

LAPAROSCOPIC SACROCOLPOPEXY IN TREATMENT OF PELVIC ORGAN PROLAPSE: LEARNING CURVE ANALYSIS.

Hypothesis / aims of study

Defining optimal surgical treatment for pelvic organ prolapse (POP) is still a challenge nowadays, especially after FDA's health alarms published in 2008 and 2011. Laparoscopic surgical correction and abdominal procedures have an increasing development, especially laparoscopic sacrocolpopexy (LS), which has shown an excellent anatomic and functional results, with a low complications rate.

Introduction of a new surgical procedure, especially if it is laparoscopic approach, requires acquire new knowledge and skills through progressive experience, known as learning-curve. This learning period is different and it depends on technical complexity and previous surgeon abilities. Our objective is to determinate the number of procedures needed to acquire technical skills in LS for POP treatment.

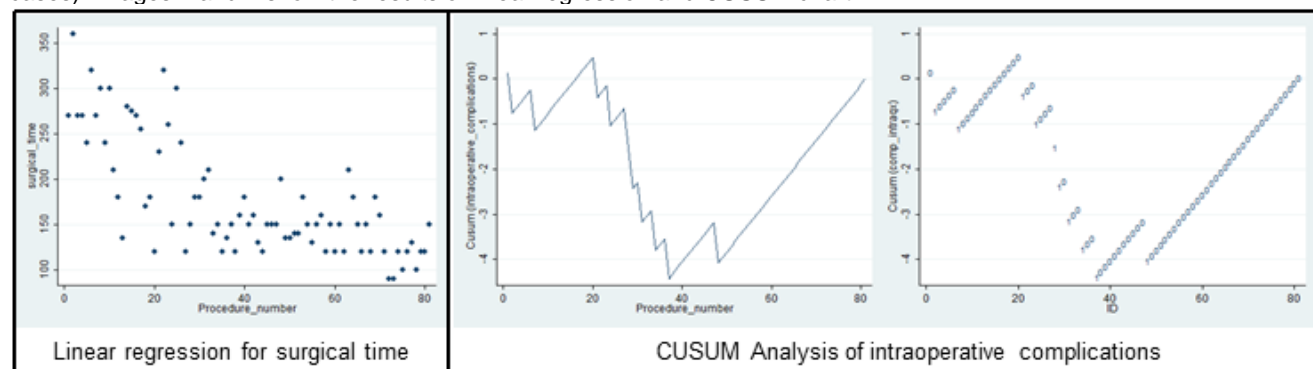
Study design, materials and methods

We analyzed the first 130 consecutive procedures of LS by 4 surgeons, carried out between November 2011 and January 2016. Chart 1 shows surgeries distribution by physician.

SURGEON A	SURGEON B	SURGEON C	SURGEON D	TOTAL
81 (62.31%)	27 (20.77%)	20 (15.38%)	2 (1.54%)	130 (100%)

To determinate the learning-curve, we decided to analyse only those procedures performed by Surgeon A because we considered, in the moment of the study's beginning, rest of physicians had a low number of surgeries. So, 81 consecutive procedures performed only by one surgeon with previous laparoscopic experience, were included in our analysis.

We analysed number of included procedures in the learning curve and the relation with surgical time and number of intraoperative complications. We divided our sample in two groups based on linear regression for surgical time and CUSUM chart for intraoperative complications. Those groups are: Learning curve cases (1 to 35) and surgical technique consolidation (36-81 cases). Images 1 and 2 show the results of linear regression and CUSUM chart.



Quantitative variables were described by median and standard deviation and qualitative variables by absolute and relative frequency. Hypothesis contrast was developed by t-student and Mann-Whitney U test for quantitative variables and Chi squared and Fisher's exact test for qualitative ones.

Results

Chart 1, shows basal characteristics in both groups.

VARIABLE	LEARNING CURVE	CONSOLIDATION	p VALUE
N	35	46	
	Mean (SD)	Mean (SD)	
Age	68.1 (8.5)	70.3 (6.8)	0.46
Gestations	3.3 (1.2)	3.0 (1.4)	0.38
	N (%)	N (%)	
Arterial hypertension	19 (54.3)	29 (63.0)	0.42
Diabetes	7 (20.0)	9 (19.6)	0.96
Cardiovascular disease	4 (11.4)	1 (2.2)	0.10
Respiratory disease	3 (8.6)	6 (13.0)	0.40
POP previous surgery	9 (25.7)	6 (13.0)	0.15
Anticoagulation therapy	4 (11.4)	0 (0)	0.03
Antiplatelet therapy	4 (11.4)	13 (28.3)	0.06

Chart 2, shows comparative analysis of both groups.

VARIABLE	LEARNING CURVE	CONSOLIDATION	p VALUE
	Media (DS)	Media (DS)	
Surgical time (minutes)	225 (66.2)	141 (26.3)	< 0.001
Hospital stay (days)	3.3 (1.6)	2.3 (0.9)	< 0.001
Bladder catheter (days)	3.1 (2.5)	2.2 (1.1)	0.03
	N (%)	N (%)	
Intraoperative complications	8 (22.9)	2 (4.4)	0.02
Bladder injury			
Rectal injury	6 (17.1)	1 (2.2)	
Vaginal injury	1 (2.8)	-	
	1 (2.8)	1 (2.2)	
Early complications (30 days)	3 (8.5)	1 (2.2)	0.21
Transfusion	-	3 (6.5)	0.18

Interpretation of results

As chart 2 shows, during learning curve period (first 35 consecutive surgeries) an increased surgical time was observed and a higher number of days of hospital stay, bladder catheter and intraoperative complications, achieving statistical signification.

On the other hand, no statistical signification was found between both groups attending to early complications and transfusion. A possible explanation of this results, is that there must be another independent variables influencing early complications not related to surgical technique, in contrast with the intraoperative ones, which are directly related.

Concluding message

According to our results, to achieve technical skills in LS, defined as reducing surgical time and low intraoperative complications rate, a minimum number of 35 procedures are required in surgeons with previous laparoscopic experience.

Disclosures

Funding: None **Clinical Trial:** No **Subjects:** HUMAN **Ethics not Req'd:** Because it is a observational study. **Helsinki:** Yes **Informed Consent:** Yes