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Isabel Ñíguez-Sevilla , María Luisa Sánchez-Ferrer * , Vicente Ruiz-Cotorruelo , Maciej Wilczak , Karolina Chmaj-Wierzchowska , Juan Antonio Solano-Calvo , Elena Perez-Munuzuri , Juan Raúl Salinas-Peña , Julián J. Arense-Gonzalo

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Preliminary Results of a Multicenter Randomized Study for Laparoscopic Repair of Pelvic Organ Prolapse: Sacropexy vs Laparoscopic Lateral Suspension

Isabel Ñíguez-Sevilla [1,2], María Luisa Sánchez-Ferrer [1,2,*], Vicente Luis Ruiz-Cotorruelo [1], Maciej Wilzac [3], Karolina Chmaj – Wierzchowska [3], Juan Antonio Solano-Calvo [4], María Elena Pérez-Muñuzuri [5], Juan Raúl Salinas-Peña [6] and Julián Jesús Arense-Gonzalo [2,7]

[1] Department of Obstetrics & Gynecology, "Virgen de la Arrixaca" University Clinical Hospital, Murcia, Spain.

[2] Biomedical Research Institute of Murcia (IMIB-Arrixaca), University Clinical Hospital "Virgen de la Arrixaca", Murcia, Spain.

[3] Uniwersytet Medyczny im.Karola Marcinkowskiego in Poznan, University of Medical Science in Poznan, Poland

[4] Universitary Hospital Príncipe de Asturias, Alcalá de Henares, Madrid, Spain.

[5] Universitary Clinical Hospital Santiago de Compostela, A Coruña, Spain.

[6] Universitary Hospital Sant Joan de Reus, Tarragona Spain.

[7] Division of Preventive Medicine and Public Health, Department of Public Health Sciences, University of Murcia School of Medicine, 30120 El Palmar, Murcia, Spain

* Correspondence: marisasanchez@um.es

Abstract: Background: Laparoscopic sacropexy (SCL) is the gold standard technique for the correction of apical pelvic organs prolapse (POP). However, other easier laparoscopic techniques such as laparoscopic lateral suspension (LLS) have become popular. Methods: A multicentre randomized study of patients undergoing laparoscopic repair of apical and anterior prolapse. Patients were randomized into 2 groups: LLS vs SCL. A non-inferiority study is proposed in which the null hypothesis is that the difference in the proportion of therapeutic failures among women who undergo LLS compared to SCL is ≥15%. It will be necessary to include 182 participants to detect a risk difference of 15% (at one year with a statistical power of 0.80). Results: we have recruited 176 women, and 106 patients have been operated with a follow-up between 1 and 12 months. There were not differences in basal characteristics. Regarding physical examination, there were no differences in stages III-IV in the POP-Q neither the symptom scales in both groups. Concerning post-surgical results there were no failures in the physical examination in any group. There were no differences in the points of the POP-Q neither in the symptom scales or Body image scale. We only found significant differences in the operative time, being shorter for the LLS. Conclusion**:** Although these are preliminary results, since the sample is 100 patients and the follow-up time is short, at the moment, we did not find post-surgical differences between the 2 techniques. However, it is necessary to complete the trial to draw relevant conclusions.

Keywords: laparoscopic; lateral suspension; sacropexy; pelvic organ prolapse

1. Introduction

Pelvic organ prolapse (POP) is a common benign condition or pathology. More than 24% of adult women have symptoms of pelvic floor disorders [1]. The percentage of parous women with POP is 40% to 60% [2]. Most women with prolapse experience symptoms that negatively impact their daily

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activities, sexual function, and quality of life. The risk of undergoing surgery for genital prolapse throughout a woman's lifespan is 11-19% [3–5] and almost a third of those who undergo surgery will require a second surgery for recurrence of the prolapse [6]. Surgical treatment of genital prolapse consumes an important portion of health resources worldwide, and it was the most frequently performed surgical procedure in women over 70 years of age between 1979 and 2006[7].

