623. PRELIMINARY RESULTS OF RANDOMIZED CLINICAL TRIAL OF SACROPEXY VERSUS LAPAROSCOPIC LATERAL SUSPENSION FOR APICAL PELVIC ORGAN PROLAPSE REPAIR

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Hypothesis / aims of study

Laparoscopic sacropexy (SCL) is the the gold standard technique for the correction of apical prolapse of pelvic organs [1]. However, other easier laparoscopic techniques such as pectopexy or laparoscopic lateral suspension (LLS) [2] have become popular. In our opinion, between these techniques, LLS is technically the easier one. However, to date there are no randomized clinical trials that compare LLS with SCL.

The hypothesis of this trial is that LLS offers anatomical and functional results that are not inferior to those of the conventional surgical technique (SCL), minimizing possible intraoperative complications.

The aim is to evaluate whether LLS is inferior to SCL with posterior flap without fixation in the puborectalis muscle for the treatment of stage > II medial and apical compartment prolapse.

The primary outcome is treatment failure, defined as the existence of any of the following 3 elements:
(1) new treatment for pelvic organ prolapse or POP (pessary placement or surgery)
(2) anatomical results, defined as any POP-Q measurement system beyond the hymen
(3) any symptoms, defined as a positive response (any degree of discomfort) to the following question on the PFDI-20: "Do you usually have a lump or something that falls off that you can see or feel in your vaginal area?"

The secondary objectives are to assess whether there are differences in complications, individual measurements in the POP-Q exam, the presence and severity of symptoms derived from prolapse, measured by the scales: the PFDI-20 and PISQ-12.

Study design, materials and methods

This is a multicenter randomized study of patients undergoing laparoscopic repair of severe apical and anterior prolapse. We divided the patients into 2 groups: LLS Group following the DELPHI consensus* and SCL Group. Hysteropexy, cervicopexy or colpopexy is possible in both groups.
The Randomization System used was a software package called RandomizeR. Sampling calculation: 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 the proportion of anatomical and/or functional failures among women who undergoing SCL is 15% or more (non-inferiority margin). It will be necessary to include 182 participants to detect a risk difference of 15% (8% failure for the LLS group versus 23% failure for the SCL group at one year with a statistical power of 0.80.
The Inclusion criteria are patients with primary or recurrent prolapse in stage > II affecting the anterior or middle vaginal compartment with or without minimal posterior defect (Stage I) according to the POP-Q.
Exclusion criteria for hysteropexy (it is possible to include it in the study but performing subtotal hysterectomy): contraindications for uterine preservation: uterine pathology, postmenopausal bleeding; risk of ovarian/tubal cancer (BRCA 1 and 2), risk of endometrial cancer, Lynch syndrome, tamoxifen treatment, inability to follow a gynecologic cancer prevention program.
Exclusion criteria are: cervical elongation (defined as POP-Q Point C minus Point D ≥4), history of reconstructive surgery for abdominal prolapse, history of reconstructive surgery for prolapse with vaginal mesh, Stage I according to the POP-Q classification or asymptomatic prolapse, medical contraindication for general anesthesia, patient preference for treatment with vaginal surgery and patients who do not wish to participate in the study.

The initial visit is scheduled where participation in the study is offered and the patient is randomized after signing the informed consent and then after surgery, review at one month, 6 months and one year with the POP-Q exam and the PFDI-20 questionnaires. and PISQ-12.

Results and interpretation

At the moment we have included 40 patients and 24 patients have been operated: 11 LLS and 13 SCL with a follow-up between 1 and 3 months currently.
There were no statistically significant differences in age, BMI, multiparity, vaginal and instrumented deliveries, macrosomic fetuses, previous constipation, chronic sports or exertion, previous abdominal or vaginal hysterectomy, or anterior or posterior plasties prior to surgery. Regarding physical examination, all patients included in both groups had stages III-IV in the POP-Q classification. In the physical examination, we also did not find significant differences in both groups for the POPQ points except for the Ap value [-2.28(±0.66) in LLS vs -1.25(±0.97) in sacropexies p =0.024]. Concerning the symptom scales, we also found no significant differences in both groups between the mean values of POPDI-6, CRAD-8, UDI-6 and PISQ-12. (Table 1)

Regarding post-surgical results, we did not find differences in the percentage of hysterectomies during the surgeries, nor in the time spent during the hysterectomy in both groups. We found statistically significant differences in the total surgical time, being lower in the LLS (117.73 ± 51.15 vs 185 ± 37.63 minutes p=0.014). Regarding pain on the first postoperative day assessed using the visual analogue scale, there were no significant differences. There were no failures in the physical examination in any group. There were no differences in 7 of the 9 points of the POP-Q, the only difference being significant in point Ba [-2.67 (±1) in the LLS vs -1.75 (±0.98) in the sacropexies p =0.019] and TVL [7.77 (±0.71) in LLS vs 9 (±0.89) in SCL, p=0.015]. There are also no significant differences after surgery in the symptom scales (neither in the POPDI-6, CRAD-8, UDI 6 nor PISQ-12) (Table 2).

