Original Article

Function, quality-of-life and complications after sacrospinous ligament fixation using an antegrade reusable suturing device (ARSD-Ney) at 6 and 12 months: a retrospective cohort study

Ping Wang[#], Mingyue Li[#], Huating Sun, Liping Ni, Honghong Cai, Wen Fan, Jinhua Zhou, Juan Wang, Hongmei Ding, Youguo Chen, Fangrong Shen^

Department of Obstetrics and Gynecology, The First Affiliated Hospital of Soochow University, Suzhou, China

Contributions: (I) Conception and design: Yi Li, G Li, Yuchuan Li; (II) Administrative support: None; (III) Provision of study materials or patients: Yi Li, Z Zhao; (IV) Collection and assembly of data: Yi Li, Z Zhao; (V) Data analysis and interpretation: Yi Li, L Zhang, Z Zhao; (VI) Manuscript writing: All authors; (VII) Final approval of manuscript: All authors.

[#]These authors contributed equally to this work.

Correspondence to: Youguo Chen; Fangrong Shen. Department of Obstetrics and Gynecology, The First Affiliated Hospital of Soochow University, 899 Pinghai Road, Suzhou 215006, China. Email: chenyouguo@suda.edu.cn; shenfr@suda.edu.cn.

Background: Pelvic organ prolapse (POP) is a common pathology in the female population. Sacrospinous ligament fixation (SSLF) is one of the traditional transvaginal procedures for POP and high sacrospinous ligament fixation (h-SSLF) optimizes it using an antegrade reusable suturing device (ARSD-Ney). Previous studies on h-SSLF have focused on the correction of anatomical positions, with less assessment of patients' function, quality of life and complications. In this study, we evaluated post-operative complications, function, and quality-of-life after h-SSLF to confirm the safety and effectiveness of it.

Methods: This was a retrospective cohort study that included 71 patients between 2018 and 2021: 50 patients for h-SSLF and 21 patients for laparoscopic sacrocolpopexy (LSC) according to patient age and background, POP-Q stage, patient preference, and so on. A clinical evaluation took place before surgery and was repeated at 6 and 12 months postoperatively. Intra- and post-operative complications and anatomical results were recorded. Patients completed self-administered questionnaires for functional pelvic problems [Pelvic Floor Disability Index-20 (PFDI-20)], quality of life [Pelvic Floor Impact Questionnaire-7 (PFIQ-7)], and sexual function [Pelvic Organ Prolapse/Urinary Incontinence Sexual Questionnaire-12 (PISQ-12)] at each medical visit.

Results: Patients in both h-SSLF and LSC groups were similar in terms of demographic characteristics except for surgery time (86.04±28.70 *vs.* 153.19±54.88, P<0.05), postoperative indwelling catheter time (3.88±1.65 *vs.* 4.90±1.84, P<0.05), and hospital stay (8.94±2.38 *vs.* 10.57±2.06, P<0.05). There were no statistically significant differences between the 2 groups in scores of PFDI-20, PFIQ-7, and PISQ-12 at pre- and post-operative 6 and 12 months (P>0.05). Functional pelvic problems (PFDI-20 scores) and their impact on patients' quality of life (PFIQ-7 scores) significantly improved at 6 and 12 months postoperatively (P<0.05). Improvements in sexual activity were noted at 6 and 12 months postoperatively (P<0.05).

Conclusions: This retrospective cohort study confirmed the positive results of h-SSLF in terms of improvement in function and quality of life following treatment for pelvic organ prolapse.

Keywords: Pelvic organ prolapse (POP); sacrospinous ligament fixation (SSLF); quality of life; bowel function; sexuality

^ ORCID: 0000-0002-6156-2141.

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Introduction

As an increase in the elderly population is expected over the coming years, pelvic organ prolapse will also become more prevalent. When conservative treatment fails, surgical treatment is a feasible option. Sacrocolpopexy is currently considered the gold standard for treatment of advanced apical prolapse; and while it offers a durable repair of the vaginal apex, it carries the increased risk of mesh complications compared with native tissue repairs (1). Sacrospinous ligament fixation (SSLF) has also gained clinical importance as a traditional transvaginal procedure. Sederl *et al.* (2) first utilized the sacrospinous ligament as a secure point of attachment for patients with vaginal vault and uterine prolapse as early as 1958, and SSLF was originally described by Richter (3). Despite its benefits, traditional SSLF also creates several problems, including inconvenience and high surgical risk.