A wide variety of surgical techniques for the treatment of POP have been described; however, the level of evidence regarding the surgical treatment of prolapse is very limited, with few prospective comparative and randomized studies [2,8]. In addition, there is little correlation between anatomical and functional results, and although functional results have the greatest impact on patients' quality of life, they are the most poorly evaluated area.

Abdominal sacropexy (SCL) (laparoscopic approach is preferred) is considered the gold standard technique for apical prolapse, with few recurrences compared to vaginal procedures [2,9]. It is based on the suspension of the uterus, cervix or the vaginal dome from the anterior vertebral ligament of the sacrum (promontory) by the interposition of a prosthetic material (synthetic mesh), which reinforces the anterior and posterior (fibromuscular) walls of the vagina. Laparoscopic sacropexy is a highly complex technique that requires advanced laparoscopic skills [10]. An extensive and deep dissection of the posterior compartment involves an increased risk of rectal perforation and the possibility of injury to the rectal irrigation and innervation with potential functional effects on defecation. The learning curve and the fear of exposing patients to excessive morbidity during this learning curve have been limited to the very gradual inclusion of laparoscopic sacropexy among the usual techniques for the treatment of apical prolapse. Several studies have analyzed the number of interventions necessary to technically master the surgical procedure and reduce operative time, but in general, it is between 18 and 40 interventions [11–13].

In addition, given the complexity of the sacropexy technique, other laparoscopic prolapse correction alternatives have emerged, such as pectopexy [14] and the laparoscopic lateral suspension (LLS) technique described by Dubuisson[15] . With the LLS, the mesh is fixed to the uterus or the vaginal vault, and the arms of the mesh are passed under the peritoneum (in an extraperitoneal manner) without being fixed to any anatomical structure. LLS is a standardized, simpler and faster technique than sacropexy, and requires fewer sutures, which allows a shorter learning curve. Nowadays, there is extensive literature on this technique [15–21] but randomized comparative clinical trials are necessary to compare the post-surgical results between of sacropexy and LLS.

For that reason, we have designed a multicenter randomized study to compare if the laparoscopic lateral suspension (LLS) technique, can offer anatomical and functional results that are not inferior to those of the conventional surgical technique (sacropexy), minimize possible intraoperative complications and facilitate the long and specific learning curve of sacropexy.

2. Materials and Methods

A multicenter randomized study of patients undergoing laparoscopic repair of severe apical and anterior prolapse. We have divided them into two groups:

-Group A: lateral laparoscopic suspension (LLS)

-Group B: Sacropexy (SCL) without posterior mesh fixation on the puborectalis muscle.

In both groups it's possible to perform hysteropexy, supracervical hysterectomy or vaginal vault prolapse after hysterectomy (it depends on each patient needs).

Exclusion criteria for hysteropexy in both groups are the contraindications for uterine preservation: Uterine pathology, including fibroids, adenomyosis, and endometrial pathology; cervical lesions; post-menopausal bleeding; cervical elongation (defined as POP-Q [22] Point C minus Point D ≥4); ovarian/tube cancer risk (BRCA 1 & 2), endometrial cancer risk, Lynch syndrome, Tamoxifen treatment, inability to follow a gynecological cancer prevention program.

The study was conducted in accordance with the Declaration of Helsinki, and approved by the Ethics Committee of CEIm Hospital Virgen de la Arrixaca (protocol code 2022-3-8-HCUVA and date

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of approval: 26 April 2022). Written informed consent was obtained from all subjects involved in the study. This Trail was registered in ClinicalTrials.gov with the Identifier NCT06815731.

Randomization system: Random Allocation Rule, a free-source software package in randomizeR: A Package for the Assessment and Implementation of Randomization in Clinical Trials (Uschner et al.) will be used. The allocator will enter the software using a personal password and will have a list of the admitted patients and their randomization.

