	329 (4.5)	74 (2.7)	236 (5.8)	19 (4.6)
4 (%)	96 (1.3)	13 (0.5)	74 (1.8)	9 (2.2)

Values are given in numbers if nothing else is stated. §: Significantly different from MP; #: significantly different from VH; $p < 0.05$. BMI: Body mass index; POP: pelvic organ prolapse. Missing: BMI: 1312 (18.1%); smoking: 1399 (19.3%); preoperative POP stage in the apical compartment: 1000 (13.8%); preoperative POP stage in the anterior compartment: 1017 (14.0%); preoperative POP stage in the posterior compartment: 1226 (16.9)

Results

In total, 7247 patients were included; of these 2786 were operated on with MP, 4045 with VH and 416 with SH (Table 1). The mean age was 62.4 years and the majority (70%) of the women had a preoperative POP stage 2 or 3 in the apical compartment. Follow-up ranged from 1 to 90 months (median 43 months). The group treated with SH was younger, had higher parity and had more frequently had cesarean section compared with the groups treated with MP and VH and furthermore had a lower BMI and smoked less than the group treated with MP. The group treated with VH was older, had a slightly higher BMI, smoked more, had been more often previously operated on for POP in the anterior or posterior compartment, had lower parity and had less frequently had cesarean delivery compared with the group treated with MP. Apart from this, the groups were comparable. Adjustments were performed for age, BMI, smoking habits, preoperative stage of prolapse in the apical compartment and previous POP surgery in the anterior and posterior compartment.

Figure 1 shows the exclusion tree.

In Table 2 the hazard ratios for reoperations after the different operation techniques are shown. The risk of reoperation was higher after SH compared with MP as well as VH in the apical compartment, anterior compartment and any compartment [hazard ratio (HR) 40.2, 4.3, and 5.0, respectively,

compared with MP and HR 8.5, 2.8 and 3.3, respectively, compared with VH], but not in the posterior compartment.

The risk of reoperation was significantly higher after VH compared with MP in the apical compartment, anterior compartment, posterior compartment and any compartment (HR 4.2, 1.6, 1.5 and 1.5, respectively).

After an SH, 16% of the women had a reoperation performed in any compartment within 1 year, while 32% had a reoperation performed within 5 years. After an MP and a VH, this was 3% within 1 year and 7% and 11%, respectively, within 5 years (Fig. 2). Kaplan-Meier curves of reoperations in the three compartments separately and combined are shown in Fig. 2.

Discussion

This nationwide register study with 7247 included patients and up to 90-month follow-up showed an exceedingly high number of reoperations after sacrospinous hysteropexies. After 5 years 32% of women operated on with SH had had a reoperation in at least one compartment; this number was 7% after MP and 11% after VH. The risk of relapse operation in the apical compartment was 40 times higher after SH compared with MP and 9 times higher after SH compared with VH.

