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A randomised controlled trial comparing abdominal and vaginal prolapse surgery: effects on urogenital function

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Objective To compare the effects of vaginal hysterectomy (combined with anterior and/or posterior colporraphy) and abdominal sacro-colpopexy (with preservation of the uterus) on urogenital function.

Design Randomised trial.

Setting Three teaching hospitals in The Netherlands.

Population Eighty-two patients undergoing surgical correction of uterine prolapse stages II–IV.

Methods Participating patients completed the urogenital distress inventory (UDI), before and at six weeks, six months and one year after surgery, to measure discomfort of prolapse and micturition symptoms. Domain scores of the UDI (ranging from 0 to 100, higher scores indicating more discomfort) were compared between groups at all time points. Findings at pelvic examination, number of doctor visits within the first year after surgery because of pelvic floor symptoms and performed or planned surgery of recurrent genital prolapse were also compared.

Main outcome measure Domain scores of the UDI at one year after surgery.

Results At one year after surgery, scores on the discomfort/pain domain (mean difference 7.1, 95% confidence interval [CI] 1.1–13.2), overactive bladder domain (mean difference 8.7, 95% CI 0.5–16.9) and obstructive micturition domain (mean difference 10.3, 95% CI 0.6–20.1) of the UDI were significantly higher in the abdominal group than in the vaginal group. Findings at pelvic examination were similar in both groups. Doctor visits because of pelvic floor symptoms were more frequent in the abdominal group than in the vaginal group. Re-operation was performed or planned in 9 of the 41 patients who underwent abdominal surgery and in 1 of the 41 patients who underwent vaginal surgery (odds ratio [OR] = 11.2, 95% CI 1.4–90.0).

Conclusions Our findings suggest that vaginal hysterectomy with anterior and/or posterior colporraphy is preferable to abdominal sacro-colpopexy with preservation of the uterus as surgical correction in patients with uterine prolapse stages II–IV.

INTRODUCTION

Uterine prolapse may negatively affect pelvic floor function, resulting in micturition symptoms, defecation symptoms and sexual dysfunction.[1] If the anatomical abnormalities and impaired pelvic floor function of patients with uterine prolapse are severe enough, surgical correction is indicated. Several surgical procedures have been described to effectively correct uterine prolapse.[2–5] A gynaecologist will often either choose to perform a vaginal hysterectomy, if necessary combined with anterior and/or posterior colporraphy or to perform a sacro-colpopexy with preservation of the uterus.[6] Retrospective studies have shown similar complication and failure rates of both techniques.[7–10] Thus far, these techniques have not been compared in a randomised trial.

We set out to compare functional and anatomical effects of abdominal and vaginal surgical correction of uterine prolapse with a multicentre randomised controlled trial.

METHODS

The study population consisted of 82 patients enrolled between January 1998 and July 2000. Only patients with intact uteri were recruited. Exclusion criteria were the presence of an adnexal mass, a history of more than two abdominal pelvic surgical procedures, extreme obesity (body mass index > 35 kg/m^2), prior inflammatory bowel

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or pelvic disease and faecal incontinence because of an internal or external anal sphincter defect. The study protocol was approved by the institutional ethical committees of the three participating hospitals (University Medical Center in Utrecht, St Antonius Hospital in Nieuwegein and Diakonessenhuis in Utrecht) and written informed consent was obtained from all patients.

A standardised urogynaecologic interview and a classification of the genital prolapse according to the recommendations of the ICS[11] was performed in all patients by the first author, both before surgery and at six weeks, six months and one year after surgery. According to this classification, uterine prolapse, cystocele and rectocele were classified as follows: stage 0: none; I: distal portion of the prolapse is >1 cm above the hymenal ring; II: prolapse is between 1 cm proximal and 1 cm distal to the hymenal ring; III: prolapse is >1 cm below the hymen but no further than 2 cm or less than the total vaginal length; and IV: complete or near complete (within 2 cm) vaginal eversion. Grading of the prolapse was performed at maximal straining in the 45° supine position.