In 2010, to simplify the procedure, Neymeyer carried out a high vaginal sacrospinous ligament fixation (h-SSLF) using an antegrade reusable suturing device, the SERAPRO® ARSD-Ney (SERAG WIESSNER, Naila, Germany) (*Figure 1*), developed at the Charité University, Berlin, which can operate blindly with guidance of the fingers and enables an elevation above the distantia sacropubica of around 16–25 mm with an elevation angle of the vagina (EAV) of β=33±3° (4,5). Dr. Fangrong Shen popularized the technology in China in 2018, which led to this study. This device enables the surgeon to perform surgery for pelvic organ prolapse (POP) with no mesh implants.

Pelvic health should be defined both as no prolapse and proper function, including urine and stool continence and sexual function (6). Previous studies on h-SSLF have focused primarily on the correction of anatomical positions. Indeed, patients with great anatomic outcomes can remain dissatisfied with the surgical cure. It is important to measure quality of life in women with POP when evaluating the efficacy of the surgical procedure. Considering that few studies have reported on the quality of life and sexuality after h-SSLF, we aimed to evaluate functional changes in these factors in Chinese women who underwent h-SSLF. We present the following article in accordance with the STROBE reporting checklist (available at https://atm.amegroups.com/article/view/10.21037/atm-22-2150/rc).

Methods

Subjects

This was a retrospective cohort study. A total of 71 patients with POP requiring surgery who were admitted and treated in The First Affiliated Hospital of Soochow University from January 2018 to January 2021 were included in this study. Women who presented with gynecological malignancy or serious medical and surgical diseases were excluded. We did not exclude women undergoing a concurrent procedure, including hysterectomy or anti-incontinence sling. Pre- and post-operative physical examinations were performed in the supine position with the Valsalva maneuver test. Genital prolapse was evaluated according to the Pelvic Organ Prolapse Quantification (POP-Q) landmarks system (7). Recurrence was considered when assessment exceeded stage 1 at any point of measure at 6 or 12 months after surgery. All the surgeries were performed by one experienced gynecologist (F Shen) in our department.

The outstanding functional and anatomical results of laparoscopic sacrocolpopexy (LSC) were confirmed by Wagner *et al.* in a long-term follow-up prospective study (8); for this reason, LSC was selected as the control operation. Surgery was determined according to patient age and background, POP-Q stage, patient preference, and so on. As a result, 50 patients underwent h-SSLF and 21 patients underwent LSC. The study was conducted in accordance with the Declaration of Helsinki (as revised in 2013). The study was approved by the Institutional Ethics Review Board of the Soochow University School of Medicine (No. 2020-276). As it was a retrospective study and patients' names were not divulged, informed consent was waived.

Patients' assessment

Patient characteristics and pre- and post-operative data including age, parity, body mass index (BMI), menopausal status, and surgical details such as operative time, blood loss, postoperative indwelling catheter time, hospital stays,

