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IMPACT ON QUALITY OF LIFE AND SEXUAL SATISFACTION OF TOTAL ABDOMINAL HYSTERECTOMY AND VAGINAL HYSTERECTOMY IN THE ABSENCE OF PROLAPSE. COHORT STUDY, MEDELLÍN, 2015

Impacto de la histerectomía abdominal total y de la histerectomía vaginal sin prolapso en la calidad de vida y la satisfacción sexual. Estudio de cohortes, Medellín, 2015

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ABSTRACT

Objective: To identify differences in quality of life and sexuality in women without genital prolapse taken to vaginal or abdominal hysterectomy.

Materials and methods: Prospective cohort study including women with no vaginal prolapse and benign conditions, with no adhesions and a uterus of less than 1000cc, amenable to surgery through the abdominal or vaginal approach, coming to a private clinic in Medellín, Colombia. The SF12 score was used for quality of life assessment two and four months after surgery, and sexuality was assessed before and four months after the procedure, using the Female Sexual Function Index. Comparisons were made using ANCOVA, adjusted on the basis of baseline values and other characteristics. Approval by the ethics committee as well as informed consents were obtained.

Results: The study included women with similar pre-operative characteristics. Of them, 24 were included in the vaginal hysterectomy group and 22 in the abdominal hysterectomy group. Quality of life and sexual function improved for the women in both groups following the procedure. Postoperative physical health: adjusted score for vaginal hysterectomy, 49.5 (SD ± 1.6) and for abdominal hysterectomy, 43.8 (SD ± 1.7), with a difference of 5.6 points (95% CI 0.87-10.4). Mental health: 51.0 (SD ± 1.7) and 59.3 (SD ± 1.6) points, respectively; adjusted difference 8.4 (95% CI 3.6-13.3). Sexuality: 22.7 (SD ± 1.8) and 26.5 (SD ± 1.7), respectively; difference, 3.8 points (95% CI -1.2-8.7).

Conclusion: Although statistically significant differences were found for quality of life, the score obtained is not clinically significant.

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Key words: Hysterectomy, vaginal hysterectomy, quality of life, sexuality.

RESUMEN

Objetivo: identificar diferencias en calidad de vida y sexualidad en mujeres sin prolapso genital intervenidas con histerectomía vaginal o abdominal.

Materiales y métodos: estudio de cohortes prospectivo. Se incluyeron mujeres sin prolapso vaginal con condiciones benignas, sin adherencias, con útero menor de 1000 cc, que fueran susceptibles de ser intervenidas tanto por vía abdominal como vaginal en una clínica privada de Medellín, Colombia. Evaluación de calidad de vida con la escala SF-12 antes, a los 2 y 4 meses posquirúrgico y de la sexualidad con la escala Índice de Función Sexual Femenina, antes y a los 4 meses posoperatorio. Comparaciones con ANCOVA ajustadas por los valores basales y por otras características. Se contó con aprobación de comité de ética y se tomó consentimiento informado.

Resultados: se incluyeron 24 mujeres en el grupo de histerectomía vaginal y 22 en el grupo de histerectomía abdominal, con características similares antes de la cirugía. Ambos grupos mejoraron en calidad de vida y en satisfacción sexual después del procedimiento. Los puntajes para histerectomía vaginal e histerectomía abdominal fueron, respectivamente: salud física posoperatoria: puntaje ajustado en histerectomía vaginal 49,5 (DE ± 1,6) e histerectomía abdominal 43,8 (DE ± 1,7), diferencia 5,6 puntos (IC 95%: 0,87-10,4). Salud mental: 51,0 (DE ± 1,7) y 59,3 (DE ± 1,6) puntos, respectivamente, diferencia ajustada 8,4 (IC 95%: 3,6-13,3). Sexualidad: 22,7 (DE ± 1,8) y 26,5 (DE ± 1,7), respectivamente, diferencia 3,8 puntos (IC 95%: -1,2-8,7).

Conclusión: aunque se encontraron diferencias estadísticamente significativas en la calidad de vida, el puntaje alcanzado no es clínicamente significativo. Es factible realizar histerectomía vaginal a mujeres sin prolapso, sin incrementar la morbilidad temprana.

Palabras clave: histerectomía, histerectomía vaginal, calidad de vida, sexualidad.