The diagnostic work-up further included a urodynamic evaluation, defecography and ano-rectal function tests.[11–13] Urodynamic investigation included simple uroflowmetry with catheterised post-void residual urine volume determination, retrograde provocative multichannel urethrocystometry and passive and dynamic urethral pressure profilometry with the prolapse protruding and with the prolapse reduced.[14]

Vaginal surgery consisted of a vaginal hysterectomy combined with anterior and/or posterior colporraphy if indicated.[2] After vaginal hysterectomy, the position of the vaginal vault was ensured, by fixating it with absorbable sutures (Vicryl 1) to the cardinal–uterosacral ligaments.

The abdominal correction involved a sacro-colpopexy with preservation of the uterus.[15] The abdomen was entered through a low midline or transverse incision. In contrast to most procedures that only identify the vaginal apex and attach graft material to this limited area, we started with a peritoneal incision, which was extended from the pre-sacral area, across the cul-de-sac of Douglas, to the top of the vagina just next to the mesentery of the colon. The prolapsed uterus was replaced in its proper position by inserting a plastic stent in the vagina. With the vagina distended, the bladder and rectum were dissected sharply from the vagina, over at least one-third of its length. Two Gore-Tex soft tissue patches, each measuring about 4 × 10 cm were used. One was anchored along the anterior vaginal wall and the frontal aspect of the cervix, the other to the dorsal side of the vagina. The rectum was lifted and fixated to the mesh with two to three non-absorbable sutures. This way, the recto-vaginal space was obliterated. The free part of the anteriorly placed implant was cut into two slings. The right and left slings were passed through the corresponding broad ligaments at an avascular point, about 1 cm medial from the external part of the isthmus tubae and were led to the dorsal side of the uterine cervix. Both slings were fixated here and secured to the dorsal patch. The periosteum of the sacrum was denuded with the sigmoid colon retracted sharply to the left. The implant was affixed transversely to the longitudinal ligament on the anterior surface of the sacrum by the use of two non-resorbable sutures, approximately 1 cm below the promontorium. The patch was then secured to the sacrum with minimal tension on the vagina.

Sacro-colpopexy with preservation of the uterus may be a surgical procedure that is not routinely performed all over the world. Some believe that this procedure is only suited as a single compartment repair. However, by dissecting the vagina from the bladder anteriorly and from the rectum posteriorly, sacro-colpopexy provides access to a multiple compartment approach.

Simultaneously, a colposuspension was performed in case of stress incontinence with the prolapse protruding (defined as evident stress incontinence) or with the prolapse reduced (defined as masked stress incontinence). If a colposuspension was indicated during vaginal surgical correction of the prolapse, a Pereyra or Raz needle bladder neck suspension was performed.[14,16,17] If a colposuspension was indicated during abdominal surgical correction of the prolapse, a modified Burch colposuspension, as described by Tanagho[18] was performed.

All surgeries were performed by experienced gynaecologists who were familiar with both techniques and who were all originally trained in the University Medical Center Utrecht. They had all performed at least 50 of each described surgical procedure prior onset of the study. Before onset of the study, for each surgical procedure, a standardised surgery report had been developed. No patients were operated on by the first author.

All women received peri-operative deep vein thrombosis prophylaxis and a single dose of intravenous prophylactic antibiotic (Augmentin) during operation. A 14-French Foley indwelling bladder catheter with a 5 mL balloon was placed in all women post-operatively and removed after two to five days. In case of bladder retention (defined as twice a residual volume after voiding of more than 100 mL), the patient started clean intermittent self-catheterisation. Post-operative pain management was the same in both groups.

For each patient, the following information was collected: duration of surgery, amount of blood loss, complications during surgery, complications during hospital stay, duration of hospital stay and late complications due to surgery. During the first year after surgery, the number of visits to a gynaecologist or general practitioner because of prolapse symptoms, micturition symptoms, defecation symptoms and other symptoms related to the performed prolapse surgery were documented for each patient. We also scored how often repeated prolapse surgery was performed or planned because of recurrence of genital prolapse. Recurrence of prolapse was defined as a combination of a stage II or more

genital prolapse in combination with symptoms of pelvic floor dysfunction.

