Laparoscopic Sacrocolpopexy vs Transvaginal Mesh Repair for Advanced Pelvic Organ Prolapse: 1 Year Results of a Multicenter Randomized Study

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Abstract: Backgrounds: Laparoscopic sacrocolpopexy is considered the most durable operation for the repair of advanced uterovaginal prolapse. However, there is still disagreement about whether the efficacy and safety of vaginally implanted mesh to address advanced uterovaginal prolapse is comparable to sacrocolpopexy. Our goal was to evaluate the anatomical and subjective outcomes of laparoscopic sacrocolpopexy versus transvaginal mesh in a randomized trial in China. Methods: A multicenter randomized trial was carried out at 6 tertiary hospitals in China. Patients with symptomatic advanced prolapse (stages III-IV) were enrolled. Between January 2013 and June 2014, a total of 100 women were randomized. 40 laparoscopic sacrocolpopexy procedures and 42 transvaginal mesh procedures were performed. Patients were randomized to undergo either laparoscopic sacrocolpopexy or transvaginal mesh. Results: At 1 year, the anatomic success rate was 92.5% in the laparoscopic sacrocolpopexy arm, compared with 83.3% in the transvaginal mesh group (P=0.35). Laparoscopic sacrocolpopexy was associated with better apical support. The laparoscopic sacrocolpopexy group had a longer operative time. Mesh exposures occurred in 2.5% of laparoscopic repairs vs. 2.4% of transvaginal mesh repairs. Conclusion: In a randomized trial, 1-year objective cure rates were not statistically different. However the success rate was 9.2% higher for laparoscopic sacrocolpopexy. The two procedures had comparable mesh exposure rates, and other complications were rare in both groups. Trial registration: clinicaltrials.gov (NCT01762384). The date of registration was Jan 7th, 2013. URL was https://clinicaltrials.gov/ct2/show/NCT01762384?term=NCT01762384&draw=2&rank=1.

Keywords: Pelvic Organ Prolapse, Laparoscopic Sacrocolpopexy, Transvaginal Mesh

1. Introduction

Approximately one in eight women with pelvic organ prolapse (POP) undergo surgery by the age of 80 [1]. Of those who undergo prolapse surgery, approximately 13% will require a repeat operation within five years [2]. Currently, several options exist for the surgical management of POP, including native tissue repairs, laparoscopic sacrocolpopexy (LSC), and transvaginal mesh (TVM) repairs using either kits or individually tailored mesh. Because advanced prolapse at the time of the initial surgery is associated with higher recurrence risk [3], in our practice mesh-augmented repairs are common, especially in older women who are more likely to present with advanced disease.

Sacropexy is currently considered the most durable procedure for repair of apical support defects with concomitant repair of anterior and posterior defects performed laparoscopically or vaginally [4, 5]. A recent review of 11 retrospective series of LSC with 1197 total patients and a mean follow-up period of 24.6 months demonstrated a 94.4% overall subjective satisfaction rate and 2.7% mesh exposure rate [6]. In a previously published case series from Peking Union Medical College Hospital we found similar results. The anatomical cure rate for LSC was 96.7% at 3 years post-surgery [7].

Vaginal repair with mesh (TVM) can also be used to address apical prolapse with concomitant repair of anterior and posterior defects. In 2006, we began to use a TVM procedure involving self-cut mesh, which provided anterior and apical compartment support. This was combined with a native tissue posterior compartment repair. In 2015 we reported our experience with up to 7-years follow-up which showed an anatomic success rate of 84% [8].

At the time of the completion of the case series that was published in 2015 [8], TVM repair had come under increasing scrutiny and heated debate because of concerns about increased risk of adverse events and lack of improvement over native tissue repairs. For example, Maher's randomized controlled trial comparing LSC and TVM for vaginal vault prolapse, the anatomical success rate of the TVM group was only 43% [9]. However, national and international professional bodies had issued guidelines supporting the appropriate use of TVM [10]. Given the relatively positive experience with TVM at Peking Union, and at other capable hospitals, it was decided to initiate an RCT comparing TVM procedure directly with LSC. The primary goal was to compare the anatomic and subjective outcomes of LSC and the TVM procedure employed at Peking Union to expand the number of RCT's documenting the outcomes for this critical comparison. An additional goal was to implement a trial that would provide the first assessment of the outcomes and complication rates of LSC and TVM in China in a level I study. Therefore, a multi-center trial was initiated to increase the generalizability of the trial results and accelerate patient recruitment. In this paper, we report on the 12-month outcomes of this randomized comparison of LSC and TVM.