A non-inferiority study is proposed in which the null hypothesis (H0) is that the difference in the proportion of treatment failures among women who undergo laparoscopic bilateral suspension (LLS) (Group A) compared to the proportion of anatomical and/or functional failures among women who undergo sacropexy without the fixation of the posterior mesh on puborectalis muscle (Group B) is 15% or more (noninferiority margin). A non-inferiority margin of 15% is used because minor differences are not considered clinically relevant. It will be necessary to include 182 participants (91 per group) to detect a risk difference of 15% (8% failure for the LLS group versus 23% failure for the sacropexy group) at 1 year with a statistical power of 0.80.

Inclusion criteria: Patients with Stage II- IV primary or recurrent prolapse affecting the anterior or middle vaginal compartment with or without minimal posterior defect (Stage I) according to the POP-Q.

Exclusion criteria: History of abdominal prolapse reconstructive surgery, history of prolapse reconstructive surgery with vaginal meshes, stage I according to the POP-Q classification or asymptomatic prolapse, medical contraindication for general anesthesia, patient preference for vaginal surgical approach or patient does not wish to participate in the study.

The primary outcome is treatment failure, a composite measure that includes any of the following: (A) new treatment for prolapse (pessary placement or surgery); (B) anatomical results, defined as any POP-Q[22] measurement beyond the hymen; and (C) symptoms, defined as a positive response (any degree of discomfort) to the following question on the validated questionnaire for prolapse symptoms (PFDI-20)[23]: "Do you usually have a bulge or something falling out that you can see or feel in your vaginal area?" For the primary analysis, this outcome will be assessed cumulatively, so that once a participant meets any of the failure criteria, her outcome will be classified as treatment failure.

The secondary objectives are to assess whether there are differences in complications, adverse events, individual anatomical measures on the POP-Q exam and the presence, severity and impact of symptoms of or discomfort from prolapse, urinary, intestinal and pain symptoms, as measured by the PFDI-20 and PISQ-12[24] questionnaires and the body image scale[25], between the lateral laparoscopic suspension (LLS) (Group A) and sacropexy (Group B).

A presurgery visit and 3 follow-up visits (1 month, 6 months and 1-year post-surgery) are plannified.

The collection of follow-up variables have been conducted by a specialist who does not know which surgical technique was performed for each patient to eliminate the possibility of bias in the assessment of post-surgical results.

3. Results

At the moment, we have included 176 patients and 106 patients have been operated: 50 LLS and 56 SCL with a follow-up between 1 and 12 months currently.

There were no differences in baseline demographic characteristics of the patients between of the two groups (Table 1). We only found differences in the mean age (but it's not clinically relevant, 57.9 years for LLS v 54.7 years for SCL). No statistically significant differences were found in BMI (body mass index), multiparity, vaginal and instrumented deliveries, macrosomic fetuses, previous constipation, chronic sports or exertion, previous abdominal or vaginal hysterectomy, or previous vaginal surgeries. Regarding physical examination, all patients included in both groups had no differences in stages III-IV in the POP-Q classification. Concerning the symptom scales, we also found

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no significant differences between the groups in the mean values of POPDI-6, CRAD-8, UDI-6 and PISQ-12.

Table 1. Pre-operative demographic characteristics.