All participating patients were asked to complete the Dutch version of the Urogenital Distress Inventory (UDI)[19,20] at two to four weeks before surgery, at six weeks after surgery, at six months after surgery and at one year after surgery. The UDI consists of 19 items and each item measures if a micturition or prolapse symptom is present and to what extent the patient is bothered by this symptom. The latter is measured on a four-point Likert scale ranging from not at all to severely bothered. After forward–backward translation, a factor analysis of the Dutch version of the UDI was performed. Data from a random population sample ($n = 2042$) and from patients presenting themselves with urogenital dysfunction at the gynecologic out patient clinic of the University Medical Center Utrecht ($n = 196$) were used.[20] We identified five domains, namely, discomfort/pain, urinary incontinence, overactive bladder, genital prolapse and obstructive micturition. Cronbach's α, a measurement of internal consistency, ranged between 0.74 and 0.82. One item (bed-wetting) had a low factor loading on all domains and was therefore excluded. The domain scores range from 0 to 100. A higher score indicates more bothersome symptoms on that particular domain.

Principle outcomes were domain scores of the UDI at six weeks, six months and one year after surgery. Secondary outcomes were findings at pelvic examination at six weeks, six months and one year after surgery, the number of doctor visits within the first year after surgery because of pelvic floor symptoms and performed or planned surgery because of recurrent genital prolapse.

The sample size calculation was based on data from a random population sample ($n = 2042$) and from patients

