

LAPAROSCOPIC SACROCOLPOPEXY VERSUS ABDOMINAL SACROCOLPOPEXY FOR VAGINAL VAULT PROLAPSE: A RANDOMIZED CONTROLLED TRIAL TRIAL REGISTRATION NUMBER: NTR 3276

Hypothesis / aims of study

Sacrocolpopexy represents the most effective treatment for vault prolapse. The open abdominal procedure is considered as the first choice treatment for vaginal vault prolapse treatment according to a Cochrane review on the topic [1]. Since the laparoscopic sacrocolpopexy has been introduced, it has gained popularity before any clinical advantage over the abdominal procedure was proved. Laparoscopic sacrocolpopexy has potential advantages in terms of reduced morbidity and recovery time. However, the laparoscopic approach has potential surgical disadvantages. Literature reports a long learning curve associated with the laparoscopic sacrocolpopexy due to difficulties like decreased degrees of movement and two-dimensional vision. The aim of this randomized multicentre trial was to evaluate functional outcome of laparoscopic compared to open sacrocolpopexy, with disease specific quality of life as primary outcome.

Study design, materials and methods

We performed a multicentre randomized controlled superiority trial in 2 university and 4 teaching hospitals in the Netherlands within the Dutch urogynecological consortium. Women with symptomatic post hysterectomy vaginal vault prolapse requiring surgical treatment were eligible. Disease specific quality of life, using the Urinary Distress Inventory (UDI) questionnaire, was the primary endpoint. A difference between both surgical techniques of 10 points on the obstructive / pain domain of the UDI one year after surgery, was considered a clinically relevant difference between both groups. The standard deviation of the score on this domain is 15 points. We needed 74 patients to show a difference of in the primary outcome (power of 80%, α error 0.05). Secondary outcome included anatomical outcome, peri-operative data and one year follow-up

Results

Between 2007 and 2012, we randomised 74 women, 37 to the open laparoscopic sacrocolpopexy group and 37 to the abdominal group. Follow-up after 12 months showed no significant difference in Urinary Distress Inventory (UDI, table 1). Both groups reported after one year a UDI score of 0.0 (IQR: 0-0) for the obstructive micturition domain ($P = .281$), as well as the score of both groups for the genital prolapse domain ($P = .929$). The pain and discomfort domain showed a score of 0.0 (IQR: 0-33) for the laparoscopic group versus 16.7 (IQR: 0-33) for the abdominal group ($P = .151$). In the laparoscopic sacrocolpopexy group blood loss was significantly less compared to the abdominal group (86 ml (IQR: 10-100) vs 200 ml (IQR: 100-300), $p < .001$). Hospital stay was also significantly less (2 days (IQR: 2-3) vs 4 days (IQR: 3-5), $p < .001$) in favour of the laparoscopic group. Although there were more severe complications in the laparoscopic group, differences were not statistically significant (table 2). At 12 months, there was no difference between both groups in anatomical outcome ($P = .320$ for the apical compartment).

Interpretation of results

This randomized controlled trial has shown no differences in disease specific quality of life. Furthermore the anatomical result is comparable between the groups, however the laparoscopic procedure leads to less blood loss and a shorter hospital stay. The laparoscopic sacrocolpopexy seems to be a safer treatment for vaginal vault prolapse, because there were less severe complications in this group, although there is no significant difference between the groups in overall complication rate.

Concluding message

This randomized controlled trial comparing laparoscopic and open abdominal sacrocolpopexy shows the laparoscopic approach to be preferable, as outcomes are equal but recovery is faster.

Table 1. Urinary Distress Inventory (UDI) Domain Scores

	Pre-operative		<i>p-value</i>	One year post-operative		<i>p-value</i>
	Laparoscopic N=36	Abdominal N=36		Laparoscopic N=36	Abdominal N=36	
Urogenital Distress Inventory	N=32	N=30		N=28	N=28	
Overactive bladder Median (IQR)	33.3 (11-56)	33.3 (17-44)	.121	0.0 (0-11)	0.0 (0-17)	.303
Incontinence Median (IQR)	16.7 (0-50)	16.7 (0-42)	.472	0.0 (0-33)	16.7 (0-33)	.521
Obstructive micturition Median (IQR)	0.0 (0-33)	16.7 (0-58)	.019	0.0 (0-0)	0.0 (0-0)	.281
Pain/Discomfort Median (IQR)	16.7 (0-33)	33.3 (33-33)	.443	0.0 (0-33)	16.7 (0-33)	.151
Genital prolapse Median (IQR)	66.7 (33-83)	66.7 (33-67)	.169	0.0 (0-0)	0.0 (0-0)	.929
Recurrent bladder infections Median (IQR)	1.0 (1-2)	1.0 (1-3)	.329	1.0 (1-1)	1.0 (1-2)	.369

Table 2. Clinical outcome

	Laparoscopic Sacropopexy N=36	Open Abdominal Sacropopexy N=36	p-value
Operative time (minutes)			
Median (IQR)	125 (108-135)	115 (94-129)	.308
Estimated blood loss (ml)			
Median (IQR)	86 (10-100)	200 (100-300)	<.001
Hospital stay (days)			
Median (IQR)	2 (2-3)	4 (3-5)	<.001
Complications during surgery (n/m)	5.6% (2/36)	0% (0/36)	.151
Bladder lesion	1	0	
Bleeding	1	0	
Complications during admission (n/m)	5.6% (2/36)	19.4% (7/36)	.067
Fatal bowel perforation	0	1	
Wound dehiscence	0	2	
Pulmonary embolism	0	1	
Ileus	0	3	
Wound infection	1	0	
Pyelonephritis (re-admission)	1	0	

References

1. C.Maher, B.Feiner, K.Baessler, C.Schmid (2013). Surgical management of pelvic organ prolapse in women (review). Cochrane Database of Systematic reviews. issue 4. doi: 10.1002/14651858. CD004014. pub5.

Disclosures

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