Technique	**LLS**			**Sacropexy**			
	n	Mean	Median (p25-p75)	n	Mean	Median (p25-p75)	**p-value**
Age	50	57.9 ±9.5	59.0 (50.0-67.0)	56	54.7 ±10.3	53.0 (47.0-61.8)	***0,047***
BMI	49	26.2 ±4.8	25.2 (22.7-28.3)	56	27.0± 3.9	26.5 (24.5-29.8)	0,122
nº Pregnancy	50	2.6 ±1.0	2.0 (2.0-3.0)	56	2.7± 1.4	2.0 (2.0-3.0)	0,886
nº Vaginal delivery	50	2.2 ±1.0	2.0 (2.0-3.0)	56	2.3 ±1.4	2.0 (1.3-3.0)	0,567
Stage of POP Q ≥II n(%)							
II		1 (2.6%)			2.0 (4.7%)		0,615
III-IV		38.0 (97.4%)			31.0 (95.3%)		
Questionnaire PFDI-20							
POPDI-6 (0-24)	40	12.4 ±5.8	12.5 (7.3-16.0)	37	14.5 ±6.2)	14.0 (11.0-19.5)	0,137
CRADI-8 (0-32)	41	12.0 ±24.8	8.0 (4.5-10.5)	36	8.1 ±4.7)	8.0 (4.3-11.8)	0,616
UDI-6 (0-24)	41	13.1 ±6.3	13.0 (9.0-18.0)	36	12.7 ±6.0)	13.0 (9.0-17.8)	0,761
PISQ-2 (0-48)	38	28.7 ±9.0	29.0 (22.8-36.0)	33	29.2 ±9.3)	28.0 (23.5-36.5)	0,917
Body Image Scale n (%)							
normal		9 (30.0%)			4.0 (28.6%)		
abnormal		21.0 (70%)			10.0 (71.4%)		0.923
POP-Q points							
Aa	48	1.6 ±1,0	2.0 (1.0-2.0)	51	2.0 ±1.2	2.0 (1.5-3.0)	***0,020***
Ba	48	1.6 ±1.2	1.5 (1.0-2.0)	51	2.5 ±2.3	3.0 (1.0-4.0)	***0,006***
C o D	48	1.5 ±1.6	2.0 (0.0-2.4)	51	2.8 ±2.4	2.0 (1.0-4.0)	***0,017***
Ap	47	-1.1 ±1.4	-1.0 (-2.0-0.0)	50	-0.7 ±2.0	-1.0 (-2.0-1.0)	0,528
Bp	44	-1.3 ±1.7	-2.0 (-3.0-0.0)	50	-0.5 ±3.0	-1.0 (-2.1-0.0)	0,172
gh	47	4.7 ±1.0	4.5 (4.0-5.0)	50	5.0 ±1.3	5.0 (4.0-6.0)	0,060
pb	45	2.8 ±1.2	3.0 (2.0-3.5)	50	3.0 ±0.9	3.0 (2.0-3.5)	0,469
tvl	47	7.4 ±1.0	7.0 (7.0-8.0)	49	7.8 ±1.3	8.0 (7.0-9.0)	0,131

BMI: Body mass index; LLS: Laparoscopic lateral suspension; SCL sacropexy; POP-Q: Pelvic organ prolapse quantification.

Regarding post-surgical results, we found statistically significant differences in the total surgical time, being lower for the LLS (76.1 ±58.6 vs 164.7 ±84.9 minutes, p 0.001), although there were not differences in the time spent during the hysterectomy in both groups. Regarding pain on the first postoperative day assessed using the visual analogue scale, there were no significant differences. None of the patients in either group had a major post-operative complication. There were no failures in the physical examination in any group. There were no differences in the points of the POP-Q. There were also no significant differences after surgery in the symptom scales (neither in the POPDI-6, CRAD-8, UDI 6 nor PISQ-12) or Body image scale (Table 2).

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Table 2. Postsurgical Results.