Table 1. Descriptive analysis of the characteristics of patients included in the randomized clinical trial sample

CHARACTERISTICS	LLS (N=11)	SACROPEXY (N= 13)	P-VALUE
Age (years), mean (SD)	58,09(9,09)	56,62 (10,45)	0,505
BMI (Kg/m^2), mean (SD)	26,43 (4,75)	26,52 (4,25)	0,931
Multiparous n(%)	90.9	76.9	0.596
Vaginal Deliveries, n(%)	72,7	69,2	0.456
instrumental deliveries (%)	81,8	69,2	0,294
macrosomic fetus (%)	72,7	76,9	0,559
Constipation (%)	18,2	23,1	1
Sport or chronic effort (%)	81,8	61,5	0,620
Previous abdominal hysterectomy, n(%)	9,1	7,7	1
Previous vaginal hysterectomy due to POP (%)	0	23,1	0,217
anterior o posterior vaginal plasties (%)	9,1	15,4	1
PFDI-20 -POPDI-6 mean(SD) -CRAD-8 mean(SD) -UDI-6 mean(SD)	 11,50(4,68) 4,33(2,42) 11,67(8,19)	 13,50(4,51) 5,50(5,80) 10(5,35)	 0,521 1 0,830
PISQ-2	22,17(13,60)	27,50 (8,81)	0,670
Aa mean (SD)	1,85(0,85)	2.3(0,85)	0.291
Ba mean (SD)	2,50(1,08)	2.80(1,76)	0.786
C o D mean (SD)	1.1 (1,72)	2.1 (1,98)	0.209
Ap mean (SD)	-2,28 (0,66)	-1,25 (0,97)	**0.024**
Bp mean (SD)	-1,89 (2,10)	-1.15(1,45)	0.076
Gh mean (SD)	5 (1,17)	4,75 (1,97)	0.869
Pb mean (SD)	3,00(0,55)	3,40(1,14)	0.370
TVL mean (SD)	7.28 (0,71)	7.75 (1,51)	0.263

Table 2: Surgical results of the variables analyzed in randomized clinical trial sample

	LLS (N=11)	SACROPEXY (N=13)	P-VALUE
Hysterectomy during surgery , n(%)	18,2	53,8	0,080
Total surgical time (min) , media (SD)	117.73(51,15)	185 (37,63)	**0.014**
Surgical time of Hysterectomy (min) , mean (SD)	30,00 (0)	38,57 (13,75)	0.521
Surgical time of other surgeries (oophorectomy) (min) , mean (SD)	20,63 (10,15)	10 (0)	**0.028**
Hemoglobin after 24 hours (hb gr/dl) , mean(SD)	12.07 (1,03)	11.43 (1,03)	0.223
VAS (pain after 1 day after surgery) (0-10)	2 (2,82)	3.25 (1,5)	0.372
PFDI-20 Postsurgery - POPDI-6 mean(SD) - CRAD-8 mean (SD) - UDI-6 mean (SD)	 5.13 (3,39) 4.63 (5,63) 3.87 (2,95)	 6.25 (5,31) 9.25(4,35) 10 (6,58)	 0.668 0.198 0.071
- -PISQ mean (SD)	23 (15,60)	16,67 (17,56)	0,858
Aa postsurgery	-2.89 (0,33)	-2.33(0,82)	0.094
Ba postsurgery	**-2,67 (1)**	-1,75(0,98)	**0.019**
C ó D postsurgery	-5,67(0,75)	-6,75(1,17)	0.059
Bp postsurgery	-2,44(1,01)	-2.08 (1,28)	0.549
Ap postsurgery	-2.44(0,58)	-1,92 (1,49)	0.851
gh postsurgery	3.83(0,93)	4.33(0,98)	0.368
pb postsurgery	3.18(0,53)	2,83(0,68)	0.210
tvl postsurgery	7.77(0,71)	**9 (0,89)**	**0.015**

Although these are preliminary results since the sample is small and the follow-up time is short, at the moment **we didn´t find post-surgical differences in treatment failure, symptoms, or in the physical examination after the operation between the 2 techniques**,

finding only significant differences in the
-**higher TVL for SCL versus LLS**
-**better correction of the Ba point for LLS**, and
-**shorter surgical time for LLS.**

Conclusion

However, 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.

References

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