INTRODUCTION

Hysterectomy is the major surgical procedure performed most frequently in gynaecology, and close to 90% of the time it is performed for benign reasons (1). The vaginal approach is the least invasive and is associated with shorter recovery time, less complications, lower costs and better cosmetic results. For this reason, the American Association of Gynaecologic Laparoscopists, in agreement with the American College of Obstetricians and Gynecologists, recommends it as the preferred approach in benign conditions (2). Notwithstanding, it is performed less frequently than the abdominal o laparoscopic approaches, even in countries where the proportion of vaginal hysterectomies has increased over the past few years (3).

The Education Committee of the United States Society of Gynaecologic Surgeons identifies three critical factors associated with the underuse of vaginal hysterectomy: inadequate training as a result of the lower number of surgeries performed during the residency; difficulty maintaining surgical skills due to the low number of procedures; and increased marketing and awareness of alternative techniques. Consequently, it suggests that promoting changes in these three areas may increase the use of this technique based on evidence regarding the vaginal approach as the initial approach to hysterectomy (2). If non stringent criteria are applied, the number of candidates for vaginal hysterectomy may increase by 30% (2, 4). Some authors advocate the use of simple algorithms for the selection of candidates to vaginal hysterectomy in the absence of prolapse (5), and it has even been shown that staff in training may achieve high rates of success in women selected using defined criteria (6). In Colombia, successful experiences using the vaginal hysterectomy technique in the absence of prolapse have already been documented (7), and it has been found that, if performed by people with training and using adequate surgical instruments, it is a viable option for the management of benign uterine disease.

Most hysterectomy procedures are performed with the aim of improving quality of life rather than saving a woman's life (8). However, reports on the impact of hysterectomy on quality of life vary significantly, ranging from reports on beneficial, negative or neutral effects (9). On the other hand, a source of concern for women before undergoing the procedure is the effect it may have on their sexuality (10), and results of studies regarding this issue are also contradictory (9). Moreover, most data on the effect of the procedure on quality of life and sexuality, as well as comparisons of the different surgical approaches and techniques, have come from patients with malignant conditions (11), hence the need for more studies in benign conditions. Having access to data on potential differences between the abdominal and the vaginal approach in relation to these aspects will result in valuable information for decision making. The objectives of this study are to assess hysterectomy for benign conditions in terms of its impact on quality of life and sexual function, and to identify any differences associated with the surgical approach to the procedure. Our hypothesis was that a difference would be found in terms of better quality of life for patients taken to vaginal hysterectomy in the absence of prolapse, compared to women undergoing total abdominal hysterectomy.

MATERIALS AND METHODS

Study design and setting. Observational analytical cohort study conducted at two sites of Clínica Medellín (Downtown and Poblado) between November 2013 and August 2015. Clínica Medellín is a private institution that provides high complexity services to users of the subsidized and contributive regimes of the General System of Social Security in Health (SGSSS), as well as to patients paying out of pocket, coming from the city of Medellin and the Department of Antioquia (Colombia). The research was implemented with the approval of the Research Ethics Committees of Clínica Medellín and Antioquia University Medical School.

Inclusion and exclusion criteria. Patients scheduled for hysterectomy due to benign conditions according to the diagnoses made by treating physicians (myomatosis, abnormal uterine bleeding, chronic pelvic pain) who had a pelvic or transvaginal ultrasound and duly completed informed consent were included. Patients with uterine prolapse, cognitive impairment preventing them from completing the questionnaires, a high clinical suspicion of adherence syndrome, an estimated uterine size greater than 1000 cc or large cannonball-shaped uterus, vaginal canal abnormalities not allowing uterine descent, with a history of radiation or prolapse, or those who refused to participate, were excluded. A convenience sampling of women who came to the research site was made, and all women who met the criteria and agreed to participate were entered in a consecutive sequence.

Data collection and study variables. All patients came from the gynaecology consults of an Health Management Organisation (HMO) under the contributive regime. The members of the research team who scheduled and performed the surgery explained the procedure, the research and the informed consent 2 to 4 weeks before the intervention during routine care at the clinics where the procedures were performed. Explanations regarding the content of the questionnaires and the interview were made by two different members of the research team who did not participate in scheduling or performing the surgery.

