Vaginal packing after laparoscopic sacrocolpopexy - postoperative pain and satisfaction: a randomized controlled trial

Zdenek Rusavy[1], Adela Marinic Veverkova[2], Martin Smazinka[1], and Vladimir Kalis[1]

[1]Univerzita Karlova
[2]University Hospital in Pilsen Charles University

March 13, 2025

Abstract

Objective: Data concerning effect on early postoperative pain and patient satisfaction after laparoscopic sacrocolpopexy (LSC) is lacking. Design: Double-blind randomized controlled trial Setting: Tertiary urogynaecology care centre, Faculty of Medicine in Pilsen, Charles University Population: Women undergoing LSC for stage $>$ 2 pelvic organ prolapse were included. The exclusion criteria were concomitant vaginal surgery including suburethral sling or where vagina was opened during the surgery (including hysterectomy). Women with lost or incompletely filled-in McGill pain questionnaire were additionally excluded from the postoperative pain and satisfaction analysis. Methods: Women were randomized to vaginal packing after LSC with a sterile gauze. The subjective perceptions of pain were measured using McGIll Pain Questionnaire on day one before pack extraction and satisfaction was assessed using VAS on postoperative day 1 and 4. Main outcome measures: Postoperative pain on day after the surgery, patient satisfaction with the surgery and postoperative course on day one and four. Results: In total, 274 women were included in analysis, vaginal pack was inserted in 132 (48%) women. The groups did not differ in basic preoperative nor surgical characteristics. Very low and comparable values of all scores of the McGill Pain Questionnaire were observed (VAS pain 3.2 $\pm$1.8 vs. 3.4$\pm$1.9, p=0.330). No difference in patient satisfaction on day one (7.3$\pm$1.8 vs. 7.4$\pm$1.7, p=0.633) nor overall satisfaction on day 5 (8.7$\pm$1.3 vs. 8.8$\pm$1.1,p=0.719) was observed. Conclusion: Laparoscopic sacrocolpopexy is associated with low levels of pain and high patient satisfaction regardless of vaginal pack insertion. Vaginal packing does not harm the patients.
Clinical trial registration: https://clinicaltrials.gov/study/NCT02943525

Vaginal packing after laparoscopic sacrocolpopexy - postoperative pain and satisfaction: a randomized controlled trial

Zdenek Rusavy[1,2], Adela Marinic Veverkova[2], Martin Smazinka[1,2], Vladimir Kalis[1,2]

[1] Department of Gynaecology and Obstetrics, Faculty of Medicine in Pilsen, Charles University, Czech Republic

[2] Department of Gynaecology and Obstetrics, University Hospital in Pilsen, Charles University, Czech Republic

Corresponding author:

prof. Zdenek Rusavy, M.D., Ph.D.

Department of Gynaecology and Obstetrics, Faculty of Medicine in Pilsen, Charles University

Alej Svobody 80, 323 00, Pilsen, Czech Republic

Email: rusavyz@fnplzen.cz

Running title: Vaginal Packing After Sacrocolpopexy: Pain and Satisfaction

Previous presentation: The data was previously presented at the 16th EUGA Annual Meeting in Varese 19 - 21. October 2023

Funding: This work was funded by Charles University, Cooperatio Program, research area Maternal and Childhood Care. The funders did not have a role in the collection, analysis and interpretation of data and in the writing of the manuscript

Author disclosure/conflict of interest: The authors declare no conflicts of interests.

Abstract :

Objective: Data concerning effect on early postoperative pain and patient satisfaction after laparoscopic sacrocolpopexy (LSC) is lacking.

Design: Double-blind randomized controlled trial

Setting: Tertiary urogynaecology care centre, Faculty of Medicine in Pilsen, Charles University

Population: Women *undergoing LSC for stage > 2 pelvic organ prolapse were included. The exclusion criteria were concomitant vaginal surgery including suburethral sling or where vagina was opened during the surgery (including hysterectomy). Women with lost or incompletely filled-in McGill pain questionnaire were additionally excluded from the postoperative pain and satisfaction analysis.*

Methods: Women were randomized to vaginal packing after LSC with a sterile gauze. The subjective perceptions of pain were measured using McGIll Pain Questionnaire on day one before pack extraction and satisfaction was assessed using VAS on postoperative day 1 and 4.