2. Methods

2.1. Study Design

The study protocol was approved by the institutional review board of Peking Union Medical College Hospital. The trial was registered with clinicaltrials. gov (NCT01762384). The date of registration was Jan 7th, 2013. The patients were recruited from 6 tertiary hospitals in China: Peking Union Medical College Hospital, Beijing; The First Affiliated Hospital of Guangzhou Medical College, Guangzhou; Obstetrics and Gynecology Hospital of Fudan University, Shanghai; The First Affiliated Hospital of Zhengzhou University, Zhengzhou; The Third Affiliated Hospital of Zhengzhou University and Henan Province Maternal and Child Health Care Hospital, Zhengzhou; Southwest Hospital of the Third Military Medical University, Chongqing.

All women who were eligible were invited to participate. After completion of the study consent, the study statistical coordinating center allocated the patients to either the LSC group or the TVM group in a 1: 1 ratio according to the randomization list that was computer-generated. The trial was non-blinded to surgeons and patients. A research staff member who was blinded to their allocation collected the questionnaires before and after procedure.

2.2. Inclusion and Exclusion Criteria

Patients aged ≥55 years with symptomatic prolapse stage III-IV were offered enrollment. Patients with uterovaginal and post-hysterectomy prolapse were included as were women who had had previous prolapse repairs. The patients could have concomitant stress urinary incontinence (SUI) or occult stress urinary incontinence. The exclusion criteria were as follows: previous repair of POP involving insertion of a mesh; active genital, urinary or systemic infection; current chronic pelvic pain; nursing, pregnant or intends to have a future pregnancy; and any medical condition or psychiatric illness that would render them unable to tolerate surgery or affect their ability to complete the study visits.

2.3. Baseline Assessment and Data Collection

The demographic characteristics and perioperative parameters were recorded at the intake visit prior to surgery and all of the patients underwent uroflowmetry and residual urine measurement preoperatively. A 1-hour pad test was used to identify urinary incontinence, while a vaginal pessary was used to reduce the prolapse to screen for occult SUI. Urodynamics were performed for concomitant SUI patients. Prior to the operation, all of the patients were required to complete the short forms of the Pelvic Floor Distress Inventory (PFDI-20), Pelvic Floor Impact Questionnaire (PFIQ-7), and, for sexually active women, the pelvic organ prolapse/urinary incontinence sexual questionnaire short form (PISQ-12), all of which were Chinese versions and validated [11-13].

2.4. Surgical Technique

The LSC and TVM procedures were performed according to the surgical technique that was previously described [14, 15]. Briefly, for the TVM procedure a single piece of polypropylene mesh (GyneMesh 10 cm× 15 cm; Ethicon, Somerville, NJ, USA) was cut into two parts for the anterior and apical compartment reconstructions. To reconstruct the anterior vaginal wall, we first made a longitudinal incision into the anterior vaginal mucosa. The vesicovaginal space was dissected until we could palpate the bilateral obturator internus muscles and the arcus tendinous fascia pelvis (ATFP) at the level of the ischial spines. We used a needle of our own design to pass the arms of the anterior mesh. The four arms of the anterior mesh were drawn from the inside to the outside and the mesh was flattened into the vesicovaginal space below the bladder. For the apical compartment, we made an incision in the midline posterior vagina from the level of the vaginal apex to approximately halfway down the posterior vagina. Sharp and blunt dissection continued laterally until the ischial spines and sacrospinous ligaments could be palpated on both sides. We made skin incisions 3 cm lateral and 3 cm inferior to the anus on both sides. We used the needle to puncture through the anorectal fossa and then through the sacrospinous ligament near the ischial spine. Rectangular strips of mesh were drawn from the inside to the outside, and the mesh strips were fixed in bilateral uterosacral ligaments. Tension-free placement was ensured. We used a bridge colporrhaphy technique to repair the distal posterior vaginal wall.

