

Trans-vaginal mesh repair improves bladder compliance in pelvic organ prolapse patients with voiding dysfunctions: A retrospective cohort study

Tzer-Bin Lin¹, HUI-HSUAN LAU², Cheng-Yuan Lai³, Ming-Chun Hsieh⁴, Hsien-Yu Peng⁴, Dylan Chou⁴, Tsung-Hsien Su², and Jie-Jen Lee⁴

¹North China University of Science and Technology College of Medicine

²Duke University Department of Obstetrics and Gynecology

³China Medical University Graduate Institute of Biomedical Sciences

⁴Christian Medical College Department of Medicine

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Abstract

Objective The objective benefit of trans-vaginal mesh (TVM) on the storage function of the bladder in pelvic organ prolapse (POP) patients waits to be established. This study investigated if TVM improves the bladder storage by specifically focusing on its effects on the compliance. **Design** A retrospective cohort study **Setting** A medical center **Population** Female patients with voiding dysfunction who underwent TVM for prolapse stage [?] II (POP Quantification system) and received urodynamic investigations before and after the operation. **Methods:** Data of pressure-flow cystometry and the derived pressure-volume analysis (PVA) were analyzed. **Main outcome measures** Bladder compliance, infused volume, and threshold pressure. **Results** Compared with the pre-operative control, TVM consistently and significantly increased the mean compliance of the filling stage (Cm; $p < 0.05$, $N=22$); and further analyses demonstrated TVM increased the compliance of the late half (C2/2; $p < 0.01$, $N=22$), while it exhibited insignificant effects on that of the early half (C1/2; $p > 0.05$, $N=22$) of the filling stage. Moreover, without affecting the infused volume (Vinf; $p > 0.05$, $N=22$), TVM decreased the threshold pressure (Pthd; $p < 0.01$, $N=22$) and post-voided residual volume (Vres; $p < 0.05$, $N=13$). **Conclusions** TVM improve storage function of POP patients via increasing bladder compliance, particularly at the late filling stage for it restored anatomical location and geometric conformation for bladder expansion. In addition, TVM also ameliorated voiding dysfunctions as it reduced urine retention, a symptom could lead to upper urinary tract damage and/or urinary incontinence.

Introduction

The urinary bladder collects and stores urine before its disposal. As a hollow organ of high compliance, the pressure of the bladder is elevated slightly in response to a considerable filling volume during the storage¹. Impaired bladder compliance is deleterious because aberrantly elevated intra-vesical pressure could lead to upper urinary tract damage² and/or urinary incontinence³.

The prevalence of pelvic organ prolapse (POP), i.e., pelvic organ(s) protrudes beyond its anatomical confines, is increasing owing to the continuously advancing age, as it affects most commonly women elder than 70 years old^{4,5}. Notably, a retrospective videourodynamic analysis demonstrates decreased bladder compliance is positively correlated with the incidence of POP⁶. Moreover, when compared with healthy volunteers, patients with stage III-IV POP displays a lower bladder compliance at urgency⁷, indicating POP patients is associated with a diminished bladder compliance.

Trans-vaginal mesh (TVM), which aims to correct anatomical abnormalities and thereby restore pelvic floor

function⁸, is a minimally invasive therapy for POP⁹. Though, in 2016, USA Food and Drug Administration issued a notification concerning the long-term safety of the TVM repair¹⁰, some TVM kits^{11,12,13} are so far viable options for treating POP because they offer a successful anatomical reconstruction and satisfied objective outcomes¹⁴. Nevertheless, the objective outcome of TVM on the storage function of the bladder, particularly the compliance, has been scarcely investigated.

In the current study, the potential benefit of TVM on bladder storage of POP patients was investigated. For this purpose, history of POP patients with voiding difficulties were reviewed; and their data of urodynamic investigations measured before and after the procedure were analyzed by focusing on changes in bladder compliance and associated parameters. Moreover, as a preclinical study has demonstrated pressure-volume analysis (PVA) as a tool that graphically and conceptually assesses the bladder compliance¹⁵; and a retrograde cohort analysis has very recently established PVA in stress urinary incontinence patients¹⁶, we established PVA of POP patients and assayed the bladder compliance as the slope of the regression line of the trajectory during the filling stage.