Main outcome measures: Postoperative pain on day after the surgery, patient satisfaction with the surgery and postoperative course on day one and four.

Results: In total, *274 women were included in analysis, vaginal pack was inserted in 132 (48%) women. The groups did not differ in basic preoperative nor surgical characteristics. Very low and comparable values of all scores of the McGill Pain Questionnaire were observed (VAS pain 3.2 ±1.8 vs. 3.4±1.9, p=0.330). No difference in patient satisfaction on day one (7.3±1.8 vs. 7.4±1.7, p=0.633) nor overall satisfaction on day 5 (8.7±1.3 vs. 8.8±1.1,p=0.719) was observed.*

Conclusion: Laparoscopic sacrocolpopexy is associated with low levels of pain and high patient satisfaction regardless of vaginal pack insertion. Vaginal packing does not harm the patients.

Clinical trial registration: https://clinicaltrials.gov/study/NCT02943525

Keywords: Prolapse, Pelvic Organ Prolapse, Sacrocolpopexy, Vaginal packing, Satisfaction

Funding:

This work was funded by Charles University, Cooperatio Program, research area Maternal and Childhood Care. The funders did not have a role in the collection, analysis and interpretation of data and in the writing of the manuscript

Introduction :

The current evidence strongly supports laparoscopic sacrocolpopexy (LSC) as the gold standard for the surgical repair of apical vaginal prolapse[1]. Over last decades, LSC has advanced significantly in its outcomes, surgical technique, concomitant surgeries, and surgical proficiency decreasing the risk of complications. However, there remains significant variation amongst surgeons in some surgical steps when performing LSC, usually owing to a lack of evidence on the matter[2]. One of these steps is packing the vagina with a sterile gauze after the procedure.

Vaginal packing was traditionally used to reduce the risk of haemorrhagic and infectious complications after vaginal reconstruction surgery [3]. However, it may be associated with urinary tract infection from bladder

catheterization, patient bother and pain upon extraction of the pack [4]. Vaginal packing after vaginal reconstructive surgery has become a well explored topic. It was demonstrated, that it was not associated with increased pain scores or postoperative morbidity [4, 5]. However, it was also not associated with any clinically meaningful reductions in adverse effects, such as vaginal bleeding, hematoma formation, or postoperative vaginal cuff infection after vaginal hysterectomy [3].

Vaginal packing was recommended after LSC by some authors[6-8], however, no evidence regarding vaginal packing after laparoscopic reconstruction exist. The primary objective of this randomized controlled trial was to compare subjective impressions of pain in women after LSC treated with and without packing. The secondary aims included comparison of patient satisfaction with the surgery on day 1 *and satisfaction with the overall postoperative course, bacteriuria and anaemia on day 4.*

Methods

This was a single-centre double-blind parallel randomized controlled trial performed at a tertiary care teaching hospital (University Hospital, Faculty of Medicine in Pilsen, Charles University) in Pilsen, Czechia. The recruitment occurred in the study period November 2016 – June 2022. Approval was obtained from the Ethics committee of the Faculty of Medicine in Pilsen, Charles University (approval number 411/2016, approved October 6, 2016) *prior to study commencement. The trial was registered in clinicaltrials.gov registry (* NCT02943525, registered October 21, 2016*). All women with pelvic organ prolapse stage > 2 according to POPQ classification admitted for LSC without concomitant hysterectomy or with*

supracervical hysterectomy were considered eligible for enrolment. Women undergoing any other surgery, concomitant vaginal surgery including suburethral sling or where vagina was opened during the surgery (e.g. during concurrent hysterectomy), were excluded from the study. Other exclusion criteria included clotting disorders, anticoagulant use as well as vaginal, uterine or ovarian malignancy. In addition, women with lost or incompletely filled-in pain questionnaire were excluded from this postoperative pain and satisfaction analysis. The primary outcome of the study was postoperative pain on day one after the surgery. The secondary outcomes were patient satisfaction with surgery on postoperative day 1 and satisfaction with the overall postoperative course, bacteriuria and anaemia on postoperative day 4.

