A 14-year multi-institutional collaborative study of Chinese pelvic floor surgical procedures related to pelvic organ prolapse

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Abstract

Background: It has been a global trend that increasing complications related to pelvic floor surgeries have been reported over time. The current study aimed to outline the development of Chinese pelvic floor surgeries related to pelvic organ prolapse (POP) over the past 14 years and investigate the potential influence of enhanced monitoring conducted by the Chinese Association of Urogynecology since 2011.

Methods: A total of 44,594 women with POP who underwent pelvic floor surgeries between October 1, 2004 and September 30, 2018 were included from 22 tertiary academic medical centers. The data were reported voluntarily and obtained from a database. We compared the proportion of each procedure in the 7 years before and 7 years after September 30, 2011. The data were analyzed by performing Z test (one-sided).

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Results: The number of different procedures during October 1, 2011–September 30, 2018 was more than twice that during October 1, 2004–September 30, 2011. Regarding pelvic floor surgeries related to POP, the rate of synthetic mesh procedures increased from 38.1% (5298/13,906) during October 1, 2004–September 30, 2011 to 46.0% (14,107/30,688) during October 1, 2011–September 30, 2018, whereas the rate of non-mesh procedures decreased from 61.9% (8608/13,906) to 54.0% (16,581/30,688) ($Z = 15.53$, $P < 0.001$). Regarding synthetic mesh surgeries related to POP, the rates of transvaginal placement of surgical mesh (TVM) procedures decreased from 94.1% (4983/5298) to 82.2% (11,603/14,107) ($Z = 20.79$, $P < 0.001$), but the rate of laparoscopic sacrocolpopexy (LSC) procedures increased from 5.9% (315/5298) to 17.8% (2504/14,107).

Conclusions: The rate of synthetic mesh procedures increased while that of non-mesh procedures decreased significantly. The rate of TVM procedures decreased while the rate of LSC procedures increased significantly.

Trial registration number: NCT03620565, https://register.clinicaltrials.gov.

Keywords: Laparoscopic sacrocolpopexy; Pelvic organ prolapse; Synthetic mesh; Transvaginal placement of surgical mesh

Introduction

Women have a lifetime risk of 11% to 19% for undergoing pelvic organ prolapse (POP) surgery.[1] However, women who underwent the transvaginal placement of surgical mesh (TVM) for POP have been reported to have increasing complications over time. A survey conducted in America showed that patterns and rates of prolapse repairs remained relatively unchanged from 1999 to 2009, with an exception of a rapid rise in mesh use.[2] A study of 10,657 procedures demonstrated that mesh repair was more likely to be associated with at least one complication than native tissue repair.[3] Complications related to synthetic mesh surgeries have attracted more attention than before in China, America and other countries, such as Australia and New Zealand.

In America, the United States Food and Drug Administration (FDA) issued an initial public health notification (PHN) in 2008 due to the significant increase in the number of reported complications related to TVM. A study to assess the effect of the 2008 PHN on mesh surgeries in the United States showed that between the last three-quarters of 2008 and the first three-quarters of 2009, there were 104,185 POP procedures, of which 27,839 (26.7%) included mesh repair, and the rate of mesh procedures increased, while the rate of non-mesh procedures decreased.[4] An updated PHN that warned of the high risk of complications related to TVM for POP specifically was released in 2011.[5] After the 2011 FDA communication regarding transvaginal mesh, there was a significant decrease in the utilization of procedures with mesh in America.[6-8] An electronic survey of American Urogynecology Society (AUGS) members conducted between December 2011 and January 2012 reported that synthetic mesh use in transvaginal POP surgery decreased after the 2011 FDA safety update, but synthetic mesh use for transabdominal POP repair and sling procedures and overall biologic graft use in POP surgery did not decrease.[9]

In England, following FDA warnings, a positive trend for meshes has only been seen in uterine-sparing surgery. Native tissue repairs constitute the vast majority of POP operations.[10] Australia and New Zealand have already revoked the approval of the use of vaginal mesh.[11] In some other countries, the process of suspending TVM has been initiated. For instance, Ireland has considered suspending TVM. Moreover, the UK National Institute for Health and Care Excellence (NICE) recommended that mesh surgery no longer be used for the treatment of POP in 2017.[12] On April 16, 2019, the FDA ruled that two companies must stop selling and distributing all remaining surgical mesh products for POP repair because they could not assure reasonable safety and the effectiveness of these devices.[11]

However, the debate is still ongoing.[13] Some studies have attempted to show that surgical mesh for transvaginal repair is more effective than native tissue repair, with comparable safety outcomes.[14] One study showed that the objective cure rate was 39.8% in the anterior colporrhaphy group and 88.1% in the mesh group, demonstrating a significantly improved objective cure rate with mesh surgery over conventional surgery.[15]

In China, it has been 14 years since the 1st National Conference on Female Pelvic Disorders was held by the Chinese Association of Urogynecology in Fuzhou in 2004. With a large database, we conduct this study to outline the development of Chinese pelvic floor surgeries related to POP over the past 14 years in the member medical centers and investigate the potential influence of the enhanced monitoring by the Chinese Association of Urogynecology since 2011.