Fig. 1 Exclusion tree. N: Number, NPR: National Patient Registry, Dugabase: Danish urogynecological database, POP: pelvic organ prolapse, MP: Manchester-Fothergill procedure, VH: vaginal hysterectomy, SH: sacrospinous hysteropexy
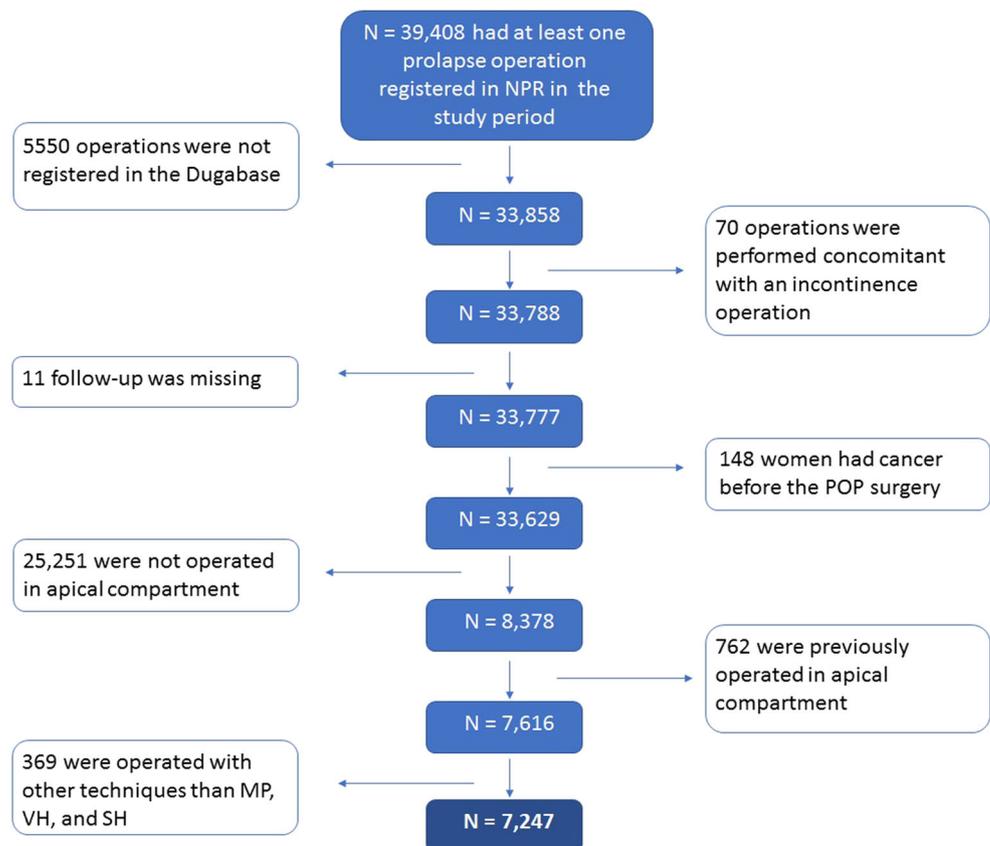
N = 39,408 had at least one prolapse operation registered in NPR in the study period

5550 operations were not registered in the Dugabase

N = 33,858

70 operations were performed concomitant with an incontinence operation

N = 33,788

11 follow-up was missing

N = 33,777

148 women had cancer before the POP surgery

N = 33,629

25,251 were not operated in apical compartment

N = 8,378

762 were previously operated in apical compartment

N = 7,616

369 were operated with other techniques than MP, VH, and SH

N = 7,247

Table 2 Risk of reoperation following vaginal native tissue surgery for primary uterine prolapse, hazard ratio (HR)

Compartment of reoperation	Primary operation	N outcome	Median time at risk (years)	Crude HR	Adjusted HR*
A: Manchester-Fothergill procedure versus vaginal hysterectomy					
Anterior compartment	MP	84	3.5	1	1
	VH	203	4.3	1.5 [1.2–2.0]	1.6 [1.2–2.0]
Apical compartment	MP	15	3.6	1	1
	VH	109	4.3	4.6 [2.7–7.9]	4.2 [2.4–7.2]
Posterior compartment	MP	102	3.5	1	1
	VH	229	4.2	1.4 [1.1–1.8]	1.5 [1.2–1.9]
Any compartment	MP	171	3.4	1	1
	VH	400	4.1	1.5 [1.3–1.8]	1.5 [1.3–1.8]
B: Manchester-Fothergill procedure versus sacrospinous hysteropexy					
Anterior compartment	MP	84	3.5	1	1
	SH	41	1.8	4.7 [3.2–6.9]	4.3 [2.9–6.4]
Apical compartment	MP	15	3.6	1	1
	SH	55	1.7	38.3 [21.2–69.4]	40.2 [21.6–74.7]
Posterior compartment	MP	102	3.5	1	1
	SH	8	2	0.7 [0.4–1.5]	0.7 [0.3–1.5]
Any compartment	MP	171	3.4	1	1
	SH	90	1.6	5.4 [4.1–7.0]	5.0 [3.8–6.5]
C: Vaginal hysterectomy versus sacrospinous hysteropexy					
Anterior compartment	VH	203	4.3	1	1
	SH	41	1.8	2.9 [2.1–4.1]	2.8 [2.0–4.0]
Apical compartment	VH	109	4.3	1	1
	SH	55	1.7	7.6 [5.5–10.6]	8.5 [6.0–12.1]
Posterior compartment	VH	229	4.2	1	1
	SH	8	2	0.5 [0.2–1.0]	0.4 [0.2–0.9]
Any compartment	VH	400	4.1	1	1
	SH	90	1.6	3.4 [2.7–4.3]	3.3 [2.6–4.3]