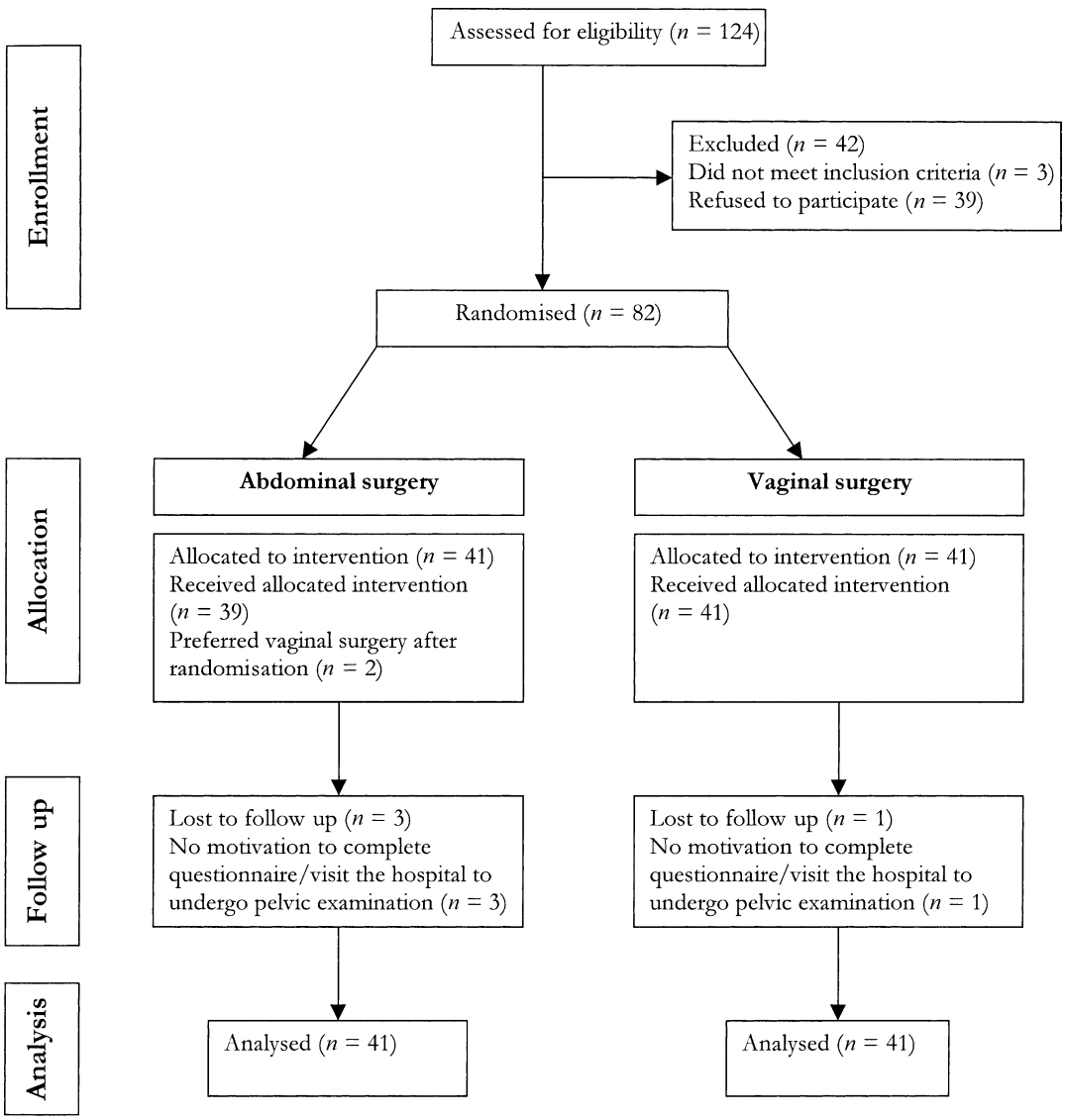

Fig. 1. Flow of participants through each stage of the trial.

Table 1. Baseline characteristics of the patients according to surgical approach. Values are means [SD] or *n* (%).

	Vaginal approach	Abdominal approach
Number of patients	41	41
Age (years)	56.4 [10.9]	57.9 [8.8]
Parity	2.5 [1.2]	2.9 [1.1]
Body mass index (kg/m^2)	26.0 [3.6]	25.1 [3.0]
History of prolapse surgery*	2 (5)	4 (10)
Anterior colporraphy	1	3
Anterior and posterior colporraphy	2	1
History of other surgery*	4 (10)	6 (15)
Heart transplantation	1	
Adnexal extirpation		1
Cholecystectomy	2	2
Appendectomy	2	3
Sterilisation		1
Comorbidity**	23 (56)	16 (39)
Rheumatoid arthritis	5	2
Hypertension	13	8
Diabetes mellitus	3	1
Hypercholesterolaemia	4	6
Hypothyroidism	5	2
Chronic obstructive pulmonary disease	2	2
Transient ischemic attack	2	
Findings at urodynamic investigation		
Evident stress incontinence	8 (20)	9 (22)
Masked stress incontinence	3 (7)	7 (17)
Detrusor instabilities	–	2 (5)
Bladder capacity (mL)	483 [119]	455 [149]
Performed surgical procedures		
Vaginal hysterectomy	41 (100)	2 (5)
Sacro-colpopexy	–	39 (95)
Anterior colporraphy	34 (83)	2 (5)
Posterior colporraphy	35 (85)	1 (2)
Colposuspension	11 (27)	16 (39)

* Some patients had undergone more than one surgical procedure.
** Some patients had more than one disease.

($n = 196$) presenting themselves with urogenital dysfunction at the gynecologic out patient clinic of the University Medical Center Utrecht.[20] Mean domain scores [SD] of the discomfort/pain, urinary incontinence, overactive bladder, genital prolapse and obstructive micturition as derived from these data were, respectively, 9.1 [13.5], 12.4 [15.4], 18.4 [21.0], 3.7 [12.1] and 7.9 [16.8] in the random population sample and 28.5 [20.3], 25.9 [24.8], 35.4 [25.7], 44.9 [35.4] and 27.9 [28.0] in the clinical sample. We considered the prolapse domain to be the most important outcome measurement. A difference in reduction of the prolapse domain score between both surgical techniques of 20% (9 points) was considered to be a clinically relevant difference between both groups. With a power of 90% and an α level of 0.05, the calculated sample size necessary was 76 (38 in each group).