For the LSC procedure the vesicovaginal and rectovaginal space was hydro-dissected with 40-50mL of normal saline. A polypropylene mesh (GyneMesh 10 cm× 15 cm; Ethicon, Somerville, NJ, USA) was cut into 2 strips of 3.5 cm in width. Nine interrupted sutures were placed through the meshes and into the dissected anterior and posterior vaginal walls. The excess anterior mesh was excised at the vault, and the excess posterior mesh was placed in the pelvic cavity. The anterior and posterior meshes were attached at the vaginal vault. For the laparoscopic part of the operation, the right paracolic gutter was exposed and the peritoneum covering the sacral promontory was opened. The peritoneal incision was continued down the right uterosacral ligament to reach the vaginal vault. The distal end of the mesh was fixed to the anterior longitudinal ligament at the sacral promontory with a total of 2 non-absorbable sutures (Ethibond; Ethicon).

All of the vaginal and laparoscopic procedures were performed by one experienced surgeon at each center. Anterior repairs were addressed by attachment of the mesh along the length of the anterior vaginal wall in both LSC and TVM procedures. No posterior repairs performed in the LSC group.

2.5. Follow-up

Our primary outcome was the anatomical success rate at 1-year follow-up. We chose a priori to define anatomic cure as no prolapse with a POP-Q stage ≥ II in any compartment. Secondary outcome measures included perioperative variables, quality of life measures, patient satisfaction, complications, and subsequent reoperations for prolapse. The patient Global impression of improvement (PGI-I) assessed the women's perception of improvement after surgery [16]. Patients were encouraged to engage in sexual intercourse beginning 3 months after the surgery. Mesh-related complications were evaluated by the IUGA/ICS Standardization and Terminology Committee's CTS Code.

2.6. Sample Size

According to our previous data [7, 8, 14] and the Maher's results [9], we estimated there would be a 98% 1-year objective success rate for LSC and an 80% 1-year objective success rate with TVM procedure using self-cut mesh. The sample size required to detect a 18% difference in the success rates with a power of 80% and alpha of 0.05 (2-sided test) was 47 patients per group. To compensate for a 5% dropout rate, the initial sample size needed was 50 patients per group, or a total of 100 subjects.

2.7. Statistical Analyses

Statistical analyses were carried out using SPSS software (www.ibm.com/analytics/academic-statistics-software). A value of $P < 0.05$ was considered statistically significant. Continuous data was analyzed using T-test or Wilcoxon test as appropriate. Categorical data were analyzed with the chi-square test or Fisher's exact test as appropriate. 18 patients who were randomized, but withdrew from the study before surgery were not included in the analysis. Therefore this was a so-called "modified intention to treat analysis" (mITT) [17]. One patient who was converted to a vaginal procedure from the LSC group was included in the LSC group for the purposes of outcomes analysis.
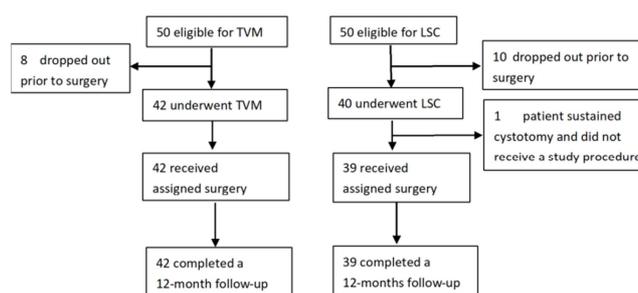
3. Results

Figure 1. *Flow of women through study.*

Between January 2013 and June 2014, 100 patients were enrolled, with 50 allocated to receive LSC and 50 allocated to receive TVM. The flow of women through study was shown in Figure 1. Eighteen women dropped out after recruitment but before their surgical procedure. No attempt to ascertain the reason for drop-out was made. Forty-two patients received TVM surgery, and 40 patients underwent LSC surgery. 1 patient sustained a cystotomy and did not undergo either study procedure. She was analyzed according to mITT protocol as a

member of her assigned group (LSC) and analyzed as an   anatomic failure.