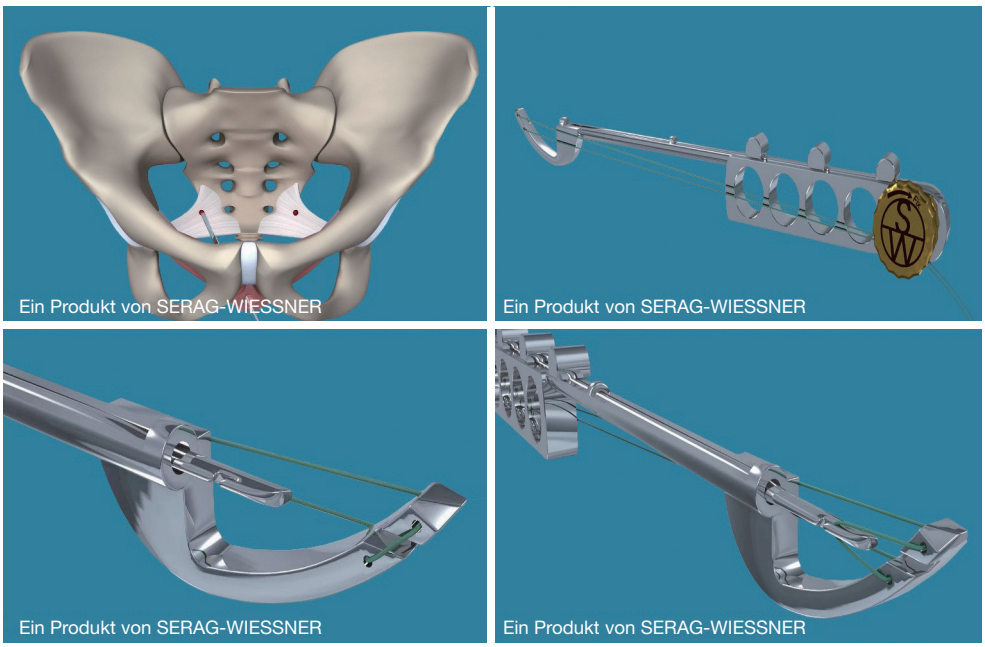

Figure 1 The antegrade reusable suturing device SERAPRO® ARSD (Source: Ein Produkt von SERAG-WIESSNER).

and complications are shown in *Table 1*.

A standard clinical evaluation by the operating surgeon was conducted before surgery and repeated at 6 and 12 months postoperatively, during each medical follow-up visit. The Short Form Pelvic Floor Distress Inventory-20 (PFDI-20) was administered preoperatively to assess the distress of the symptoms of PFD; it consisted of 3 subscales: Pelvic Organ Prolapse Distress Inventory (POPDI), Colorectal-Anal Distress Inventory (CRADI), and Urinary Distress Inventory (UDI) which assessed POP, anorectal, and urinary symptoms, respectively (9). The Pelvic Floor Impact Questionnaire-7 (PFIQ-7) was designed to assess life impact in women with pelvic floor disorders and, similar to the PFDI-20, contains all of the items included in the original Incontinence Impact Questionnaire (IIQ) as well as items related to other pelvic floor disorders. It has been confirmed that PFIQ-7 and PFDI-20 are complementary questionnaires (10) that have been shown to be psychometrically valid and reliable (9). Clinicians and researchers usually use them together, so PFIQ-7 was also used preoperatively, and at 6 and 12 months after surgery. The higher the obtained scores, the greater the impact on patients' quality of life. The Pelvic Organ Prolapse/Urinary Incontinence Sexual Questionnaire-12 (PISQ-12) was used to estimate sexual function; higher scores indicated better function.

Surgical technique

The cases receiving LSC underwent surgery in the lithotomy position under general anesthesia. The vaginal bladder space and the vaginal rectal space were separated, the appropriate size of the anterior and posterior lobe mesh was cut; the anterior lobe mesh was placed in the vaginal bladder space and the posterior lobe mesh in the vaginal rectal space. The anterior lobe mesh was fixed to the anterior vaginal wall with sutures at the level of the bladder. The posterior lobe mesh was sutured to the posterior vaginal wall and then the vaginal incision was closed. As the sacral promontory was exposed laparoscopically, the upper end of the posterior lobe mesh was sutured with a 0/2 non-absorbable suture and fixed to the anterior sacral ligament, at which point the mesh was tension-free.

The cases receiving h-SSLF also underwent surgery in the lithotomy position under general anesthesia. Firstly, the reusable suturing device (ARSD-Ney) was mounted on the right index finger and introduced into the vaginal cavity. Subsequently, the right ischial spine and the sacrospinous ligament (SSL) were palpated through the vaginal wall. Then the index finger was stabilized intimately to the upper SSL as close as possible to the sacrum, which is approximately at the S3 level. The anchor was deployed, and adequate pull-out force was tested. A 1 cm longitudinal

Table 1 Patient characteristics and pre- and post-operative data between the 2 groups

Variables	h-SSLF (n=50)	LSC (n=21)	P value
Baseline variables			
Age (y)	62.64±9.63	59.00±11.07	0.220
Parity	1.78±0.89	1.43±0.68	0.109
BMI (kg/m^2)	23.78±2.57	23.33±1.98	0.476
Menopausal age (y)	51.21±2.65	50.86±3.21	0.689
POP-Q stage (%)			
II	14 (28%)	6 (28.57%)	0.961
III	30 (60%)	10 (47.62%)	0.337
IV	6 (12%)	5 (23.81%)	0.370
Surgical details			
Surgery time (min)	86.04±28.70	153.19±54.88	0.000*
Blood loss (mL)	86.80±91.44	93.33±88.68	0.782
Postoperative indwelling catheter time (d)	3.88±1.65	4.90±1.84	0.024*
Hospital stay (d)	8.94±2.38	10.57±2.06	0.008*
Complications			
Buttock pain	5 (10%)	1 (4.76%)	0.797
Dyspareunia	2 (4%)	0	0.886
UI	6 (12%)	1 (4.76%)	0.619
Defecatory disturbance	1 (2%)	1 (4.76%)	1.000
Infections	0	0	
Recurrence (%)	6 (12%)	1 (4.76%)	0.619