The patients were enrolled either in consultation office or after admission to the hospital after signing the informed consent. Prior to the surgery the women underwent a complex urogynecologic examination including POP-Q staging, quality of life assessment and pelvic floor ultrasound. The surgical technique remained constant for the study period as described previously in detail [9, 10]and was performed by four certified urogynaecologists proficient in the LSC surgical technique. Upon completion of the procedure, a surgical nurse opened an opaque sealed envelope to reveal each subject's allocated study arm (1:1 randomization). This timing was chosen to reduce any bias or change in the surgical procedure as a result of the subject's randomization [4]. Patients in the intervention arm had a 100% cotton, fine mesh gauze, 7x150cm, soaked with 3% boric acid solution tightly packed into their vagina. *The patients and the caring staff were both blinded regarding the allocated group until assessment of the primary outcome on day 1 after the surgery to avoid any bias. The postoperative pain was managed according to a standard clinical protocol equally regardless of allocated group. It was a standard to provide continuous morphine 0.5 – 2 mg per hour on the day of the surgery and then paracetamol 1g or metamizole 2.5g for breakthrough pain. The day after the surgery before potential extraction of the pack, the women were asked to complete the validated Czech version of the short form McGilll Pain Questionnaire [11]. The short form of the McGill Pain Questionnaire provides five scores: sensory, affective, and total scores from the descriptors, and overall intensity scores from the Present Pain Intensity and Visual Analog Scale [12]. Patient satisfaction was evaluated on a scale from 0 for "not satisfied" to 10 for "very satisfied" on the postoperative day 1 for overall satisfaction after surgery and on postoperative day 4 for overall satisfaction with the postoperative course. VAS was measured in mm and recorded in cm after rounding. Midstream urine sample was collected for culture and blood was taken for haemoglobin level assessment on postoperative day 4.*

An independent statistician provided statistical analysis and advice throughout the study. The power calculati-

on for the main outcome measure was adopted from a study by Thiagamoorthy et al., which calculated that 86 patients in each group were required to reject the null hypothesis of no difference between the groups with alpha 0.05 and 90 % power [5]. The power calculation for patient satisfaction assessment using VAS was adopted from the study by Westerman et al.; 37 participants per group were needed to detect a mean difference of 14 mm on a 100-mm VAS with 90% power and an alpha of 0.05 [4]. More women were enrolled in the groups for assessment of surgical outcome and complications in one-year follow-up in the second part of this randomized controlled trial. All data were stored and collected using a clinical database and evaluated by the following statistical analyses depending on distribution of normality: Wilcoxon pair test, $\chi 2$ test, Kruskal-Wallis test, Fisher exact test, Median Two Sample test. P-*value under 0.05 was considered statistically significant.*

Results:

A total of 620 LSC were performed in our department in the study period and 512 women were enrolled in the study and randomized. The McGill pain questionnaire was completed by 274 women and these were included in this early postoperative analysis. Vaginal pack was inserted in 132 (48%) women (Figure 1). There were no differences regarding the concomitant surgery on the uterus - 92 women had vaginal vault prolapse, 138 women underwent a concomitant supracervical hysterectomy and the uterus was preserved in 44 women (Table 1). Similarly, the groups did not differ in basic preoperative characteristics (age, BMI, smoking), nor surgical characteristics including duration of the surgery, estimated blood loss, Redon drainage insertion and perioperative complications (Table 1). There were 6 bladder perforations, three in each group and one intraperitoneal hematoma requiring drainage on postoperative day 2 in the packing group. No adverse events associated with vaginal packing were noted.

Low values of postoperative pain were observed in all scores of McGill Pain questionnaire including VAS. No difference in postoperative pain was detected between the groups as demonstrated in Table 2. Similarly, patient satisfaction with the surgery on day one before pack extraction or overall satisfaction on day 4 did not differ (Table 3).