Technique			**LLS**				**Sacropexy**
	N	Mean	Median (p25-p75)	N	Mean	Median(p25-p75)	p-value
Operative time (min)	47	76.1 ±58.6	85.0 (0.1-110.0)	51	164.7 +84.9	180.0 (140.0-210.0)	***<0.001***
other surgeries time (min)	23	8.0 ±11.7	0.0 (0.0-15.0)	10	5.5 +11.2	0.0 (0.0-10.0)	0,466
surgeries complications	45	1.1 ±7.2	0.0 (0.0-0.0)	49	1.1 +7.9	0.0 (0.0-0.0)	0,964
Hemoglobin 24h after surgery	44	11.7 ±3.9	11.9 (8.6-12.5)	49	11.5 +2,5	11.5 (10.1-12.6)	0,969
VAS: pain 1º day after surgery (0-10)	22	3.5 ±2.1	4.0 (1.8-5.0)	20	3.6 ±2.2	3.0 (2.0-5.0)	0,929
Questionnaire PFDI-20:							
POPDI-6 (0-24)	33	5.5 ±4.9	6.0 (1.0-8.0)	41	5.1 ±5.5	4.0 (0.5-8.0)	0,594
CRADI-8 (0-32)	33	4.7 ±4.9	3.0 (1.5-6.0)	41	6.4 ±5.8	4.0 (2.0-10.5)	0,274
UDI-6 (0-24)	33	5.9 ±4.5	6.0 (1.5-10.0)	41	7.5 ±6.1	6.0 (2.5-11.0)	0,407
PISQ-2 (0-48)	20	20.7 ±11.7	17.0 (13.0-30.8)	31	27.0 ±11.0	27.0 (18.0-38.0)	0,056
Body Image Scale n (%)							
Normal		12 (93,3%)			9 (81,8%)		
abnormal		1 (7,7%)			2 (18,2%)		0.576
POP-Q points							
Aa	35	-2,2+1.3	-2.0(-3.0--1,5)	42	-2.3+1.1	-3.0(-3.0—2.0)	0,377
Ba	35	-2.8 ±1.4	-3.0 (-3.0--2.0)	42	-2.3 ±1.1	-3.0 (-3.0--2.0)	0,077
C o D	35	-4.0 ±3.5	-5.0 (-6.0--1.0)	42	-5.0 ±2.6	-6.0 (-7.0--4.4)	0,161
Ap	34	-1.8 ±1.3	-2.0 (-3.0--1.0)	41	-2.1 ±1.2	-3.0 (-3.0--1.5)	0,191
Bp	34	-2.7 ±1.2	-3.0 (-3.0--2.0)	41	-2.1 ±1.3	-3.0 (-3.0--1.3)	0,189
gh	35	4.0 ±1.0	4.0 (3.0-5.0)	41	4.2 ±1.2	4.0 (3.5-5.0)	0,452
pb	34	3.0 ±0.8	3.0 (2.0-3.5)	41	2.8 ±1.1	3.0 (2.0-3.3)	0,539
tvl	35	7.6 ±1.0	8.0 (7.0-8.0)	41	8.1 ±1.2	8.0 (7.0-9.0)	0,066

LLS: Laparoscopic lateral suspension; SCL sacropexy; POP-Q: Pelvic organ prolapse quantification.

4. Discussion

Laparoscopic sacropexy (SCL) is considered the gold standard technique for apical prolapse, but new alternative surgical techniques have became popular in last years. But they need to be compared with the gold standard one. In addition, there is little correlation between anatomical and functional results, and although functional results have the greatest impact on patients' quality of life, they are the most poorly evaluated area.

To date, there are a very few published studies that have compared SCL vs LLS. A Group of Pisa University [20] prospective, open-label, multicentre, non-inferiority trial with 300 patients who underwent SCL (n=200) or LLS (n=100) for the treatment of apical prolapse. At the 12 months follow-up, no differences in the objetive cure rate of the apical prolapse were found. Another weakness was the design, the performed hysterectomy in all the SCL and hysteropexy in all patients in the group of LLS. Furthermore, the mixed robotic and laparoscopic surgeries without stratifying the results. The most important difference with our study is that this was not a randomized trial.

In 2024, a randomized controlled clinical trial was published by a Turkish group[26], but with a modest sample size (22 patients each group). Hysteropexy with LLS and sacrohysteropexy had been compared. Previous hysterectomy was a exclusion criteria. One of their weaknesses was the use of V-shape tailored mesh (2x25cm) and not the pre-shaped mesh marketed for the standardized technique. Other weakness was that the patient selection criteria included women with stage II or

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higher apical prolapse with or without anterior prolapse, but the standard technique includes dissection of the vesicovaginal space to correct the anterior prolapse, as in SCL.