Methods

2.1. Study Design

This study was reviewed and approved by the ethics committee of Mackay Memorial Hospital, Taipei, Taiwan (22MMHIS361e; 2022/12/08) and was registered in ClinicalTrials.gov (NCT05682989). Informed consent was obtained from all the patients involved. History of POP patients who had voiding difficulties and underwent primary TVM surgery for symptomatic POP [?] stage II (POP-Q system) from January 2007 to December 2022 in Mackay Memorial Hospital were reviewed. Patients with a history of vesico-/recto-/urethra-vaginal fistula or pelvic radiation, and those who did not complete pre- and post-operative followed-ups were excluded from the analysis. The primary outcome assayed in this study was the bladder compliance; and the secondary outcomes were the compliance-associated parameters including infused volume, voiding threshold, and post-voided residual volume.

2.2. Cystometry investigation

All the protocol of cystometry complied with the guidelines of the International Continence Society (ICS)¹⁷. Briefly, a multi-channel urodynamic study, in which warm saline (37 °C) was continuously infused (80 ml/min) into the bladder of patients, was recorded (MMS UD-200, Medical Measurement System, Enschede, Netherlands) and analyzed (Biopac MP36, Biopac Systems, Santa Barbara, US) using data-acquisition systems. The detrusor pressure (Pdet), abdominal pressure (Pabd), vesical pressure (Pves), urethral flow (Flow), infused volume (Vinf), voided volume (Vvod), and intra-vesical volume (Vive) were online recorded.

2.3. Pressure-volume analysis

Derived from the cystometry, the pressure-volume analysis (PVA) of voiding cycles was established by plotting Vive against Pdet (Figure 1A and B)^{15,16,18}. The mean compliance (Cm) during the filling stage was calculated by dividing the infused volume by the threshold pressure (i.e., change in Vive/change in Pdet; $\Delta\text{Vive}/\Delta\text{Pdet}$). The compliance of the early and the late halves of the filling stage (C1/2 and C2/2, respectively) were respectively done by dividing the change in Vive by the corresponding change in Pdet between the starting and the half as well the half and the end of the filling stage. Post-voided residual volume of a voiding was calculated by the volume difference between the infused volume and voided volume (Figure 1B).

2.4. Statistical analysis

The characteristics of patients were summarized using descriptive statistics. Data were expressed as mean \pm SEM. Difference in values between groups was assessed using paired student's t-tests. A significance in difference was set at $p < 0.05$.

Results

Database of patients

History of 22 POP patients (mean age=67.22±1.23 years old) who had voiding difficulties were reviewed and analyzed. All of these patients displayed at least stage II prolapse in all the three compartments. Urodynamic evaluations were respectively carried out at a mean of 39.72±9.24 days before and 112.27±5.38 days after the TVM.

3.2 TVM increases bladder compliance

Derived from time-domain cystometry performed pre- and post-operatively (Figure 2A PRE and 2B POST, respectively), pressure-volume analyses (PVAs) of voiding were established by plotting intra-vesical volume (Vive) against detrusor pressure (Pdet) (Figure 2C and 2D. Peng et al., 2020;2021; Lau et al., 2022); and the trajectory of each PVA shaped a loop demonstrating a voiding cycle. The left border of the loops which displayed progressively increased Vive with slightly elevated Pdet, represented the filling stage; and the slope of the regression line of the left border (red) was measured as the mean compliance (Cm) of the filling phase($Cm=\Delta Vive/\Delta Pdet$).

Illustrative PVAs showed, when compared with the pre-operative control (Figure 2C PRE), TVM markedly increased the mean compliance of the filling stage as it tilted the regression line counterclockwise and thereby increased the slope of the line (Figure 2D POST). The increased Cm was confirmed by summarized data demonstrating TVM consistently increased Cm in most patients (Figure 3A; 17 out of 22, 77%) and significantly increased the mean value of Cm of the patient (Figure 3B. $p<0.05$, $N=22$).

3.3 TVM increases compliance of late filling

Notably, in pre-operative PVA, the trajectory markedly deviated to the right and downwards at the late half compared to the early half of the filling stage (Figure 3C PRE), indicating the pre-operative compliance was decreased at late filling stage. The heterogeneity of compliance before TVM was confirmed by that the regression line of the late half of the filling stage (blue C2/2) tilted clockwise compared to that of the early half (green C1/2; Figure 2C PRE). Quite differently, post-operative PVA displayed a relatively stable trajectory without marked deviation that resulted in a fairly constant slope through the entire filling stage (Figure 2D POST). The homogeneity of compliance in the post-operative PVA was confirmed by that the regression lines of the early and late halves of the filling stage (green C1/2 and blue C2/2, respectively) displayed resemble slopes (Figure 2D POST). Summarize data measured pre-operatively showed when compared to the mean compliance of the early half of the filling stage (Figure 3C PRE C1/2) that of the late half (C2/2) was significantly decreased before operation ($p<0.01$, $N=22$). In contrast, after TVM, no statistical difference was evidenced between the mean compliance of the early and late filling (Figure 3E POST C1/2 and C2/2, respectively; $p>0.05$, $N=22$). Moreover, while it failed to statistically affect C1/2 ($p>0.05$, $N=22$), TVM post-operatively increased C2/2 when compared with the pre-operative control ($p<0.01$, $N=22$), indicating the increased C2/2 contributed essentially to the TVM-enhanced bladder compliance.