The mean haemoglobin levels on day 4 were comparable (12.7±1.2 vs. 12.8±1.2 g/dl, p=.516). Significant bacteriuria incidence ([?]10^5 colony-forming units (CFU) per mL of urine) did not differ between the groups (17 (12.9%) vs 18 (12.7%), p = .319). In the majority of cases, it was asymptomatic. These were not nosocomial infections as the pathogens included common urinary pathogens such as Escherichia coli (45.7%), Enterococcus faecalis. (31.4%).

Discussion

Main findings

In this randomized controlled trial, we were able to demonstrate that vaginal packing after LSC is not associated with increased pain. This finding is in agreement with studies assessing pain after vaginal reconstructive surgeries. Using similar methodology Thiagamoorthy et al. have shown comparable pain scores in groups with and without packing after vaginal hysterectomy with or without associated prolapse surgery. Summed score of the McGill Pain questionnaire was used for comparison. In this study the individual scores of the short form McGill Pain Questionnaire were evaluated separately as was recommended by the author of the questionnaire [12]. Interestingly, upon comparison with a study of vaginal packing after vaginal hysterectomy using the same measure [5], it seems that LSC is less painful in follow-up. A recent study on vaginal packing following vaginal pelvic reconstructive surgery has shown even lower VAS pain scores [13].

High patient satisfaction with the surgery and overall postoperative course, which was not affected by vaginal packing was observed in this study. This result is in line with a previous study comparing patient satisfaction after vaginal reconstruction surgery, although the satisfaction levels were higher in that study [4]. LSC is more demanding surgery, with a higher anaesthesiologic risk and possibly higher early postoperative morbidity. In the study period the patients spent the day of the surgery on the postoperative intermediate care unit for closer monitoring. This could have affected the patient satisfaction.

Vaginal packing did not have any effect on urinary tract infections. No symptomatic urinary tract infection

was treated in the study period. Asymptomatic bacteriuria on postoperative day 4 was found in 13% of patients. No difference between the groups was found. In spite of the fact that the patients did not have a midstream urine culture test performed before the surgery, given the cultured strains, the bacterial colonization was probably pre-existing. The rate of asymptomatic bacteriuria in or sample is not surprising as 6 – 16% prevalence of asymptomatic bacteriuria among women aged 65 to 90 years was reported[14]. Foley catheter was inserted until the morning after the surgery regardless of study group assignment.

Interpretation

Implementation of the Enhanced Recovery After Surgery (ERAS) and same day discharge after LSC are increasingly discussed in the literature[15]. A recent survey reported that management of packs and catheters was a barrier for implementing day-case POP surgery in 92 % of UK practitioners [16]. Restriction of the use of vaginal packing after pelvic organ prolapse surgery was recommended as a part of Enhanced Recovery After Surgery (ERAS) pathways[17, 18]. Our data show that inserting vaginal packing after LSC did not induce pain or dissatisfaction in our patients. However, its effect on the outcome of laparoscopic pelvic floor reconstruction remains to be determined.

Strengths and Limitations

Strengths of our study include the randomized design and large sample size, far exceeding the calculated sample size. The single laparoscopic reconstructive surgery with standardized surgical technique and standard postoperative regimen remained constant for the duration of the study period. Finally, the use of validated scales and a robust instrument for pain assessment enabled thorough analysis of patient pain.

On the other hand, the greatest limitation of the study is the generous analgesic policy on the day of the surgery that was provided at our department at time of the study period. However, care did not differ between the groups and opioid analgesics were discontinued well ahead of completion of the McGill questionnaire in the morning after the surgery. Although the standards of analgesic care after other surgeries have changed in time with a reduction in opioid use, the regimen was not changed for the women enrolled in the study. It is also possible that patients may have been able to feel their packing and be aware of their group allocation.