Patients were assigned through randomisation to have pelvic reconstructive surgery by either a vaginal or abdominal approach. The randomisation code was developed using a computerised random number generator. The details of the series were unknown to any of the participating gynaecologists or to the co-ordinator and were contained in a set of sealed envelopes. After written consent of the patient to participate in the study, the appropriate envelope was opened by the first author, who had sole access to the envelopes. The card inside indicated if the patient was to be operated by vaginal or abdominal approach, and this information was given to the medical officer who was treating the participating patient.

The data were analysed by intention-to-treat. To examine differences between groups, we used an unpaired *t* test for continuous variables and a Fisher's exact test for dichotomous variables. For differences in UDI domain scores, a repeated measurement analysis was performed. Repeated measurements analysis provides insight into the question ''Which treatment has the best results over the total follow up period?'' Two-sided significance tests were used throughout. A P value of <0.05 was considered to be statistically significant. The statistical package used to perform the analysis was SPSS 10.0.

The recommendations of the CONSORT statement[21] on standards on reporting of randomised controlled trials have been adopted.

RESULTS

After randomisation, both groups consisted of 41 patients. Figure 1 shows the flow of participants through

Table 2. Domain scores of UDI before surgery and one year after surgery according to surgical route. Values are means [SE] or mean difference {95% CI}.

UDI domains	Before surgery		One year after surgery		
	Vaginal approach ($n = 41$)	Abdominal approach ($n = 41$)	Vaginal approach ($n = 40$)	Abdominal approach ($n = 38$)	Mean difference {95% CI}
Discomfort/pain	19.4 [2.7]	24.0 [3.0]	7.0 [1.9]	14.1 [2.4]	7.1 {1.1 to 13.2}
Urinary incontinence	24.7 [4.7]	21.8 [3.0]	7.2 [2.1]	13.2 [3.5]	6.0 {−2.0 to 14.0}
Overactive bladder	28.0 [3.4]	31.7 [3.8]	9.4 [2.2]	18.1 [3.5]	8.7 {0.5 to 16.9}
Genital prolapse	58.0 [4.7]	68.3 [4.3]	5.1 [3.0]	9.2 [3.8]	4.1 {−5.4 to 13.6}
Obstructive micturition	19.9 [4.3]	24.4 [4.7]	9.0 [2.5]	19.3 [4.2]	10.3 {0.6 to 20.1}

Table 3. Group comparison of clinical outcomes. Values are means [SE], or *n* (%) and mean difference {95% CI} or OR {95% CI}.

Clinical outcome	Vaginal approach ($n = 41$)	Abdominal approach ($n = 41$)	Mean difference (95% CI)
Duration of surgery (min)	107 [4.7]	97 [3.6]	10 {−2 to 22}
Amount of blood loss (mL)	248 [34.1]	244 [51.5]	4 {−119 to 127}
Duration of admission (days)	7.6 [0.3]	7.7 [0.2]	0.1 {−0.6 to 0.7}
			OR (95% CI) (vaginal *vs.* abdominal)
Complications during surgery	3 (7)	1 (2)	3.2 {0.3 to 31.7}
Bleeding needing transfusion	2	1	
Bowel lesion	1		
Complications during admission	10 (34)	14 (24)	1.6 {0.6 to 4.2}
Lower urinary tract symptoms	8	8	
Dullness upper leg		1	
Fever of unknown origin	1	3	
Wound infection	1		
Vault abscess		2	
Late complications	1 (2)	3 (7)	0.3 {0.0 to 3.2}
Development of vaginal stricture requiring excision*	1		
Incisional peritoneal hernia requiring surgery		1	
Infected implant requiring surgery*		2	

* Surgery required re-admission to the hospital.

each stage of the trial. Table 1 shows the base-line characteristics of the study population. No relevant differences in patient characteristics between the groups were observed.