3.4 TVM reduced the threshold pressure

Next, we assayed the impact of TVM on the compliance-associated parameters, namely the infused volume (Vinf) and the threshold pressure (Pthd; the maximal detrusor pressure at the end of the filling stage) because Cm is defined as $Vinf/Pthd$. When compared with the pre-operative control, TVM did not result in a consistent trend of increase/decrease in the infused volume (Figure 4A Vinf, 8/14 out of 22 patients; 36/64%, respectively). Moreover, no statistical difference was evidenced between the mean value of Vinf measured pre- and post-operatively (Figure 4B $p>0.05$, $N=22$).

On the other hand, TVM consistently decreased Pthd in most patients (Figure 4C; 18 out of 22, 82%) and significantly decreased the mean value of Pthd of the patient when compared with the pre-operative control (Figure 4D $p<0.01$, $N=22$). Collectively, these findings reveal TVM-decreased compliance was resulted from reduced pressure with minimal affected infused volume during bladder filling.

3.5 TVM decreases residual volume

Finally, we investigated if TVM-increased bladder compliance is associated with impaired voiding efficacy in

POP patients by analyzing the residual volume in response to TVM. In 13 out of the 22 POP patients, their pre-operative PVA displayed more infused volume than voided volume, indicating an amount of post-voided residual volume (Vres) in the bladder (Figure 2C PRE). Without markedly affecting the volume difference between the top and the bottom borders, TVM shifted the loop downward, indicating the Vres was decreased post-operatively (Figure 2D POST). The TVM-decreased Vres was confirmed by statistical analyses showing that when compared to the pre-operative control, TVM consistently decreased Vres in most patients (Figure 4E; 11 out of 13, 85%) and significantly decreased the mean value of Vres of the patient (Figure 4F $p < 0.05$ $N=13$), implying rather than impaired voiding efficacy, TVM brought about improved bladder emptying signifying improved voiding efficacy.

4. DISCUSSION

Main findings

Though, USA Food and Drug Administration had a press announcement concerning the long-term safety¹⁰, TVM is still an option for POP reconstruction because it offers satisfied anatomical and objective outcomes¹². In contrast to studies consistently demonstrating advantages of TVM on the voiding^{19,20}, the current study explored the potential benefit of TVM to the storage function by specifically focusing on the bladder compliance.

Our results reveal TVM post-operatively increased bladder compliance of POP patients, namely the bladder displayed a reduced pressure in response to the storage volume during the filling stage. The TVM-increased compliance could benefit POP patients, because aberrantly elevated intra-vesical pressure during storage is deleterious as it would cause vesico-ureteral reflux², over-activate the micturition reflex²¹, and result in stress urinary incontinence²².

Notably, in contrast to urodynamic studies analyzing the bladder compliance by dividing the change in volume by that in pressure ($C = \Delta V / \Delta P$); and thereby offer a mean value of compliance over the entire filling stage²³, a recent study exploring compliance dynamics has demonstrated PVA not only graphically and conceptually assesses the bladder compliance but also provides a protocol that is able to specifically analyze compliance of targeted periods during bladder filling¹⁸.

PVAs in this study demonstrates while the post-operative trajectory displayed a relatively constant slope during entire filling, the pre-operative trajectory markedly deviated to the right and downwards at the late filling stage, indicating the compliance was decreased specifically at this stage. The decreased compliance in the late filling of pre-operative patients was confirmed as the patient statistically displayed a lower C2/2 compared to C1/2. Even though a clear-cut value defining a low bladder compliance waits to be established, studies have reported a level of low compliance in human from 12.5 to 40 ml/cmH₂O^{3,24,25}. Considering our mean C1/2 before TVM were 105.82 ± 16.41 ml/cmH₂O, a value far higher than these levels, we suggest the impaired compliance in POP patients is possibly attributed to the compliance decrement at the late filling.