The study hypothesis was hidden from the participants when given the questionnaires, and the interviewers abstained from providing personal opinions about the surgical technique to be used, although they gave accurate information about the risks and benefits of each technique at the time of the informed consent process. Although the women had no knowledge of the study hypothesis, they were aware of the objectives of the research. The clinical and demographic data planned as part of the protocol were collected prospectively and in a standardized fashion at the time of the routine

visit and were entered in the electronic clinical records and then transcribed to a spreadsheet. Before initiating data collection, the researchers agreed on a standardized operational definition of the variables.

SF-12® Health Survey tool was used to assess quality of life before the intervention. The SF-12 is a generic measurement questionnaire consisting of 12 questions. Like the original tool, the Medical Outcomes Study (MOS) 36-Item Short Form - SF-36, it consists of two summary scores or measurements: physical health, with sub-scores for physical function, physical role, body pain and general health; as well as mental health, which includes sub-scores for vitality, social function, emotional role and mental health. Together they express an overall quality of life measurement (12). Likert- type answer options range between 3 and 6, depending on the item, and assess intensity or frequency. The precursor tool has already been validated in Colombia (13), and the SF-12 version, submitted to reliability testing and preliminary standardization in Colombia, considered the previous cultural adaptation (14). The Female Sexual Function Index (FSFI) questionnaire was also administered prior for sexuality assessment. This tool consists of six domains that explore libido, arousal ability, lubrication, orgasm quality, problems with penetration and satisfaction with sex life (15), and it meets reliability and validity criteria (16). Each Likert-type item consists of 5 or 6 options given a score from 0 to 5; the higher the final score on the scale, the better the sexuality, with value possibilities ranging from 2 to 36 (15). No process of validation of this scale was found to have occurred in Colombia, although a version in Spanish was identified in Chile (17), as was the application of this version in Colombia and other Latin-American countries (18, 19). The research team assessed the drafting of the questions and found them applicable to the population to be included in this study.

Group assignment. Agreement was reached between the patient and the treating gynaecologist regarding the approach to the surgery after confirming that the patient was suitable for either of the two approaches considered in the research. The TeLinde technique was selected for the abdominal hysterectomy approach, while the vaginal approach was the one previously described (modified Heaney technique) (7).

Postoperative evaluation consisted of routine follow-up visits at 8-10 days, and instructions to consult should any of the signs of alarm explained by the treating specialists occur. The SF-12 and FSFI tools were administered 2 and 4 months after the surgery.

Variables. Age (number of years), schooling, social security, uterine size (maximum diameter documented in the surgical report), chronic pelvic pain (pain in the pelvic area lasting 6 months or more), history of anxiety and depression (diagnosed by a physician or prescription of antidepressants by a physician within one year prior to the pre-operative consultation), a history of debilitating chronic diseases (included in this category were degenerative bone diseases, osteoporosis, arthritis, multiple sclerosis, fibromyalgia, systemic lupus erythematosous, neurological sequelae), dyspareunia (pain during intercourse during the months prior to the surgery), intra-operative and postoperative complications (bladder, rectal, ureteral injury and vaginal dome abscess according to diagnosis documented by the treating specialist in the medical record).

Statistical analysis. The hypothesis considered that patients taken to vaginal hysterectomy in the absence of prolapse would show a favourable difference of at least 10 points on the SF-12 scale compared with women taken to total abdominal hysterectomy. The 10 points were selected because they represent a clinically significant difference. For a power of 90% and a confidence of 95%, 23 patients were required in each group. The higher standard deviation for two components of the Schmidt study was selected for the calculation (physical component, mean 50, SD 9.6; and mental component mean 50, SD 10.3) (20). Likewise, 22

women were required in each group in order to detect a difference of at least 5 points on the sexual satisfaction scale (FSFI), with a 90% power, with an assumed standard deviation of 5 (SD in the study by Blümel), and a 95% confidence level.

The data were entered in an MS Office Excel® 2010 spreadsheet and then exported, stored and processed in the PASW Statistics 22 ® (SPSS 22) software package.