Table 2 shows UDI domain scores before surgery and at one year after surgery for both groups. In both groups, all UDI domain scores reduced after surgery. The maximal reduction was observed in the score on the prolapse domain of the UDI. For all domains of the UDI, the reduction in score was higher in the vaginal group than in the abdominal group. At one year after surgery, the vaginal group scored significantly lower on the discomfort/pain domain, overactive bladder domain and the obstructive micturition domain, as compared with the abdominal group. Repeated measurements analysis of the UDI domain scores, showed that the differences between both groups in these three domain scores were statistically significant over the total follow up period. As UDI scores were at baseline somewhat higher in the abdominal group than in the vaginal group, we adjusted in the repeated measurement analysis for differences in UDI scores before surgery.

Clinical outcomes are presented in Table 3. There was no statistically significant difference between the groups in duration of surgery, amount of blood loss, duration of hospital stay and number of complications. The mean duration of surgery in the vaginal group was longer than in the abdominal group, but this difference was not statistically significant. Three of the abdominally operated and one of the vaginally operated patients had to undergo repeated surgery because of a late complication.

Findings at pelvic examination were similar before surgery and at six weeks, six months and one year after surgery. Before surgery, a stage II or more cystocele was present in 85% of the vaginal group and 88% of the

Table 4. Group comparison of doctor visits related to performed surgery and second genital prolapse surgery performed or planned in the first year after surgery. Values are *n* (%) and OR {95% CI}.

	Vaginal approach ($n = 41$)	Abdominal approach ($n = 41$)	OR (95% CI) (abdominal *vs.* vaginal)
Visited a doctor because of symptoms related to surgery	13 [32]	25 [61]	3.4 {1.4 to 5.0}
Visited a doctor because of prolapse symptoms	5 [12]	16 [39]	4.6 {1.5 to 14.3}
Visited a doctor because of defecation symptoms	5 [12]	12 [29]	3.0 {1.6 to 9.4}
Visited a doctor because of micturition symptoms	3 [7]	8 [20]	3.1 {0.8 to 12.5}
Visited a doctor because of other symptoms	10 [24]	11 [27]	1.1 {0.4 to 3.1}
Second prolapse surgery performed	–	5 [12]	*
Second prolapse surgery performed or planned	1 [2]	9 [22]	11.2 {1.4 to 90.9}

CI = confidence interval.

* Cannot be calculated.

abdominal group and a stage II or more rectocele was present in 37% of the vaginal group and 32% of the abdominal group. At one year after surgery, only 5% of patients in both groups had a stage II or more vault prolapse (vaginal group) or uterine prolapse (abdominal group). A stage II or more cystocele was present in 39% of the vaginal group and 36% of the abdominal group and a stage II or more rectocele was present in 15% of the vaginal group and 5% of the abdominal group.

Table 4 shows the number of patients who had visited a doctor because of symptoms related to surgery and the number of patients in whom repeated prolapse surgery was planned or performed within the first year after surgery. Abdominally operated patients more often presented themselves with prolapse symptoms ($P = 0.01$), defecation symptoms ($P = 0.10$) and micturition symptoms ($P = 0.19$) as compared with vaginally operated patients. In abdominally operated patients, repeated prolapse surgery within the first year after the initial prolapse operation, was performed in five patients and planned in another four patients. In these nine patients, the indication to perform surgery was a cystocele in five cases and a recurrence of uterine prolapse in four cases. In the vaginal group, a second prolapse operation within the first year after initial surgery, was planned in only one patient. This patient had a vaginal vault prolapse.

DISCUSSION

We performed a multicentre randomised trial to compare the functional and anatomical effects as well as the morbidity of abdominal and vaginal surgery of patients with uterine prolapse stages II–IV (ICS). Quality of life related to discomfort and pain during micturition, overactive bladder symptoms and obstructive micturition symptoms was better after vaginal surgery than after abdominal surgery. Although the anatomical results of the initial surgery were similar, patients who had undergone abdominal surgery presented themselves more often with persisting or recurring prolapse symptoms as compared with patients who had undergone vaginal surgery. Within the first year after prolapse surgery, repeated prolapse surgery was more often planned or performed in the abdominal group as compared with the vaginal group.