Methods

Ethical approval

This multi-institutional collaborative study was approved by the institutional ethics committee of our hospital (S-096) and registered on the public domain (https://register.clinicaltrials.gov; registration number: NCT03620565). Only case volume information was exchanged between the participating centers, and all patient information was de-identified.

Study design and participants

Before our study was carried out, we had to choose a representative cut-off time point to determine how the pelvic floor procedures developed over 14 years and whether enhanced monitoring had any effect on their development retrospectively. Among the pelvic floor surgeries related to POP, synthetic mesh surgeries such as TVM and laparoscopic sacrocolpopexy (LSC) have become increasingly acceptable; however, there is increas-

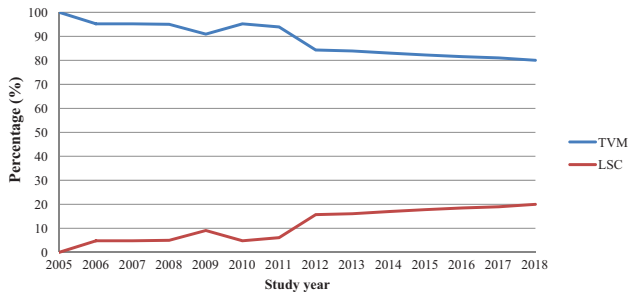

Figure 1: Proportions of TVM and LSC among synthetic mesh surgeries related to POP each year. LSC: Laparoscopic sacrocolpopexy; POP: Pelvic organ prolapse; TVM: Transvaginal placement of surgical mesh.

ing concern related to postoperative complications. In 2011, the FDA in America released warnings related to postoperative complications following synthetic mesh surgeries, and the Chinese Association of Urogynecology enhanced the monitoring of the use of synthetic mesh surgeries with respect to POP in the same year. We calculated the proportion of TVM and LSC synthetic mesh surgeries performed each year [Figure 1]. According to the line chart, we could see a clear decline in the proportion of TVM procedures; however, the proportion of LSC procedures was the opposite. In addition, 2011 was the beginning of enhanced monitoring. For these reasons, we attempted to compare the situation in the 7 years before September 30, 2011 (October 1, 2004–September 30, 2011) with that in the 7 years after October 1, 2011 (October 1, 2011–September 30, 2018) to investigate the potential influence of the enhanced monitoring conducted by the Chinese Association of Urogynecology.

After the cut-off time point was decided, we chose how many member hospitals were capable of participating in our study. Pelvic floor reconstructive surgeries were performed between October 1, 2004 and September 30, 2018 by professional female pelvic medicine and reconstructive surgery (FPMRS) surgeons at 22 academic medical centers that are members of the Chinese Association of Urogynecology and represent a broad geographic range across China. The Chinese Urogynecology Association is composed of 27 academic medical institutions and represents the level of the most senior surgeons who are specialized and certified in FPMRS in China. Five hospitals were not able to participate in this study because of problems with data collection: two hospitals were excluded because they lacked data from 2011, while the other three hospitals were excluded because of inadequate data. A total of 44,594 pelvic floor reconstructive procedures related to POP performed in the 22 tertiary academic institutions were enrolled in the final analysis.

Data collection

After the cut-off time point and participating hospitals were chosen, we needed to determine the kind of information we wanted to examine and how it was reported. Pelvic floor surgeries related to POP in our study included synthetic mesh and native tissue procedures. Synthetic mesh procedures included TVM and LSC procedures. The participating hospitals were asked to report the number of pelvic surgeries related to POP performed each year from October 1, 2004 to September 30, 2018 and the number of each specific procedure performed without revealing any patient information. The data we requested were stored in a database at each hospital beginning from October 1, 2004. The data were reported retrospectively and voluntarily by the tertiary academic institutions and obtained from the database for analysis by the chief resident of the department of gynecology of each hospital. After all the data were reported, we assessed and confirmed all the information with the primary hospital to avoid statistical mistakes.

Statistical analysis

Categorical variables were presented as numbers and percentages. Z test (one-sided) was used to test the difference in the means of the mesh group and non-mesh group, TVM group and LSC group during the 7 years before September 30, 2011 and the 7 years after October 1, 2011, respectively. Significance of the trend was defined by a P value <0.05. The data were analyzed with SPSS Statistics version 23.0 (IBM Corporation, Chicago, IL, USA).