For the SF-12 questionnaire analysis, the answer selected by the patient was transformed into the value recommended in the manual, the 4 items that have a reverse coding initially were recoded (a lower number means better health status), and the proposed recalibration for the answers to item 1 was performed (12). The score for the subscales was derived by adding the answers to the questions in each subscale (for example, physical function includes questions 2a and 2b). The score for each subscale was transformed into a score ranging from 0 to 100, assigning the percentage of the maximum possible value that could be reached for each subscale. Compliance with the correlation values between the subscales was verified as a criterion for assessing the quality of the data and of the transformations. The indicator variables were then weighed and added in order to obtain the summary measurement for the Mental Health and Physical Health scales. Finally, the values for each patient were standardised in accordance with the United States norm (12) and the norm published for Colombia (14). Since scores are set at a mean of 50 and a standard deviation of 10, values higher or lower than 50 reflect better or worse health condition, respectively, as compared to the reference population. Regarding the FSFI, the score for each domain is multiplied by a factor determined by the developers of the scale, and the final result in the arithmetic sum of all the domains (15). Different studies have proposed that a score of 26.55 or lower may qualify as sexual dysfunction in a woman (21).

All the patients were included in the data analysis. The Shapiro-Wilk test was used for assessing data distribution for the quantitative variables and, based on the results, those with normal distribution are summarised as means and standard deviation (SD), and those with no normal distribution or which were discreet are summarised as medians and 25th and 75th percentiles (p25-p75). For comparisons between the groups, the Student *t* test was used for quantitative variables with normal distribution and the Mann-Whitney U test was used for those with no normal distribution. Qualitative variables were described using absolute frequencies and proportions, and chi square was used for comparisons given that no cells with expected values lower than 5 were found in any of the comparisons. The ANCOVA analysis was conducted for comparing FSFI and SF-12 scores between the abdominal and vaginal hysterectomy groups; in this analysis, the dependent variable was the number obtained with the measurements on the scales (SF-12 two months after surgery, and FSFI 4 months after surgery), the factor was the type of surgery, and in all cases, adjustment was made for the baseline measurement in the respective scales. Data normality assumptions were verified within each group, including independence, linearity between the dependent variable and the covariable, variance homogeneity (Levane test) and slope homogeneities. Adjusted analyses were performed by including in the ANCOVA model any other characteristics that could potentially modify the effect of the surgical technique on quality of life or sexuality. The effect size of the differences between the groups was estimated using Cohen's D test. All tests were made using two tails and a significance level of 0.05. The results for the FSFI scale domains are presented for descriptive purposes, but no formal statistical comparisons were made because the *a priori* hypotheses only considered the analysis of overall scores on the scales. No imputation was made for the data of the only woman who was lost to follow-up.

RESULTS

During the study period, the surgical team performed 108 hysterectomy procedures. Of these, 75 (69.4 %) were performed through the vaginal approach, 29 (26.8 %) through the abdominal approach, 3 were laparoscopy-assisted and 1 was a fully laparoscopic procedure. Overall, 46 patients were included in the study, 24 in the vaginal hysterectomy group in the absence of prolapse, and 22 in the abdominal hysterectomy group. No measurements on the scales were obtained at 4 months for one of the patients in the abdominal hysterectomy group. Groups were similarin terms of baseline social and demographic characteristics (Table 1). There were no statistically significant differences in the baseline measurements of quality of life and sexuality.

The administration of the SF-12 scale at 2 and 4 months revealed changes with regard to the baseline value after the first two months (Figure 1), and there were no statistically significant differences in the comparison between the 2 and 4-month assessments, either for the mental health domain ($p = 0.686$) or for the physical health domain ($p = 0.679$), with a high correlation (Spearman correlation coefficient 0.87); consequently, only the findings at the 2-month time point were considered for analysing the effect of the surgical technique (Table 2). Improvement was observed in both groups as compared to the baseline level (Table 1), and statistically significant differences were found between the groups in terms of both physical and mental health. The direction of the results did not change when other variables were added to the adjustment (age, uterine size, surgical indication, marital status), and there was only a minimum, not statistically significant, change in magnitude regarding the value adjusted only for the baseline score. Postoperative physical health: score adjusted by baseline value in the vaginal hysterectomy group, 49.5 (SD ± 1.6) and 43.8 (SD ± 1.7) for the abdominal hysterectomy group, with an adjusted difference of 5.6 points (95% CI: 0.87-10.4). Adjusted scores by baseline values for mental health: 51.0 (SD ± 1.7) and 59.3 (SD ± 1.6) points, for abdominal hysterectomy and vaginal hysterectomy respectively, with an adjusted difference of 8.4 (95 % CI: 3.6-13.3). Adjusted scores by baseline values for sexuality: 22.7 (SD ± 1.8) and 26.5 (SD ± 1.7), for abdominal hysterectomy and vaginal hysterectomy respectively, with an adjusted difference of 3.8 points (95% CI -1.2-8.7).