The HRs are calculated using multivariate Cox proportional hazard model adjusted estimates with 95% confidence intervals. Analyses were performed separately for each compartment

*Adjustments are made for age, BMI, smoking, preoperative prolapse stage in the apical compartment and previous surgery in the anterior and posterior compartment

In total, 2786 were operated on with MP, 4045 with VH and 416 with SH. N: Number, HR: hazard ratio, MP: Manchester-Fothergill procedure, VH: vaginal hysterectomy, SH: sacrospinous hysteropexy

Strengths

Owing to the Danish databases, information about all operations performed in Denmark in the study period was collected and analyzed in this study. Registration in NPR as well as in DugaBase is mandatory by law, providing very high completeness, and the DugaBase has previously been evaluated and found to have very high validity [6]. Such a large unselected sample size is unique.

In addition to a large sample size, a strength of this study is the complete follow-up of all women because of the unique Danish identification number. The healthcare system in Denmark is free of charge; therefore, the financial status of the patients did not influence the choice of reoperation.

Limitations

A limitation of this study is that information about conservative treatment and anatomical as well as symptomatic prolapses could not be obtained through the databases. The number of relapses might be higher than the number of reoperations.

Another limitation of this study is that the type of operation relies on the preference of the surgeon as well as of the patient. The high number of reoperations after SH could be a result of an insufficient operation technique or insufficient surgical skills of the surgeon. However, it is the code of practice in Denmark that urogynecological procedures including SH are only performed by urogynecological specialists. Furthermore, our previous study found that 90% of the SHs performed in

Fig. 2 Kaplan-Meier plots showing the proportion of reoperated patients due to prolapse over time in the apical compartment, anterior compartment, posterior compartment and any compartment
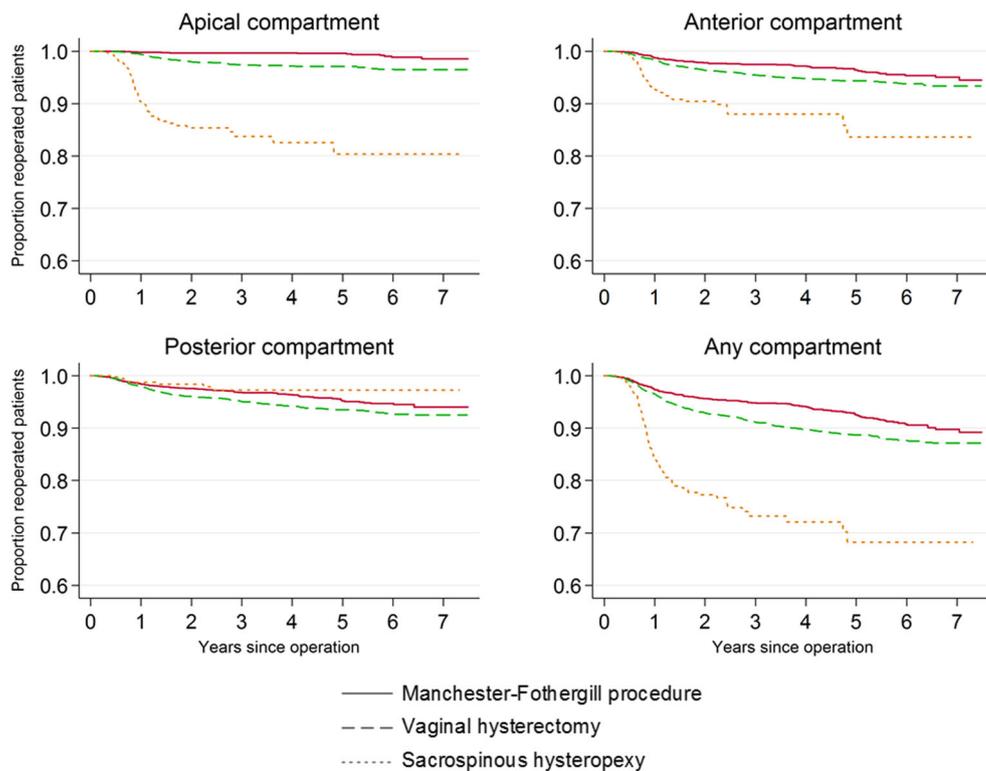
Denmark were performed at hospitals with the highest level of urogynecological specialization [10]. Thus, it is more likely the SH procedure which is insufficient rather than the surgical skills of the doctors performing the SH.