Conclusion

Laparoscopic sacrocolpopexy is a safe surgery associated with low levels of pain and high patient satisfaction regardless of vaginal pack insertion. Vaginal packing does not seem to do any harm to our patients. The effect on the quality of reconstruction, recurrence rate and quality of life in a one-year follow-up remains to be evaluated.

Acknowledgement

This work was funded by Charles University, Cooperatio Program, research area Maternal and Childhood Care. The funders did not have a role in the collection, analysis and interpretation of data and in the writing of the manuscript. The authors would like to thank to Ing. Stanislav Kormunda for statistical analysis.

Author disclosure/conflict of interest: The authors declare no conflicts of interests.

Contribution to authorship: ZR – study design, data collection, data analysis, manuscript writing, AMV – patient recruitment, data collection, data analysis, manuscript editing, MS – data collection, manuscript editing, VK – study design, manuscript editing.

Details of Ethics approval: date of approval: October 6th 2016, number 411/2016

Clinical trial registration: registered in October 21st 2016, initial participant enrollment November 14th 2016, clinical trial identification number: NCT02943525, URL of the registration site: https://clinicaltrials.gov/study/NCT02943525

Data availability statement: Deidentified data was uploaded to the Mendeley Data repository, doi: 10.17632/bnz2kcfkm2.1

References:

1. Maher C, Yeung E, Haya N, Christmann-Schmid C, Mowat A, Chen Z, et al. Surgery for women with apical vaginal prolapse. Cochrane Database of Systematic Reviews. 2023(7).2. Shahid U, Chen Z, Maher C. Sacrocolpopexy: The Way I Do It. International Urogynecology Journal. 2024;35(11):2107-23.3. Porta-Roda O, Cornet-Cortada A, Font-Vilamitjana A, Huguet-Galofre E, Lleberia-Juanos J, Sola-Arnau I. Vaginal packing after vaginal hysterectomy: systematic review and recommendations. International Urogynecology Journal. 2023;34(4):789-96.4. Westermann LB, Crisp CC, Oakley SH, Mazloomdoost D, Kleeman SD, Benbouajili JM, et al. To pack or not to pack? A randomized trial of vaginal packing after vaginal reconstructive surgery. Urogynecology. 2016;22(2):111-7.5. Thiagamoorthy G, Khalil A, Cardozo L, Srikrishna S, Leslie G, Robinson D. The value of vaginal packing in pelvic floor surgery: a randomised double-blind study. International urogynecology journal. 2014;25(5):585-91.6. Manodoro S, Werbrouck E, Veldman J, Haest K, Corona R, Claerhout F, et al. Laparoscopic sacrocolpopexy. Facts, views & vision in ObGyn. 2011;3(3):151.7. Gleason JL, Richter HE, Varner RE. Berek and Novak's Gynecology 15th Ed.8. Gilleran JP, Zimmern P. Abdominal mesh sacrocolpopexy for recurrent triple-compartment pelvic organ prolapse. BJU international. 2009;103(8):1090-4.9. Smazinka M, Kalis V, Havir M, Havelkova L, Ismail KM, Rusavy Z. Obesity and its long-term impact on sacrocolpopexy key outcomes (OBELISK). International Urogynecology Journal. 2020;31(8):1655-62.10. Kalis V, Smazinka M, Rusavy Z, Blaganje M, Havir M, Havelkova L, et al. Laparoscopic sacrocolpopexy as the mainstay management for significant apical pelvic organ prolapse (LAP) study. European journal of obstetrics, gynecology, and reproductive biology. 2020;244:60-5.11. Knotek P, Blahuš P, Šolcová I, Žalský M. Standardizovaná česká verze krátké formy dotazníku bolesti McGillovy univerzity. Bolest. 2000;2:113-7.12. Melzack R, Raja SN. The McGill pain questionnaire. Anesthesiology. 2005;103(1):199-202.13. Edell H, Li X, Myrox P, Michael A, Jolliffe C, Abraham T, et al. Vaginal Packing After Pelvic Floor Reconstructive Surgery: Does the Soaking Agent Used for Packing (Bupivacaine, Estrogen or Saline) Impact Postoperative Pain Scores? Journal of Minimally Invasive Gynecology. 2024;31(12):1050-6.14. Detweiler K, Mayers D, Fletcher SG. Bacteruria and urinary tract infections in the elderly. Urologic Clinics. 2015;42(4):561-8.15. Evans S, McCarter M, Abimbola O, Myers EM. Enhanced recovery and same-day discharge after minimally invasive sacrocolpopexy. Urogynecology. 2021;27(12):740-5.16. Curtis TJ, Mukhopadhyay S, Giarenis I, Gray TG. A national survey of UK practice for day-case vaginal prolapse surgery: Unrealistic expectations? European Journal of Obstetrics & Gynecology and Reproductive Biology. 2024;293:72-7.17. Yoong W, Sivashanmugarajan V, Relph S, Bell A, Fajemirokun E, Davies T, et al. Can Enhanced Recovery Pathways Improve Outcomes of Vaginal Hysterectomy? Cohort Control Study. Journal of Minimally Invasive Gynecology. 2014;21(1):83-9.18. Zacharakis D, Diakosavvas M, Prodromidou A, Kathopoulis N, Angelou K, Kalantzis C, et al. Enhanced recovery protocols in urogynecologic and pelvic floor reconstructive surgery: a systematic review and meta-analysis. Urogynecology. 2023;29(1):21-32.