The only randomized trial conducted to date with a bigger sample size, has 89 patients (46 LLS and 43 SCL), but they performed hysterectomy at the same time for all the patients[27]. In this study, the anatomic results were similar for both techniques and with no differences in the operative time.

The LLS represents a significant advanced in the field of reconstructive surgery of POP, and a good alternative to SCL. As with any surgical technique, continuous research is needed to improve the procedure, optimize its results and to better define its indications. LLS is a valuable new tool with growing literature evidence that can be used to treat advanced POP. It expands the surgeon's surgical arsenal and may provide the opportunity to better tailor the type of suspension depending on the type of prolapse. In fact, in the experience of the participants in the Delphi process[19], LLS is more effective in correcting advanced anterior prolapse compared to SCL. Therefore, if this is concluded with future trials, LLS could be the alternative to SCL in predominantly apical and anterior defects, while SCL may be more appropriate for the management of prolapses where anterior, apical and posterior defects predominates.

Mastery of LLS allows the management of those rare cases in which the sacral promontory is difficult to access or has vascular anatomical variations that complicates the dissection. As an additional advantage, the surgical skills required to perform LLS are simpler than those required to perform SCL, as confirmed by the expert panel[19].

The main strength of our study is the design, a multicentre and randomized study, with a large sample size. In addition, our study shows a comparative analysis of two different abdominal apical POP repairs, LLS and SCL. On the other hand, we had collected quality-of-life questionnaires to assess subjective outcomes and a systematic assessment of lower urinary tract, lower gastrointestinal tract and pelvic organ prolapse symptoms, sexuality and body image scales. The main limitation of the study was that these are preliminary results, and we need to finish the study to have relevant conclusions.

5. Conclusions

Although these are preliminary results since the sample is 106 patients and the follow-up time is short, at the moment we haven't found post-surgical differences in treatment failure, symptoms, or in the physical examination after the operation between the 2 techniques, finding only significant differences with a shorter surgical time for LLS. By far, it is necessary to complete the study and extend it to other centers to complete the clinical trial as soon as possible and be able to draw relevant conclusions.

Author Contributions: Conceptualization, I.Ñ.S and M.L.S.F.; methodology, I.Ñ.S., M.L.S.F. and J.J.A.G.; software, J.J.A.G.; validation, I.Ñ.S., M.L.S.F.; formal analysis, M.L.S.F. and J.J.A.G.; investigation, I.Ñ.S., M.L.S.F., V.L.R.C., M.W., H.C.W., J.A.S.C. and M.E.P.M. ; resources, I.Ñ.S., M.L.S.F., V.L.R.C., M.W., H.C.W., J.A.S.C. and M.E.P.M.; data curation, I.Ñ.S., M.L.S.F., V.L.R.C., M.W., H.C.W., J.A.S.C. and M.E.P.M.; writing—original draft preparation, I.Ñ.S and M.L.S.F.; writing—review and editing, I.Ñ.S and M.L.S.F.; visualization, I.Ñ.S and M.L.S.F.; supervision, I.Ñ.S and M.L.S.F.; project administration, I.Ñ.S and M.L.S.F.; All authors have read and agreed to the published version of the manuscript.

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Informed Consent Statement: Written informed consent was obtained from all subjects involved in the study.

Data Availability Statement: All the data used to support the findings of this study are included in the article.

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Conflicts of Interest: The authors declare no conflicts of interest.

Abbreviations

The following abbreviations are used in this manuscript:

POP	Pelvic organ prolapse
SCL	Sacropexy (Laparoscopic)
LLS	Laparoscopic Lateral Suspension
POPQ	Pelvic organ prolapse quantification
PFDI-20	Pelvic Floor Distress Inventory Questionnaire-Short Form 20
POPDI-6	Pelvic Organ Prolapse Distress Inventory
CRAD-8	Colorectal–Anal Distress Inventory
UDI-6	Urinary Distress Inventory
PISQ-12	Pelvic Organ prolapse/Urinary Incontinence Sexual Function Questionnaire
BMI	Body mass index

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