Only three women had resumed their sexual activity within the first two months after the procedure. For this reason, a comparison during this predetermined period is not valid and results are shown only for the 4-month assessment. Seven women were not sexually active within the four weeks prior to the surgery or before the assessment at four months after the procedure; an additional six women did not have intercourse in the four weeks prior to the surgery and 1 did not have intercourse in the period prior to the postoperative measurement. Sexuality comparisons were made for all the women included in the study and for the subgroups that had sexual activity both before and after the surgery (17 women in the abdominal hysterectomy group and 15 in the vaginal hysterectomy without prolapse group) and for those that did in either of the two assessment time points. Both groups showed improvement as compared to baseline values; similarly, results did not change when other variables were adjusted. Table 3 shows the scores obtained in each of the domains of the FSFI scale for the two groups and the range of possible minimum and maximum values that may be taken by the domains.

DISCUSSION

Our hypothesis that patients taken to vaginal hysterectomy in the absence of prolapse would show a difference of at least 10 points on the SF-12 scale as compared to the women taken to total abdominal hysterectomy, and a difference of 5 points on the

Table 1.
Baseline characteristics of the participants

Characteristics	TAH n = 23	VHAP n = 24	p Value
Age: Mean (± SD)*	41.2 (± 6.0)	44.6 (± 4.8)	0.048
Marital status			
In wedlock	15 (65%)	17 (70%)	0.791
Not in wedlock	8 (35%)	7 (30%)	
Occupation			
Housewife	11 (65%)	11 (69%)	0.805
Others	6 (35%)	5 (31%)	
Prior gynaecological disease			
Hemorrhage or abnormal uterine bleeding	0 (0 %)	23 (95,8%)	
Chronic pelvic pain	15 (65%)	14 (58%)	0.627
Anxiety and depression	2 (9%)	0 (0%)	0.086
Dyspareunia	7 (30%)	9 (38%)	0.609
Prior chronic debilitating disease			
Cerebrovascular disease	1 (4%)	0 (0%)	0.105
Systemic Lupus Erythematosous	2 (9%)	0 (0%)	
None	20 (87%)	24 (100%)	
Indication for hysterectomy			
Abnormal uterine bleeding	22 (96%)	20 (83%)	0.286
Myomatosis	1 (4%)	3 (13%)	
Tracheocele	0 (0%)	1 (4%)	
Intra-operative complications	0 (0%)	0 (0%)	
Uterine size - Mean in cm (SD)	11 (2.8)	10 (2)	0.106
Quality of life SF-12			
Physical Component - Mean (SD)	35.2 (10.5)	31.5 (11.8)	0.239
Mental Component - Mean (SD)	41.2 (11.8)	45.7 (12.6)	0.213
Sexualily FSFI**			
Desire. Median (p25-p75)	3.3 (2.4-4.4)	3.3 (1.5-4.2)	0.920
Arousal. Median (p25-p75)	3 (1.1-4.7)	2.4 (0-3.9)	0.430
Lubrication. Median (p25-p75)	3.5 (1.1-5.1)	3.5 (0-5.6)	0.704
Orgasm. Median (p25-p75)	3.4 (0.9-5.3)	2.4 (0-4.3)	0.199
Pain. Median (p25-p75)	3.0 (0.9-4.5)	2.4 (0-4.4)	0.415
Satisfaction. Median (p25-p75)	3.6 (2.3-5.0)	3.2 (1.3-5.5)	0.573
Overall sexuality. Median (p25-p75)	21.0 (8.3-28.0)	18.3 (4.4-25.3)	0.385
Overall sexuality. Mean (SD)	19.0 (± 10.5)	16.5 (± 11.6)	0.428

* T of student
** U of Mann-Whitney
TAH: Total abdominal hysterectomy.
VHAP: Vaginal hysterectomy in the absence of prolapse.