Figure 1: Patient flow diagram

Table 1: Basic and perioperative characteristics

	Packing n = 132	No packing n = 142	P-value
Age; mean ± SD	59.7 ± 11.6	60.9 ± 11.5	0.388[a]
BMI; mean ± SD	26.7 ± 3.6	26.1 ± 3.3	0.146[a]
Smoking; n (%)	24 (18.2%)	22 (15.5%)	0.550[b]
Laparoscopic sacrocolpopexy; n (%)	40	52	0.269[b]
LSCH + sacrocervicocolpopexy; n (%)	74	64	0.069[b]
Sacrohysterocolpopexy; n (%)	18	26	0.292[b]
Operation time; mean ± SD	108.5 ± 27.5	104.6 ± 22.6	0.142[a]
Blood loss; mean ± SD	149.8 ± 75.4	136.3 ± 58.4	0.184[a]
Complications; n (%)	4 (3.0%)	3 (2.1%)	0.714[c]
Redon drainage; n (%)	11 (8.3%)	8 (5.6%)	0.379[b]

BMI – Body mass index, SD – Standard deviation, LSCH – Laparoscopic supracervical hysterectomy, [a] Wilcoxon Two Sample test, [b] Chi-square test, [c] Fisher´s exact test

Table 2: Comparison of perception of pain after laparoscopic sacrocolpopexy

	Packing n = 132	No packing n= 142	p- value
PRI-S; mean ± SD	1.5 ± 1.8	1.5 ± 1.7	0.399 [a]
PRI-A; mean ± SD	0.1 ± 0.5	0.1 ± 0.7	0.472 [a]
PRI-T; mean ± SD	1.6 ± 1.9	1.6 ± 2.2	0.578 [a]
PPI; mean ± SD	2.0 ± 0.8	2.1 ± 1.0	0.989 [a]
VAS pain, cm; mean ± SD	3.2 ± 1.8	3.4 ± 1.9	0.330 [b]

PRI-S: Pain Rating Index - Sensory, PRI-A: Pain Rating Index – Affective, PRI-T: Pain Rating Index – Total, PPI: Present Pain Intensity, VAS: Visual Analog Scale. [a] Median two sample test [b] Wilcoxon Two Sample test

Table 3: Comparison of patient satisfaction after laparoscopic sacrocolpopexy

	Packing n = 132	No packing n= 142	p- value
VAS satisfaction D1, cm; mean ± SD	7.3 ± 1.8	7.4 ± 1.7	0.633
VAS satisfaction D4, cm; mean ± SD	8.7 ± 1.3	8.8 ± 1.1	0.719

VAS: Visual Analog Scale, SD – Standard Deviation. Wilcoxon Two Sample test,