Table 1. *Baseline demographics and POP-Q assessments of the two groups.*

Demographic variables	LSC, N=40	TVM, N=42	*P* value
Age[a] (y), mean±SD	60.6±3.9	62.1±4.0	0.08
Body mass index[a]	24.2±3.1	25.1±2.7	0.17
Menopausal years[b]	10 (6)	13 (10)	0.27
Parity[b]	2 (1)	2 (2)	0.28
Sexually active	18 (45%)	9 (21.4%)	0.02
Comorbidities			
Diabetes	1 (2.5%)	6 (14.3%)	0.11
Hypertension	16 (40.0%)	13 (31.0%)	0.39
Pulmonary disease	2 (5.0%)	0 (0%)	0.23
Heart disease	2 (5.0%)	3 (7.1%)	1.0
Surgical History			
Previous hysterectomy	5 (12.5%)	5 (11.9%)	1.0
Previous POP procedure	5 (12.5%)	3 ((7.1%)	0.47
Pre-operative examinations			
Residual urine[b] (mL)	0 (0,9)	0 (35)	0.12
Average flow rate[b] (mL)	12 (8)	11 (0)	0.99
Bladder capacity[b] (mL)	380 (75)	383 (146)	0.99
Stress urinary incontinence	5 (12.5%)	9 (21.4%)	0.38
Occult stress urinary incontinence	5 (12.5%)	5 (11.9%)	1.0
Urgency incontinence	3 (7.5%)	6 (14.3%)	0.48
POP-Q stage apical			0.26
0	2 (5.0%)	1 (2.4%)	
1	1 (2.5%)	1 (2.4%)	
2	3 (7.5%)	7 (16.7%)	
3	29 (72.5%)	31 (73.8%)	
4	5 (12.5%)	2 (4.8%)	
POP-Q stage anterior			0.27
0	0	0	
1	2 (5.0%)	0	
2	5 (12.5%)	1 (2.4%)	
3	29 (72.5%)	39 (92.9%)	
4	4 (10.0%)	2 (4.8%)	
POP-Q stage posterior			0.66
0	0	0	
1	12 (30.0%)	7 (16.7%)	
2	16 (40.0%)	24 (57.1%)	
3	10 (25.0%)	11 (26.2%)	
4	2 (5.0%)	0	

[a]The data are presented as the means (standard deviations), and the *P* value was calculated with an independent samples t test.
[b]The data are presented as the medians (IQR), and the *P* value was calculated with the Wilcoxon rank sum test.
[c]The data are presented as n (%), and the *P* value was calculated with the chi-square test or Fisher's exact test as appropriate. LSC=Laparoscopic Sacrocolpopexy, TVM=Total Vaginal Mesh.

Table 2. *Table of concomitant surgeries and perioperative variables.*

	LSC, N=40	TVM, N=42	*P* value
Concomitant surgery[d]			
Anti-incontinence surgery	5 (12.5%)	10 (23.8%)	0.19
Hysterectomy±BSO	35 (87.5%)	37 (88.1%)	0.93
Operative time (min)	125 (69)	90 (38)	P<0.001
Blood loss (mL)	100 (50)	50 (50)	0.11
Postoperative hospital stay (days)	5 (1)	7 (3)	0.20
Return to spontaneous micturition (days)[a]	2 (1)	3 (2)	0.003
Pain score on postoperative Day 1	3 (4)	4 (2)	0.21
Cost (RMB; yuan)[b]	19319 (7392)	20899 (18097)	0.68
Febrile morbidity[c,d]	2 (5.0%)	2 (4.8%)	0.64

[a] Return to micturition was defined as voiding within 6 hours of catheter removal and having a measured PVR <100mL. [b] "Cost" was defined as the out-of-pocket cost to the patient for the entire inpatient stay. [c] Postoperative febrile morbidity was defined as a temperature ≥38°C recorded on two occasions at least 4 hours apart after the 24 hours following the procedure. [d]The data are presented as n (%), and the *P* value was calculated with the chi-square test or Fisher's exact test as appropriate. Other data are presented as the medians (IQR), and the *P* value was calculated with the Wilcoxon rank sum test.
LSC=Laparoscopic Sacrocolpopexy, TVM=Total Vaginal Mesh.