*, statistically significant. The data were recorded as mean ± SD or percentages. h-SSLF, high sacrospinous ligament fixation; LSC, laparoscopic sacrocolpopexy. BMI, body mass index; UI, urinary incontinence; POP-Q, Pelvic Organ Prolapse Quantification.

shallow and high mucosal incision was made at the posterior vaginal wall. The anchor's suture was mounted on a virgin needle and inserted backwards through the vaginal wall at its point of entrance, passed under the vaginal wall, then through the cervical isthmus and out to the vaginal cavity again through the posterior colpotomy. Finally, the small posterior vaginal incision was closed.

Statistical analysis

The baseline characteristics, surgical details, complications, and recurrence of the patients were recorded as mean ± SD or percentages. The between-group differences were compared by independent-samples *t*-test. Repeated measures analysis of variance (ANOVA) was used to test for within-group differences. The chi-squared test was used to test for between-group differences in preoperative and postoperative outcomes. A P value <0.05 was considered statistically significant. All data were analyzed with SPSS 21.0 software (SPSS, Inc., Armonk, NY, USA).

Results

Demographic characteristics

The follow-up period was the 6 and 12 months after the procedure. The mean age in group h-SSLF and group LSC was 62.64±9.63 and 59.00±11.07 years, respectively. No statistically significant differences were found between the 2 groups with respect to age, parity, BMI, menopausal age,

Table 2 Comparison of PFIQ-7 questionnaire results between the 2 groups

Variables	N	Preoperative	Postoperative (6-month)	Postoperative (12-month)	P value		
					P1	P2	P3
h-SSLF	50	19.70±6.91	2.32±2.92	1.72±2.40	0.000	0.000	0.204
LSC	21	19.71±8.11	1.19±2.11	2.38±3.79	0.000	0.000	0.065
P value		0.994	0.114	0.379			

The data were recorded as mean ± SD. P1 indicates the P value between preoperative and postoperative (6-month); P2 indicates the P value between preoperative and postoperative (12-month); P3 indicates the P value between postoperative (6-mouth) and postoperative (12-month). PFIQ-7, Pelvic Floor Impact Questionnaire-7; h-SSLF, high sacrospinous ligament fixation; LSC, laparoscopic sacrocolpopexy.

POP-Q stage, blood loss, and complications. The 2 groups were similar in terms of their demographic characteristics (*Table 1*). However, there were significant differences when comparing group h-SSLF with group LSC in surgery time (86.04±28.70 *vs.* 153.19±54.88, P<0.05), postoperative indwelling catheter time (3.88±1.65 *vs.* 4.90±1.84, P<0.05), and hospital stay (8.94±2.38 *vs.* 10.57±2.06, P<0.05). Meanwhile, buttock pain (10%) and urinary incontinence (UI; 12%) were prominent complications in the h-SSLF group.

Quality of life scores

Table 2 shows the changes of the PFIQ-7 scores preoperatively and at postoperative 6 and 12 months between the 2 groups. In group h-SSLF (n=50), the mean pre- and post-operative 6 and 12 months scores were 19.70±6.91, 2.32±2.92, and 1.72±2.40, respectively. In group LSC (n=21), the means of the 3 scores were 19.71±8.11, 1.19±2.11, and 2.38±3.79, respectively. There were no statistically significant differences in both groups between 6- and 12 months after surgery. There were also no statistically significant differences between the 2 groups as to scores at preoperative measurement and postoperative 6 and 12 months. Meanwhile, scores for both group h-SSLF and LSC decreased significantly at 6 and 12 months postoperatively compared to preoperative: P1 and P2<0.05 in both groups. The P1 indicates the P value between preoperative and postoperative (6-month) while P2 indicates the P value between preoperative and postoperative (12-month).