Table 2.
Comparison of SF-12 scores two months after surgery and of the IFSI scores four months after surgery between the vaginal hysterectomy groups and total abdominal hysterectomy

Variables	TAH Mean (SD) n = 22	VHAP Mean (SD) n = 24	TAH Mean adjusted* (SD)	VHAP Mean adjusted* (SD)	Difference (IC 95 %)*	*p**	Effect size**
Physical health	43.7 (± 8.4)	49.6 (± 7.2)	43.8 (± 1.7)	49.5 (± 1.6)	5.6 (0.87-10.4)	0.022	3.54
Mental health	50.8 (± 10.3)	59.5 (± 1.9)	51.0 (± 1.7)	59.3 (± 1.6)	8.4 (3.6-13.3)	0.01	5.15
IFSI (all)	23.4 (± 10.4)	24.7 (± 10.2)	22.7 (± 1.8)	26.5 (± 1.7)	3.8 (-1.2 a 8.7)	0.13	2.22
IFSI (with sexual activity before and after)	26.6 (± 7.3)	27.5 (± 8.9)	25.9 (± 1.8)	28.1 (± 1.6)	2.2 (-2.6 a 7.0)	0.36	1.41
IFSI (with sexual activity before or after)	27.3 (± 5.3)	29.8 (± 5.9)	27.4 (± 1.3)	29.6 (± 1.3)	2.2 (-1.5 a 5.9)	0.23	1.73

* Value adjusted for initial measurement according to the ANCOVA analysis
** Effect size: The effect size of the differences between the groups was estimated using Cohen's D test
TAH: Total abdominal hysterectomy.

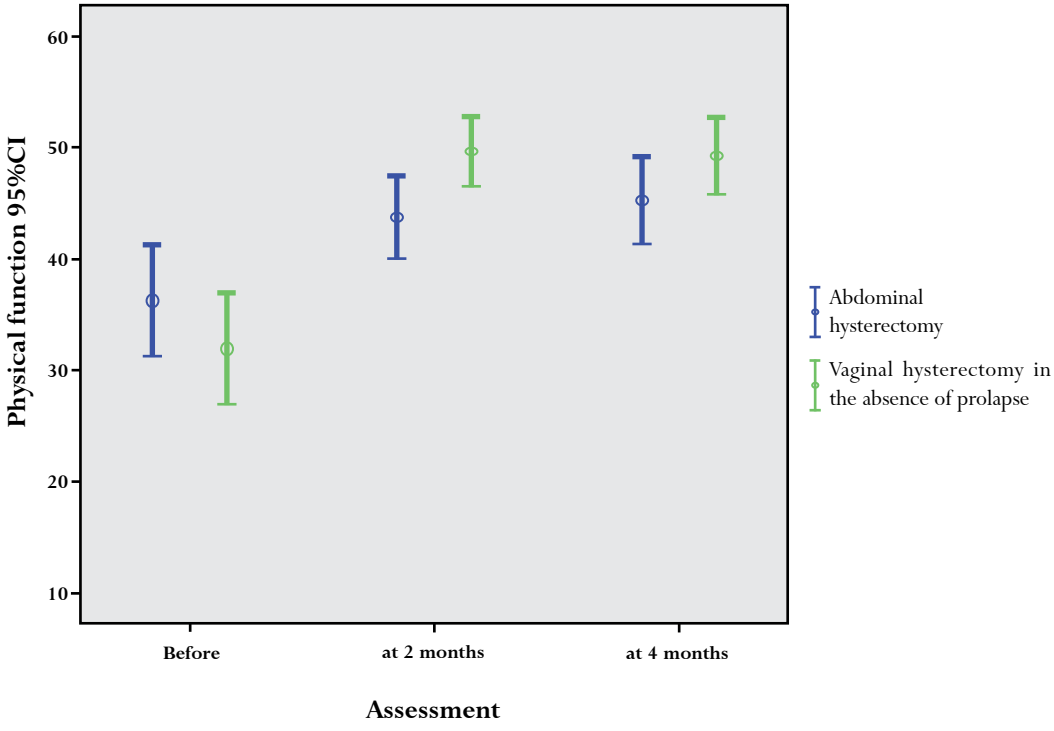
FSFI, construable as clinically significant, was not proven in this study. Although differences in the two domains that measured quality of life reach statistical significance, the numerical difference is very low. Therefore, it can be concluded that there is no clinically significant difference between the two techniques as relates to those aspects.