Table 3. *Comparison of preoperative and 1-year post-operative POP-Q measurements.*

	LSC，N=40		TVM，N=42		Mean difference of differences (TVM-LSC)[a]	Between group P-value
	Pre	Post	Pre	Post		
Aa	1.23±1.64	-2.46±0.76	2.05±0.96	-2.36±0.88	-0.76	0.48
Ba	3.15±2.06	-2.41±0.75	3.60±1.27	-2.33±0.87	-0.42	0.63
C	2.93±2.68	-7.31±1.36	2.79±2.08	-6.12±1.67	1.30	< 0.001
Gh	4.55±1.15	3.87±0.70	5.14±0.81	4.00±0.54	-0.45	0.30
Pb	2.73±0.68	3.05±0.72	2.64±0.96	3.33±0.82	0.33	0.06
TVL	7.75±1.03	7.79±1.06	7.79±1.00	7.62±0.66	-0.19	0.27
Ap	-1.03±1.86	-2.77±0.43	-0.90±1.32	-2.50±0.74	0.15	0.10
Bp	0.13±2.50	-2.74±0.44	-0.05±1.78	-2.48±0.74	0.47	0.11

[a]Difference of differences analysis.
LSC=Laparoscopic Sacrocolpopexy, TVM=Total Vaginal Mesh.

Table 4. *The quality of life outcomes preoperatively and 1-year postoperatively and between the 2 groups.*

	LSC, N=40			TVM, N=42			*P* value[a] Difference in Differences, LSC and TVM groups
	Pre	Post	Decrease from pre to post[b]	Pre	Post	Decrease from pre to post[c]	
PFDI-20	68	14	54.5±46.9	95	35	60.3±53.0	0.70
POPDI-6	33	2.2	30.8±17.1	41	9.9	30.6±21.0	0.75
CRADI-8	8.8	3.0	6.1±13.0	10	6.6	3.8±15.2	0.07
UDI-6	26	7.5	18.0±26.0	34	15	19.5±23.4	0.81
PFIQ-7	90	15	75.0±58.5	105	27	78.1±62.7	0.85
UIQ	30	6.3	23.9±32.1	35	6.9	27.9±32.1	0.69
CARIQ	8.4	2.7	5.9±17.9	10	5.5	4.8±20.7	0.47
POPIQ	49	2.8	46.4±27.6	50	8.9	41.2±30.2	0.45
PISQ-12	30	34	-5.5±8.4	30	30	1.5±5.2	0.08

[a]Wilcoxon rank sum test.
[b]P-value <.01 for all changes in questionnaire scores for LSC patients.
[c]P-value <.01 for all changes in questionnaire scores for TVM patients except: PISQ-12 P=0.5, CARIQ P=0.16 and CRADI-8 P=0.14.
LSC=Laparoscopic Sacrocolpopexy, TVM=Total Vaginal Mesh.

Table 5. *Surgical complications and persistent adverse outcomes.*

Complication	LSC, N=40	TVM, N=42
Cystotomy	1 (2.5%)	0
Hematoma formation	1 (2.5%)	3 (7.1%)
Delayed free voiding	0	2 (4.8%)
De novo stress incontinence	2 (5.0%)	4 (9.5%)
De novo urge incontinence	1 (2.5%)	1 (2.4%)
De novo constipation	2 (5.0%)	1 (2.4%)
Mesh exposure	1 (2.5%)	1 (2.4%)
De novo dyspareunia	2 (5.0%)	1 (2.4%)

LSC=Laparoscopic Sacrocolpopexy, TVM=Total Vaginal Mesh.

No statistically or clinically significant differences between the two groups were found with respect to their demographics or other preoperative variables except for sexual activity (Table 1).

At the 1-year follow-up examination, the anatomic success rate was 37 of 40 (92.5%) in the LSC arm, compared with 35 of 42 (83.3%) in the TVM group. This difference did not reach statistical significance (P=0.35).

Table 2 contains the perioperative outcomes. The LSC surgery took longer to perform (125 vs. 90 minutes, p<0.0001) and was associated with a faster return to spontaneous micturition (2 vs. 3 days, p=0.0031). The estimated blood loss, postoperative hospital stay, pain score on postoperative Day 1, febrile morbidity and cost were comparable between the two groups. The percentages of patients undergoing various concomitant surgeries were also comparable between the groups.

At 1 year follow-up the LSC arm had more improvement in apical support (Difference in Point C: 1.30 cm; 95% CI: 0.14~2.46, P<0.001), while the anterior and posterior support was comparable (Table 3). There were no significant differences in total vaginal length between the two arms (Difference in TVL -0.19cm; 95% CI: -0.57~ 0.19, P=0.27). There was a significant improvement in quality of life scores in both groups but no significant difference in the improvement of quality of life between the two groups (Table 4). The PGI-I was not significantly different between groups, with 95.0% of the subjects in the LSC group being very much/much better at the 1-year follow-up, compared with 95.2% in the TVM group (P=0.64).