The data at one year following surgery did not show a statistical significant difference on the prolapse domain of the UDI. Because of this, some might argue that, strictly speaking, the findings of our trial should be reported as negative. However, we argue that the overall findings in our study are still positive in favour of the vaginal surgical procedure based on the significant difference in three domains of the UDI and in rate of repeat surgery.

One of the concerns about our study may be that the observed effects of both treatments are explained by differences in the gynaecologists' skills to perform vaginal or abdominal surgery. However, this is not very likely because all gynaecologists who performed the surgeries in this study are familiar with both techniques. Furthermore, by providing a detailed description of the surgical techniques in the study protocol, variations in the performance of surgery between gynaecologists have been limited.

Clinical outcomes (complication rate, duration of surgery and hospital stay, amount of blood loss) observed in our study are comparable to those reported by others.[22–24]

The observed recurrence rate is in the range of those reported by others.[22,23] It is important to realise that a prospective study involving regular follow up visits to a gynaecologist is more likely to find a high recurrence rate, as compared with a retrospective study in which medical records are studied to investigate the recurrence rate.

Only one other randomised trial comparing vaginal and abdominal genital prolapse surgery has been published. Benson *et al.*[22] compared the effects of abdominal colposacral suspension and vaginal bilateral sacrospinous vault suspension. In this study, an additional vaginal surgical procedure was simultaneously performed in at least 50% of the patients of the abdominal group. In our study, vaginal and abdominal surgical procedures were purposely never combined.

One of the strengths of our study is that we focussed on the effects of prolapse surgery on health-related quality of life. Such an approach has been recommended by experts in the field of pelvic floor surgery. However, until now, this recommendation has not been widely followed. We observed more discomfort of overactive bladder symptoms (urgency, frequency and nocturia) after abdominal surgery than after vaginal surgery. This could indicate that abdominal surgery is associated with relatively more irritation of the bladder. Possibly, the tissue patch inserted during abdominal prolapse surgery can be held responsible for this irritation of the bladder. Another explanation may be that the innervation of the bladder is injured by the dissection of the bladder from the anterior wall of the vagina.

The observed difference between both groups in the prevalence of other micturition and prolapse symptoms and quality of life related to these symptoms is more difficult to explain. Possibly, differences in damage of the pelvic floor muscle and its innervation account for the observed difference, but further research is needed to support such hypothesis.

UDI domain scores before surgery were higher in the abdominal group as compared with the vaginal group. These differences are random, as we randomised for surgical approach. By adjusting the repeated measurement analyses for differences in UDI scores before surgery, we ruled out the possibility of finding illegitimately non-existing differences between both surgical techniques due to differences between the two groups at baseline.

Surprisingly, abdominally operated patients more often underwent repeated prolapse surgery as compared with

vaginally operated patients, whereas both surgical techniques had similar anatomical results. As described, abdominally operated patients experience more often symptoms of pelvic floor dysfunction compared with vaginally operated patients. This is most likely the reason why abdominally operated patients more often visit a gynaecologist. A gynaecologist who is visited by a patient with a stage II or more genital prolapse (observed in more than 30% of all patients at six months after surgery) who also reports symptoms of pelvic floor dysfunction, is likely to indicate this patient for repeated prolapse surgery. This indicates that the recurrence or persistence of symptoms of pelvic floor dysfunction rather than the presence of anatomical abnormalities determines whether the patient will undergo repeated prolapse surgery.

In conclusion, this randomised trial confirms that vaginal hysterectomy combined with anterior and/or posterior colporraphy is equally effective in treating the anatomical abnormalities of patients with uterine prolapse stages II–IV as compared with sacro-colpopexy with preservation of the uterus. However, abdominally operated patients are bothered more by overactive bladder symptoms, prolapse symptoms and obstructive micturition symptoms. This may result in a difference in doctor's visits between abdominally and vaginally operated patients and finally even in a difference in indications for re-operation. Our results indicate that, as compared with sacro-colpopexy, vaginal hysterectomy combined with anterior and/or posterior colporraphy is the treatment of choice in patients with uterine prolapse grade II or more.

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