On the other hand, while the TVM-increased Cm was associated with post-operatively enhanced C2/2, the C1/2 remained relatively unaffected after the procedure. Together with that the post-operative Cm (103.01 ± 13.44 ml/cmH₂O), C1/2 (116.13 ± 12.92 ml/cmH₂O), and C2/2 (112.84 ± 21.57 ml/cmH₂O) in this study were all higher than the reported level of low compliance, these findings collectively reveal TVM benefits to the storage function of POP patients by specifically ameliorating the impaired compliance during the late filling.

Possible mechanism involved

Though the pathophysiology why compliance decrement occurs specifically at the late filling and the rationale how TVM ameliorates the impaired compliance are unclear, it worth notice that instead of a homogenous decrement in the entire filling stage, POP patients displayed decreased compliance at the late filling compared with the early stage, implying the compliance impairment is not resulted from a modified viscoelastic property of the bladder itself.

Moreover, considering pre- and post-operative C1/2 was statistically indistinctive; and both of them were above the level recognized as low bladder compliance, these results reveal the bladder of POP patients exhibits a relatively unaffected viscoelasticity property during the early filling stage before the surgical intervention. We thereby suggest, in POP patients, the compliance at low filling volume remains relatively unaffected because the bladder distension is not limited by the prolapsed organ at the initial stage. Nevertheless, as the filling volume increased, prolapsed organ restricts the normal expansion of the bladder that makes the bladder distends to un-restrained space in a manner failed to comply with its geometric conformation and/or anatomical location. An abnormal overstretch of part of the detrusor shifts the length-tension curve to a higher tension in response to elongation thereby results in a higher pressure to the filling volume²⁶.

In the current study, patients received TVM to correct their anatomical abnormalities thereby relieved the restriction of bladder expansion caused by the prolapsed organ. As the restriction from the prolapse organ occurs mainly during the late filling, the benefit of TVM to the compliance is more significant in the late compared to the early filling. Though our proposal in part explains the involved pathophysiology of the heterogeneity of compliance in POP patients and the therapeutic rationale of TVM, a simultaneous compliance analysis in associated with real-time ultrasound images²⁷ is need to validate this proposal.

TVM ameliorates voiding dysfunctions

In addition to bowel and/or sexual disorders, POP patients also suffer from voiding dysfunctions²⁸ that results in urine retention as a sequelae of inadequate bladder emptying^{29,30}. Lasting urine retention is detrimental as it could result in frequency/recurrent urinary tract infections²⁹ or damage to the upper urinary tract².

Notably, urine retention in associated with a decreased compliance, deficits observed in pre-operative patients of this study, could be one of the causes underlying the urine incontinence as the accumulated volume could result in an abnormal pressure elevation that impels urine to be forced out. Particularly, as POP affects most commonly women elder than 70 years old^{4,5} and our previous publication has demonstrated the maximal urethral closure pressure deteriorates with age growth³¹; we thereby suggest a diminished bladder compliance in accompanied with urine retention in aged patients collectively prompts the pathological progression of urine incontinence in POP patients.

Remarkably, data in this study demonstrated that in patients displaying urine retention before operation, TVM effectively reduced the residual volume. Because the kinking- and/or compression-enhanced outlet resistance is recognized to underlie the development of voiding difficulties in POP patients^{32,33}, this result suggests TVM ameliorates the voiding dysfunction possibly via reliving the kinking and/or compression of the urethra. Together with above findings, these results reveal TVM benefits to POP patients not only for it improves storage function but also for it mends voiding deficits by ameliorating urine retention that avoid the development of urine incontinence.

Strengths and limitations

By aiming to elucidate the impact of TVM specifically on bladder compliance, only the trajectory of the filling stage was analyzed in this study. Nevertheless, plotting a complete loop of the voiding cycle would provide more information other than the compliance. For example, compared with the pre-operative PVA, the right border of the loop was marked shifted to the left after TVM, indicated a post-operatively depressed voiding pressure; moreover, the distance between the top and bottom borders remained relatively constant after the procedure, revealing TVM barely affected the voided volume. In addition, recent animal^{15,18} and clinical¹⁶ studies have demonstrated the loop enclosed area in the PAV represents the thermodynamic workload of each voiding cycle. Hence, more studies analyzing entire loop trajectory in PVA will clarify detailed impacts of TVM on both storage and voiding functions of POP patients; and thereby benefit to clinicians in making therapeutic decisions.

Though TVM offers a successful anatomical reconstruction¹⁴ and results in this study consistently support its therapeutic benefits, TVM possibly causes bladder damage, post-operative lower urinary tract symptoms, pelvic pain, dyspareunia, and mesh erosion^{34,35} as side effects. Particularly, because mesh erosion is a potenti-

al complication^{36,37}, the US Food and Drug Administration has issued a public health notification regarding the long-term safety and complications with the TVM¹⁰. Considering a long-term analysis has reported a 3.7% risks of erosions at 7 years after the TVM reconstruction³⁸, a longer follow-up is needed to approve the lasting effect of the benefits presented in this study because we have measured the outcome at a mean of 112.27 ± 5.38 days after the procedure in this study.