The majority of studies comparing results with the different approaches to hysterectomy have focused on complications, surgical time, length of hospital stay and cost-effectiveness. Quality of life or impact on sexuality are not part of the 22 outcomes included in the most recent systematic review by the Cochrane Collaboration comparing surgical approaches to hysterectomy for benign conditions, despite the fact that it included 47 studies with 5102 women (1). The outcomes closest to these areas were return to normal activity, which was faster after vaginal hysterectomy compared to the abdominal approach, and satisfaction, for which no differences were found. In those studies, inclusion and exclusion criteria were the same for both groups, suggesting that women without uterine prolapse were included in the two groups; moreover, it is clear in some studies that the aim of the research is precisely to study that situation (22).

Health-related quality of life is defined as that associated with the healthcare conditions, based on the subjective experience of the patients about their overall health status; it is considered essential for adequate assessment of the effects of the disease and of any medical interventions (23). Only one clinical trial related specifically to women without uterine prolapse, and with quality of life and overall satisfaction as the primary endpoint, was found in the literature (8). The median for "functional

Figure 1.
Change in quality-of-life measurement

1a. Physical Health



1b. Mental Health

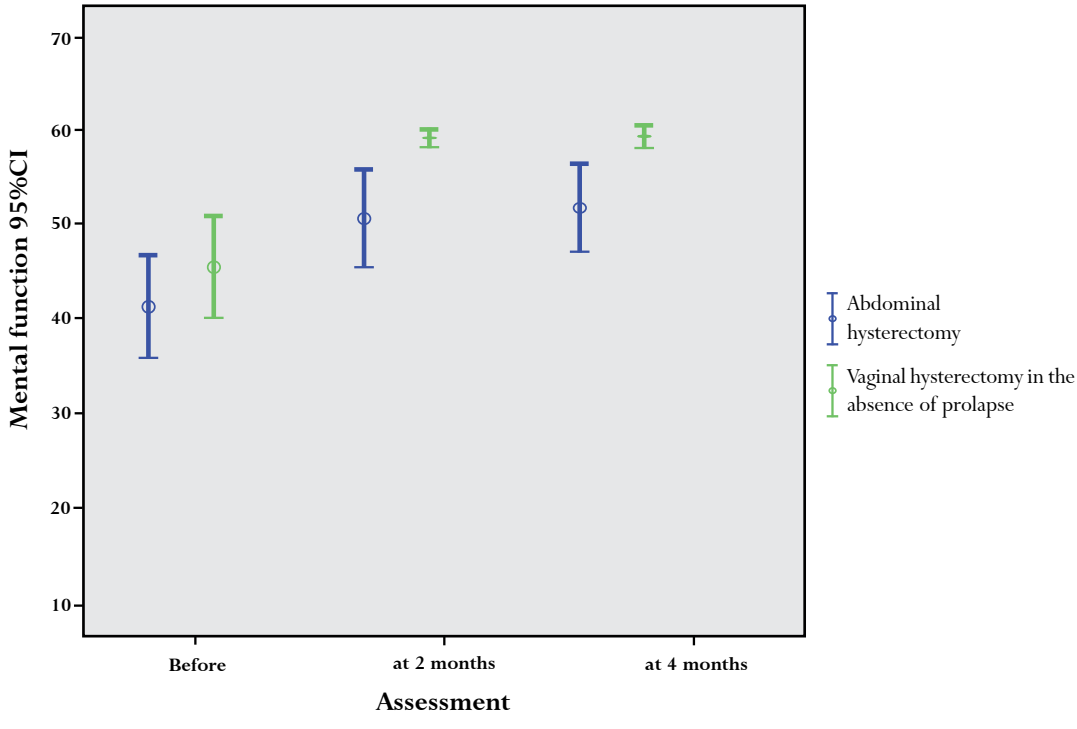


Table 3.
Items on the FSFI scale four months after surgery, total abdominal hysterectomy vs. vaginal hysterectomy in the absence of prolapse

Variables	TAH n = 18	VHAP n = 22	Range of possible values in the domain*
Desire: Median (p25-p75)	4.2 (3.6-5.4)	4.8 (4.2-6.0)	1.2-6.0
Arousal: Median (p25-p75)	4.4 (3.9-5.0)	5.4 (4.2-5.7)	0.0-6.0
Lubrication: Median (p25-p75)	5.4 (3.9-5.7)	5.4 (4.5-6.0)	0.0-6.0
Orgasm: Median (p25-p75)	4.8 (4.1-5.5)	5.2 (4.4-6.0)	0.0-6.0
Pain: Median (p25-p75)	4.4 (3.7-6.0)	4.8 (4.4-6.0)	0.0-6.0
Satisfaction: Median (p25-p75)	4.8 (4.5-5.9)	5.6 (4.8-6.0)	0.0-6.0
Desire**: Median (p25-p75)	3.3 (2.4-4.4)	3.3 (1.5-4.2)	0.0-6.0