Perioperative complications in the LSC group included 1 cystotomy, and one woman in the LSC group and 3 women in the TVM group who had pelvic hematoma without an obvious infection, that resolved spontaneously (Table 5). Two women in the TVM group had delayed voiding, with a maximum length of 15 days. Subsequent surgical treatment (mid-urethral sling procedure TVT-O; Ethicon) for de novo SUI within 12 months was carried out in only 1 woman, while the other 5 patients with de novo SUI considered their symptoms tolerable and chose to continue the expectant management. One woman (2.5%) in the LSC group had a mesh exposure that qualified as 2AaT3S1 according to the IUGA classification system and 1 (2.4%) in the TVM group had 2AaT3S2vaginal mesh exposure. They were both managed

conservatively in the office using mesh trimming and/or vaginal estrogen. In the LSC group, 18 women (45%) were sexually active at the time of enrollment, and 19 (47.5%) were sexually active at their 1-year visit. In the TVM group, 9 women (21.4%) were sexually active before the operation all 9 resumed sexual activity at their 1-year visit. The rates of de novo dyspareunia were not statistically different between the LSC and TVM groups (5.0% vs. 2.4%). The PISQ-12 scores improved in LSC group after procedure (decrease from pre to post:-5.5±8.4, P=0.02), but not changed in TVM group (decrease from pre to post: 1.5±5.2, P=0.51).

4. Discussion

4.1. Main Findings

In our study there was a 9.2% difference between LSC and TVM, which did not represent a statistically significant difference between the two groups in the anatomic success rate after 1 year of follow-up. Subjective outcomes questionnaires showed improvements in both cohorts with no significant differences between the cohorts with the exception of the PISQ-12 which improved in the LSC cohort but not in the TVM cohort. Perioperative outcomes were similar in the two groups and serious complications were uncommon with no difference between the groups. Mesh exposure rates were not different.

The results of this study were similar to those of previously published RCTs comparing LSC to TVM. In accordance with previous studies, LSC was associated with a larger improvement in point C than TVM [18, 19]. Both procedures are associated with high satisfaction rates. We identified 2 recent RCT's that compared outcomes and complications of laparoscopic sacrocolpopexy and transvaginal mesh for advanced apical prolapse by Bateller and Lucot [20, 21]. In both of these studies, the anatomic outcomes were similar for LSC and TVM cohorts and complication rates were higher for the TVM cohort.

In a recent paper by Vani Dandolu, during a minimum 2-year follow-up in a large cohort of individuals who had undergone apical prolapse surgeries, mesh removal/revision was higher in the TVM group (5.1%), than the LSC group (1.7%) [22]. Complications in our study were relatively rare and were not significantly different between the two groups, which may be due to the short follow-up time.

4.2. Strengths and Limitations

A major strength of this study is its randomized and multicenter design. Another strength is the use of standardized and validated measurement instruments. Additionally, physicians blinded to the group allocation of subjects documented the post-operative POP-Q exams, nurses and research assistants not involved in the surgery and unaware of group assignment administered the preoperative and postoperative questionnaires. All patients who underwent surgery on protocol did return for follow-up at one year.

The limitations of our study were the relatively short follow-up period of 12 months and the limited sample size,

which did not reach our own enrollment targets and was smaller than in the other RCTs. Many readers would consider the 9.2% difference in anatomic failure to be clinically significant. It was possible that the difference seen in primary outcome might have reached statistical significance with larger sample or longer time. We experienced a 20% drop out after randomization and before surgical procedure. This raised outcomes that some defect in the consent process may have introduced bias that affected the study.

5. Conclusion

In conclusion, at one year post-operatively, in a multi-center, randomized trial of TVM and LSC, both appear to be effective in the treatment of uterovaginal prolapse with low complication rates. A Anatomic success rate of TVM was 9.2% lower than LSC although this difference did not reach statistical significance. In These results support the view that LSC is the "gold standard" procedure for advanced apical prolapse, but also support the idea that there remains a place for TVM when the procedure is used in properly selected patients by appropriate surgeons.

Acknowledgements

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