Conclusion

In conclusion, our results reveal TVM post-operatively increases the compliance of the bladder possibly attributed to the TVM-diminished bladder pressure in response to urine filling. In addition, TVM ameliorates urine retention that could avoid development of urine incontinence. Our findings would benefit to clinicians in make therapeutic decisions as well as providing objective data for pre-operative consultation.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available from the corresponding author, upon reasonable request.

ETHICS STATMENT

This study was reviewed and approved by the ethics committee of Mackay Memorial Hospital, Taipei, Taiwan (22MMHIS361e; 2022/12/08).

AUTHOR CONTRIBUTIONS

HH L and TB L: design study. HHL, TH Su, and JJ Lee: collect data. HH L and HY P: draft the manuscript. CY L, D C and MC H: analyze data, statistical analysis. TB L: finalize the manuscript.

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LEGENDS

FIGURE 1. Pressure-volume analyses and derived parameters.

(A) and (B) Pressure-volume analysis established by plotting the intra-vesical volume (Vive) against detrusor pressure (Pdet) of a voiding. The trajectory of pressure-volume data shapes a loop representing a voiding cycle; and the left boundary of the loop indicates the filling stage. **(A)** The mean compliance (Cm; red) during the filling stage was calculated by dividing the change in Vive by that in the Pdet ($C_m = \Delta V_{ive} / \Delta P_{det}$). The compliance of the early half (C1/2, green) and late half (C2/2, blue) of the filling stage were respectively calculated by dividing the half of ΔV_{ive} by the corresponding ΔP_{det} as well as dividing the ΔV_{ive} between the end and the half of the filling stage by the corresponding ΔP_{det} . **(B)** Post-voided residual volume of a voiding cycle is calculated by the volume difference between the infused and voided volume.

FIGURE 2. Pressure-flow studies and pressure-volume analyses.

(A) and (B) Representative cystometry measured pre- and post-operatively, respectively (PRE and POST). These cystometry show tracings of the detrusor pressure (Pdet), vesical pressure (Pves), abdominal pressure

(Pabd), urethral flow (Flow), infused volume (Vinf), voided volume (Vvod), and intra-vesical volume (Vive). **(C) and (D)** Pressure-volume analyses established by plotting the Vive against Pdet. The regression line of the filling stage (red dashed line) is marked tilted counterclockwise after TVM that indicates an increased mean compliance (Cm). Moreover, before TVM, the trajectory displays a more infused than voided volume, indicating an amount of post-voided residual volume accumulated in the bladder.

FIGURE 3. Effects of TVM on the compliance.

(A) Individual and **(B)** summarized data of the mean compliance (Cm) of the filling stage measured pre- and post-operatively (PRE and POST, respectively; * $p < 0.05$, vs. PRE; $N=22$). **(C) and (D)** Pre- and post-operatively measured pressure-volume loops, respectively. Pdet, detrusor pressure; Vive, intra-vesical volume. Before TVM, the regression line of the late half of the filling stage (blue dashed line) tilted clockwise compared to that of the early half (green dashed line). In contrast, after TVM, the regression lines of the early and late halves of the filling stage displayed resemble slopes (green and blue dashed lines, respectively). **(E)** Before TVM, the mean compliance of the late half of the filling stage (C2/2) is significantly decreased compared with that of the early half (C1/2), while after TVM, no statistical difference is evidenced between mean compliance of the early and late halves of filling stage (C1/2 and C2/2, respectively). When compared to the pre-operative control, TVM displays insignificant effect on the C1/2 but post-operatively increases the C2/2 (** $p < 0.01$, vs. PRE; ## $p < 0.01$, vs. C1/2; NS, $p > 0.05$ vs PRE or C1/2; all $N=22$).

FIGURE 4. Effects of TVM on the compliance-associated parameters.

(A)-(F) Individual (upper) and summarized (lower) data of the **(A) and (B)** infused volume (Vinf), **(C) and (D)** threshold pressure (Pthd), as well as **(E) and (F)** post-voided residual volume (Vres) measured pre- and post-operatively (PRE and POST, respectively). (NS $p > 0.05$, $N=22$; ** $p < 0.01$, $N=22$; * $p < 0.05$, $N=13$, all vs. PRE).