Results

Among all hospitals that provided data, there were 22 hospitals with complete information. Figure 1 shows the proportions of TVM and LSC among synthetic mesh surgeries related to POP that were performed each year. The numbers and proportions of different types of pelvic floor reconstructive surgeries related to POP from October 1, 2004 to September 30, 2011 and October 1, 2011 to September 30, 2018 are shown in Table 1.

Among the 44,594 pelvic floor reconstructive procedures, 19,405 (54.1%) procedures involved synthetic mesh and 25,189 (45.9%) procedures did not. The number of pelvic floor reconstructive procedures related to POP from October 1, 2011 to September 30, 2018 was about twice that of procedures from October 1, 2004 to September 30, 2011 (30,688 *vs.* 13,906) for both synthetic mesh and native tissue repairs (14,107 *vs.* 5298 and 16,581 *vs.* 8608, respectively). The number of both TVM and LSC procedures from October 1, 2011 to September 30, 2018 had a significant rise compared with that from October 1, 2004 to September 30, 2011 (11,603 *vs.* 4983 and 2504 *vs.* 315, respectively).

Regarding pelvic floor surgeries related to POP, the rate of synthetic mesh procedures increased significantly from 38.1% (5298/13,906) during October 1, 2004–September 30, 2011 to 46.0% (14,107/30,688) during October 1, 2011–September 30, 2018, while the rate of non-mesh procedures decreased from 61.9% (8608/13,906) to 54.0% (16,581/30,688) ($Z = 15.53$, $P < 0.001$).

However, regarding synthetic mesh surgeries, the rate of TVM procedures decreased from 94.1% (4983/5298) during October 1, 2004–September 30, 2011 to 82.2% (11,603/14,107) during October 1, 2011–September 30, 2018, with a significant difference ($Z = 20.79$, $P < 0.001$).

Table 1: The number and proportion of different types of pelvic floor reconstructive surgeries related to POP for the periods October 1, 2004 to September 30, 2011 and October 1, 2011 to September 30, 2018.

Groups	Procedures, *n/N* (%) (October 1, 2004–September 30, 2011)	Procedures, *n/N* (%) (October 1, 2011–September 30, 2018)	*Z*	*P* values
Pelvic floor surgeries related to POP			15.53	<0.001
Mesh	5298/13,906 (38.1)	14,107/30,688 (46.0)		
Non-mesh	8608/13,906 (61.9)	16,581/30,688 (54.0)		
Synthetic mesh procedure			20.79	<0.001
TVM	4983/5298 (94.1)	11,603/14,107 (82.2)		
LSC	315/5298 (5.9)	2504/14,107 (17.8)		

LSC: Laparoscopic sacrocolpopexy; POP: Pelvic organ prolapse; TVM: Transvaginal placement of surgical mesh.

In addition, there was a significant increase in the rate of LSC, from 5.9% (315/5298) during October 1, 2004–September 30, 2011 to 17.8% (2504/14,107) during October 1, 2011–September 30, 2018.

Discussion

According to the data which have been outlined, we could see that despite the FDA's PHN warning about the high risk of complications related to TVM for POP, the number of mesh surgeries still continued to rise. For procedures related to POP, the proportion of synthetic mesh procedures in the 7 years before 2011 increased from 38.1% to 46.0% in the 7 years after October 2011 while the rate of non-mesh procedures decreased from 61.9% to 54.0%. Regarding synthetic mesh surgeries, the rate of TVM procedures decreased from 94.1% to 82.2% while the rate of LSC increased from 5.9% to 17.8%.

The reasons for the increase in the rate of synthetic mesh procedures in China are probably as follows: (1) The enhanced recognition of diseases led to an increase in both the number of visits and the demand for surgery; (2) after the establishment of the Chinese Urogynecology Association in 2005, more hospitals began to recruit their own professional pelvic surgery doctors to promote and apply the pelvic floor surgical technique; (3) with international communications and cooperation strengthened, the opportunities to study abroad, participate in international conferences and introduce advanced synthetic mesh surgery from abroad are likely increased; (4) after professional training on mesh-related surgeries, the number of physicians who mastered synthetic mesh surgery, especially the LSC procedure increased; and (5) some studies supported that synthetic mesh procedures could achieve better outcomes than native tissue procedures. A study in 2011 demonstrated that the primary outcome was significantly better among patients in the synthetic mesh repair group than in the native tissue group (60.8% *vs.* 34.5%) 1 year after surgery.[16]

The 2011 PHN highlighted the increased reporting of complications associated with the use of surgical mesh in procedures specifically for POP. In American, thousands of lawsuits pertaining to the TVM procedure claimed that the lives of women had been devastated by complications related to the surgery, including bleeding, pelvic pain, dyspareunia, infection, urinary problems, organ perforation, nerve damage and mesh removal.[4] The Chinese Association of Urogynecology also began to realize the increasing complications reported after TVM procedures since 2011; the association did not forbid but enhanced the monitoring of appropriate patient selection, adequate assessments, structured surgeon training and good surgical techniques to minimize the risk of postoperative complications.