A third limitation is that the databases did not contain information on the suspension of the vaginal cuff during VH. It is the code of practice in Denmark to suspend the vaginal cuff, as we found in a recent matched cohort study where all surgical descriptions were reviewed. All 298 VHs had a description of a suspension of the vaginal cuff (either low or high uterosacral ligament suspension) [11]. However, the type of suspension could not be unraveled in the present study, and therefore the conclusions should be interpreted with cautiousness. If some of the VHs happened to be unsuspended, the difference between VH and SH might be even larger, while the difference between MP and VH might be narrower. However, we have previously found comparable differences between MP and VH [11].

As for other register-based studies, a limitation of this study is the lack of technical information such as suture type, why the specific operation type was chosen and the education level of the surgeon.

Vaginal hysterectomy

This study supports our previous studies showing higher rates of re-operation, conservative re-intervention and recurrence after VH than after MP [11, 12]. Our matched cohort study found significantly higher risk of recurrence after VH than after MP in all three compartments. The risk of recurrence in the apical compartment was ten times [confidence interval (CI): 1.3–78.1] higher after VH than after MP [11]. This correlates well with the 4.30 (CI: 2.46–7.56) times higher risk of relapse operation after VH than after MP found in this study.

Recently, a meta-analysis by de Oliveira et al. concluded that the rate of reoperations was significantly lower after hysterectomy than after uterus-preserving operations when treating apical prolapse [13]. However, the study pooled uterus-preserving techniques, and the MP was not included. This study shows large variation in the rate of reoperation after different types of uterus-preserving techniques, making pooling problematic.

Sacrospinous hysteropexy

A randomized study showed in 2010 that the recurrence rate of apical prolapse (defined as stage 2–4) after 1 year was 21% after SH. Within 1 year 6% had a relapse operation after SH [14]. This is consistent with the finding of this study that 10% had a reoperation performed in the apical compartment within 1 year.

A recent systematic review by Meriwether et al. reviewed uterine-preserving surgeries for the repair of POP. They found a lower rate of repeat surgery for prolapse after MP (2.1) than after vaginal native tissue hysteropexies including SH (4.1) [15]. Since SH was

included in a pooled group and since the operation techniques were not directly compared, the results are not fully comparable to the results of this study. However, the results show consistency with the results of this study.

This study finds significantly higher rates of reoperations after SH in the anterior and apical compartments, but not in the posterior compartment. This could be due to the posterior orientation of the vagina postoperatively after SH leaving the anterior and apical compartment more susceptible to abdominal pressure while protecting the posterior compartment.