* Range of possible values in the domain taken from Rosen *et al* (15)
** For all the women in the study
TAH: Total abdominal hysterectomy
VHAP: Vaginal hysterectomy in the absence of prolapse

capacity" one month after surgery was 72.5 (p25-75: 55-90) in the 30 women in the abdominal hysterectomy group, and 95 (75 to 100) in the 30 women in the vaginal hysterectomy group, with a statistically significant difference ($p = 0{,}002$). For the "physical aspect", the median was 37.5 (0-100) and 100 (25-100) ($p = 0{,}008$), respectively. No differences were found regarding overall satisfaction, assessed with a non-validated scale, although the study found that a larger proportion of women would select the same surgical approach again. Unlike our study, they used the SF-36 tool, including some of its subdomains, but not so the physical and mental domains, as recommended; no adjustment was made for baseline levels and, therefore, results are not comparable.

In the e-VALuate clinical trials there was no head-to-head comparison between the women taken to either abdominal or vaginal hysterectomy, but rather an independent comparison between those groups and other groups in which a laparoscopic procedure was performed (24). All the procedures were associated with improvement in the physical and mental components of the SF-12 tool and the body image score measured four months after surgery when compared to baseline, with a highly significant difference for the physical component score on the SF-12 at six weeks in favour of laparoscopic surgery vs. abdominal hysterectomy, but no difference when compared to the vaginal approach. Similar to that large clinical trial (1346 women taken to surgery and 937 with a one-year follow-up), our study did not find differences in the mental health domain.

Women express their concern for any effects that hysterectomy may have on sexuality. The systematic review mentioned above did not include the impact on sexuality as an endpoint. In the e-VALuate trial, all procedures were associated with improvement in sexual activity at four months, relative to baseline; scores at six weeks were higher for laparoscopic

surgery than for abdominal hysterectomy, and there was no evidence of a difference with vaginal hysterectomy (1). A six-month prospective observational study conducted in 2003 in the Netherlands did not find a difference between vaginal, total abdominal and subtotal hysterectomy in relation to sexual wellbeing (25). Ultimately, the authors conclude that sexual pleasure improves after hysterectomy regardless of the surgical approach, a result that is similar to what we found in our study.

Several considerations must be borne in mind when interpreting the results of our study: the main limitation is obviously the observational nature of the study, and it is clear that conclusions with the highest validity regarding the interventions are derived from clinical trials. The study lacks statistical power to identify differences in terms of complications, although that was not the objective, and that is an area that has been sufficiently documented in the literature. The population was intervened by the same surgical team and, although the inclusion criteria restriction resulted in two very similar groups, it is not possible to rule out a potential confounder in the form of an unmeasured characteristic. The follow-up period was only four months, although it is unlikely that results may change with a longer time period and that any changes that may happen after that time might be attributable exclusively to the surgical technique. Criteria restriction to ensure that each woman could be taken indistinctly to abdominal or vaginal hysterectomy and that the surgical team had equal experience in both approaches limits potential selection bias. This may be reinforced by the similarity of characteristics among the groups and the absence of changes in the results with the multivariate analyses performed. The strengths of the study include its prospective nature, which enabled measurement of quality of life and sexuality before the surgery, the sample size calculated for obtaining clinically significant differences, and the loss of only one woman to follow-up.

Although each surgeon selects the approach based mainly on his or her own experience and skills and on patient characteristics, including uterine size and descent, concomitant extrauterine pelvic diseases, surgical history, obesity, parity, need for concomitant oophorectomy, availability of surgical instruments (1), it is important to continue to encourage them to use the vaginal approach. The Heaney technique for vaginal hysterectomy in the absence of prolapse, together with the modifications introduced by the Londrina school in Brazil, is an excellent option considering the well-known benefits and minimum complications of this approach, as evidenced in this study. Achieving this goal will require improved training during residence, as well as overcoming the barriers that still persist among many specialists (26, 27).

CONCLUSION

Although statistically significant differences were found in terms of quality of life, the score reached is not clinically significant

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