The reason for the increasing rate of LSC procedures is partly because the number of physicians who mastered synthetic mesh surgery, especially LSC surgery, increased after professional training on mesh-related surgeries was provided. Another reason is that laparoscopic placement seems to be more accepted than vaginal placement. The LSC procedure is favored mainly because it has a similar success rate, a lower rate of complications and a better capability in preserving sexual function than the TVM procedure. In addition, because of its minimal invasiveness, the laparoscopic approach can reduce the hospital stay and blood loss.

A study demonstrated that the rates of grade II complications and total reoperation were lower after LSC than after TVM (17.0% *vs.* 26.0%; 4.7% *vs.* 10.9%).[17] A large series study suggested that LSC might confer a low risk of mesh exposure because only 5 patients (0.7%) among 660 who underwent LSC between 2005 and 2017 developed complications related to mesh exposure. Two were successfully managed conservatively with topical estrogen. Three required surgical excision of the mesh.[18] Additionally, one of our member hospitals retrospectively analyzed 670 patients with POP who underwent LSC ($n = 350$) or TVM ($n = 320$) between January 2011 and December 2016. The study found that the complication rates of intraoperative bleeding, intraoperative bladder injury and postoperative perineal pain in the LSC group were lower than those in the TVM group ($P < 0.05$), and objective satisfaction was numerically higher in the LSC group than in the TVM group (94.9% *vs.* 91.9%).[19]

For some women, vaginal mesh surgery is the best option, but the risks of complications must be documented and communicated clearly. LSC shows no serious adverse events and leads to higher postoperative satisfaction than TVM according to many studies. Nevertheless, treatment should be selected in accordance with the willingness and

condition of each patient. As the FDA recommended, surgeons should obtain specialized training in techniques for mesh placement. It is due to the little attention paid to the influence of surgeon factors which partly decided the adverse outcomes after mesh surgeries related to POP. A study completed in 2017 which shows that the cumulative reoperation rates for low-, intermediate-, and high-volume providers. In this study, low-volume surgeons were defined as those performing 1 case annually, intermediate-volume surgeons performed two cases annually, and high-volume surgeons were defined as those performing three or more cases annually. The cumulative reoperation rates were 6%, 2%, and 3%, respectively among 1657 surgeries for POP performed with mesh. The differences in reoperation rates between low and intermediate and low- and high-volume surgeons were statistically significant ($P = 0.007$ and 0.003, respectively).[20] The Royal College of Obstetricians and Gynaecologists (RCOG) suggested that the patient be aware of and consent to the well-documented risks and that the medical system document robust governance measures for consent documentation, auditing and adverse event reporting.[21]

Limitations of this study included the following aspects: (1) It was difficult to provide an accurate conclusion because the information was obtained from 22 hospitals in China retrospectively; (2) the preferences of different surgeons determined by the variation in clinical practice and surgery skills may affect the type and number of operations performed; (3) analyses of certain information associated with the surgeries, such as previous treatments, surgery indications, patient preference, complications and long-term outcomes, were lacking, failing to provide a complete conclusion; and (4) analyses of conservative treatments, such as the use of a hysterophore and pelvic floor muscle training (PFMT) at outpatient clinics, were also lacking, failing to provide a complete overview of the current treatment of pelvic floor diseases.

The strengths of this study included the following: (1) Our study was a rare report to analyze the current status of pelvic floor surgeries and provide data for a long time period in China; (2) our study was a rare report to analyze the enhanced monitoring conducted by the Chinese Association of Urogynecology since 2011; (3) our study was also a rare report to provide data over fourteen years (from October 1, 2004–September 30, 2018); and (4) we analyzed and observed the data and trends by center to reduce the possibility that the general trends were affected by an individual center.

The number of different procedures in October 1, 2011–September 30, 2018 was twice that in October 1, 2004–September 30, 2011. Regarding pelvic floor surgeries related to POP, the rate of synthetic mesh procedures increased significantly, whereas that of non-mesh procedures decreased significantly. For synthetic mesh surgeries related to POP, we suspect that the rates of TVM procedures decreased owing to the awareness of the long-term postoperative complications and the recommendation of conservative treatment. In contrast, the rate of LSC procedures increased significantly because of a lower rate of complications and a better capability in preserving sexual function than TVM procedures and the increasing number of physicians who mastered the procedure.

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Conflicts of interests

None.

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