This study shows exceedingly high numbers of reoperations after SH compared with after MP as well as after VH. The operation technique should be restricted until evidence can guarantee the durability of the operation.

Compliance with ethical standards

References

1. Løwenstein E, Ottesen B, Gimbel H. Incidence and lifetime risk of pelvic organ prolapse surgery in Denmark from 1977 to 2009. Int Urogynecol J Pelvic Floor Dysfunct. 2014;26:49–55. https://doi.org/10.1007/s00192-014-2413-y.
2. Wu JM, Hundley AF, Fulton RG, Myers ER. Forecasting the prevalence of pelvic floor disorders in the US women: 2010 to 2050. Obstet Gynecol. 2009;114:1278–83. https://doi.org/10.1097/AOG.0b013e3181c2ce96.
3. Maher C, Feiner B, Baessler K, et al. Surgical management of pelvic organ prolapse in women. Cochrane Database Syst Rev. 2010: CD004014. https://doi.org/10.1002/14651858.CD004014.pub4.
4. Schmidt M, Schmidt SAJ, Sandegaard JL, et al. The Danish National Patient Registry: a review of content, data quality, and research potential. Clin Epidemiol. 2015;7:449. https://doi.org/10.2147/CLEP.S91125.
5. Hansen UD, Gradel KO, Larsen MD. Danish Urogynaecological database. Clin Epidemiol. 2016:709–12.
6. Guldberg R, Brostrøm S, Hansen JK, et al. The Danish urogynaecological database: establishment, completeness and validity. Int Urogynecol J Pelvic Floor Dysfunct. 2013;24:983–90. https://doi.org/10.1007/s00192-012-1968-8.
7. Schmidt M, Pedersen L, Toft H. The Danish civil registration system as a tool in epidemiology. Eur J Epidemiol. 2014:541–9. https://doi.org/10.1007/s10654-014-9930-3.
8. Danish Urogynecological database, available online at: http://www.dugabase.dk/. Accessed December 12, 2017.
9. Sundararajan V, Henderson T, Perry C, et al. New ICD-10 version of the Charlson comorbidity index predicted in-hospital mortality. J Clin Epidemiol. 2004;57:1288–94. https://doi.org/10.1016/j.jclinepi.2004.03.012.
10. Husby KR, Lose G, Klarskov N. Trends in apical prolapse surgery between 2010 and 2016 in Denmark. 2018. https://doi.org/10.1007/s00192-018-3852-7.
11. Tolstrup CK, Husby KR, Lose G, et al. The Manchester-fothergill procedure versus vaginal hysterectomy with uterosacral ligament suspension: a matched historical cohort study. Int Urogynecol J. 2018;29:431–40. https://doi.org/10.1007/s00192-017-3519-9.
12. Tolstrup CK, Lose G, Klarskov N. The Manchester procedure versus vaginal hysterectomy in the treatment of uterine prolapse: a review. Int Urogynecol J. 2016 1–8 . https://doi.org/10.1007/s00192-016-3100-y.
13. de Oliveira SA, Fonseca MCM, Bortolini MAT, et al. Hysteropreservation versus hysterectomy in the surgical treatment of uterine prolapse: systematic review and meta-analysis. Int Urogynecol J. 2017; 1617–1630 . https://doi.org/10.1007/s00192-017-3433-1.
14. Dietz V, Van Der Vaart CH, Van Der Graaf Y, et al. One-year follow-up after sacrospinous hysteropexy and vaginal hysterectomy for uterine descent: a randomized study. Int Urogynecol J. 2010;21:209–16. https://doi.org/10.1007/s00192-009-1014-7.
15. Meriwether K V, Balk EM, Antosh DD, et al. Uterine-preserving surgeries for the repair of pelvic organ prolapse: a systematic review with meta-analysis and clinical practice guidelines. Int Urogynecol J. 2019.