According to the PFDI-20 questionnaire in *Table 3*, we recorded scores of POPDI-6, CRADI-8, UDI-6, and total score, respectively. The preoperative and postoperative scores of PFDI-20 in both groups showed statistical significance (P<0.05) except for those of CRADI-8. The differences between the 2 groups were not statistically significant when comparing the preoperative, and 6- and 12-month postoperative categorical items.

The mean preoperative and postoperative 6 and 12 months scores on the PISQ-12 questionnaire (*Table 4*), evaluating the impact of POP on sexual life, were 29.74±8.56, 35.37±7.43, and 39.21±5.35 in group h-SSLF (n=19), respectively, and 26.93±7.01, 36.36±4.34 and 38.29±5.55 in group LSC (n=14). As to the handling of missing data, we didn't count them in our study. In group h-SSLF, there was no significant difference between pre- and postoperative 6 months, while there was a greater difference between pre- and postoperative 12 months, and postoperative 6 and 12 months. Unlike group h-SSLF, group LSC showed significant differences between pre- and postoperative 6 months, pre- and postoperative 12 months, but not for postoperative 6 and 12 months. Significant improvements were seen among the 33 sexually active women. Absence of sexual activity was owing to partner absence or partner-related pathology.

Discussion

In the present study, group h-SSLF shared similar recurrence rate and scores of PFDI-20, PFIQ-7, and PISQ-12 to those of group LSC. Functional pelvic problems (PFDI-20 scores) and their impact on patients' quality of life (PFIQ-7 scores) significantly improved at 6 and 12 months postoperatively. Improvement regarding sexual activity was significant at 6 and 12 months postoperatively. As the excellent functional results and quality-of-life of LSC for POP have been reported widely (8,11,12), and there were no significant differences between the 2 groups in these areas in our study, the improvement in functional results and quality of life at 12 months were effectively supported. Okcu *et al.* (13) identified no significant difference among

Table 3 Comparison of PFDI-20 questionnaire results between the 2 groups

Variables	h-SSLF	LSC	P value
POPDI-6			
Preoperative	8.64±3.29	7.62±3.09	0.229
Postoperative (6-month)	0.80±1.39	0.19±0.60	0.057
Postoperative (12-month)	0.82±1.51	0.71±1.45	0.786
P value (P4)	0.000	0.000	
CRADI-8			
Preoperative	0.38±1.23	0.33±0.86	0.875
Postoperative (6-month)	0.18±0.90	0.24±0.63	0.788
Postoperative (12-month)	0.22±0.93	0.24±0.63	0.935
P value (P4)	0.750	0.980	
UDI-6			
Preoperative	9.02±5.24	6.71±4.58	0.084
Postoperative (6-month)	2.44±2.23	2.33±2.06	0.852
Postoperative (12-month)	2.56±2.41	2.33±2.08	0.708
P value (P4)	0.000	0.000	
Total score			
Preoperative	18.04±8.09	15.05±8.22	0.161
Postoperative (6-month)	3.58±2.89	2.76±2.47	0.261
Postoperative (12-month)	3.46±3.36	3.24±3.33	0.800
P value (P4)	0.000	0.000	

The data were recorded as mean ± SD. P4 indicates the P value between preoperative and postoperative (12-month). h-SSLF, high sacrospinous ligament fixation; LSC, laparoscopic sacrocolpopexy; POPDI-6, Pelvic Organ Prolapse Distress Inventory-6; UDI-6, Urinary Distress Inventory-6; CRADI-8, Colorectal-Anal Distress Inventory-8.

Table 4 Comparison of PISQ-12 questionnaire results between the 2 groups

Variables	N	Preoperative	Postoperative (6-month)	Postoperative (12-month)	P value		
					P1*	P2*	P3*
h-SSLF	19	29.74±8.56	35.37±7.43	39.21±5.35	0.064	0.001	0.003
LSC	14	26.93±7.01	36.36±4.34	38.29±5.55	0.005	0.000	0.328
P value		0.323	0.660	0.632			

The data were recorded as mean ± SD. P1* indicates the P value between preoperative and postoperative (6-month); P2* indicates the P value between preoperative and postoperative (12-month); P3* indicates the P value between postoperative (6-month) and postoperative (12-month). h-SSLF, high sacrospinous ligament fixation; LSC, laparoscopic sacrocolpopexy.

their 2 groups in terms of POPDI-6, UDI-6, CRADI-8, and PISQ-12 scores, which are in line with our study results.

The comparison of results between the patients who underwent h-SSLF and LSC, in addition to surgery time, postoperative indwelling catheter time, and hospital stay, did not reflect significant differences in terms of baseline variables or surgical details. The data in *Table 1* clearly show

that group h-SSLF had shorter surgery time, postoperative indwelling catheter time, and hospital stay than group LSC, which led to less risk of infection and lower medical costs. Ohno *et al.* (14) considered SSLF as a cost-effective surgery in their study.

Complications such as buttock pain, dyspareunia, de novo UI, and de novo defecatory disturbances rates were also comparable between the 2 procedural groups. Although suture placement is not recommended in the medial third of the sacrospinous ligament, as the S4 root is most commonly present there (15,16), this may easily result in nerve damage in the form of buttock pain. While *Table 1* shows no significant difference in buttock pain between group h-SSLF and LSC (10% *vs.* 4.76%, P>0.05), there was a significant improvement in buttock pain, which was at 10% a few days after surgery, and dropped to 0 at 6 months and 12 months postoperatively. Feiner *et al.* (17) reported 1 case of persisting thigh pain, which gradually settled by 12 months. The studies mentioned above had results similar to ours. Buttock pain can be explained by injury to nerves surrounding the sacral plexus and branches of the pudendal nerve.

Urinary symptoms were improved for all the h-SSLF group cases according to the UDI-6, and *Table 1* shows less postoperative indwelling catheter time than group LSC. These 6 patients with de novo UI represented 12% of the population in group h-SSLF, and UI was one of the leading long-term complications of sacrospinous ligament fixation in this study. The risk of postoperative UI after surgery for pelvic floor prolapse has been mentioned previously. Perez *et al.* (11) reported 6.3% of de novo SUI after LSC at 12 months, while in the study of Claerhout *et al.* (18), the rate of de novo UI was 7.3%. These surgeries could have involved concomitant anti-incontinence slings. In such cases, patients should be made aware of the risk and benefits of this surgery. Indeed, patients should be informed about the potential risk of postoperative UI in advance when no concomitant incontinence procedure is performed.

The study of Salman *et al.* (19) reported that no rectal injury occurred intraoperatively, which is consistent with our results. The data regarding functional outcome for the bowel (CRADI-8 scores) after h-SSLF and LSC showed hardly any improvement for most patients. However, on the one hand, there were only a few patients with mild rectal problems before surgery; and on the other hand, there were no new rectal problems postoperatively.

Despite the relatively small number of sexually active women, sexuality improved in most of our patients who completed the PISQ-12 questionnaire, whether in group h-SSLF or group LSC. It has previously been concluded in many studies that sexual function is significantly improved after prolapse surgery (20,21). Nevertheless, 2 sexually active women reported a negative change in the quality of their sex life after h-SSLF, which was probably owing to surgical wounds or psychological factors.

To our knowledge, there was few previously documented studies evaluating the functional results and quality-of-life after h-SSLF and comparing the 2 surgical methods. Consequently, these evaluations can be regarded as strengths of the current study. However, the fact that this study was not a randomized controlled trial, existence of systematic bias and contained a limited number of cases can be considered as study limitations. In the next study we will include more patients as time goes on to refine our research. Based on traditional SSLF, h-SSLF simplifies surgical procedures and provides a shorter learning cycle for gynecologists, as well as similar surgical outcomes and quality of life in follow-up to LSC.

Conclusions

This retrospective cohort study confirmed the excellent results of h-SSLF using ARSD-Ney in terms of improvement in function and quality of life following treatment for POP. The early onset improvement remained stable during the first postoperative year, and further research is required to investigate its long-term efficacy. The above data further support h-SSLF as an effective surgical technique for POP.

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Footnote

Reporting Checklist: The authors have completed the STROBE reporting checklist. Available at https://atm.amegroups.com/article/view/10.21037/atm-22-2150/rc

Data Sharing Statement: Available at https://atm.amegroups.

com/article/view/10.21037/atm-22-2150/dss

Conflicts of Interest: All authors have completed the ICMJE uniform disclosure form (available at https://atm.amegroups.com/article/view/10.21037/atm-22-2150/coif). The authors have no conflicts of interest to declare.

Ethical Statement: The authors are accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. The study was conducted in accordance with the Declaration of Helsinki (as revised in 2013). The study was approved by the Institutional Ethics Review Board of the Soochow University School of Medicine (No. 2020-276). As it was a retrospective study and patients' names were not divulged, informed consent was waived.

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