## Data Article

# Data on correction of pelvic organ prolapse by laparoscopic lateral suspension with mesh: A clinical series 

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#### Abstract

This DIB article provides additional data on laparoscopic lateral suspension with mesh for correcting pelvic organ prolapse. Data come from a multicentric sample of Italian women (https:// doi.org/10.1016/j.ejogrb.2019.07.025). Data are collected retrospectively. Descriptive and raw data on surgery and descriptive and raw data on symptoms of pelvic organ prolapse pre-surgery and post-surgery are provided. Kaplan-Meier curves and scores of 7-items King's Health Questionnaire for quality of life assessment are also reported.


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[^0]Specifications Table

| Subject | Medicine |
| :---: | :---: |
| Specific subject area | Urogynecology |
| Type of data | Tables |
|  | Charts |
|  | Graph |
| How data were acquired | Data were collected between May 2016 and April 2018 among patients suffering of pelvic organ prolapse and treated by laparoscopic lateral suspension with mesh. The surgical records, the recovery charts and the follow-ups records were reviewed. |
|  | To some patients, the King's Health Questionnaire for General Health Perception (simplified in 7items) has been administered pre surgically and at each follow-up. To view the King's |
|  | Questionnaire, refer to: http://citeseerx.ist.psu.edu/viewdoc/download?doi=10.1.1.1020. $44 \&$ rep $=$ rep $1 \&$ type $=$ pdf. |
| Data format | Raw |
|  | Analyzed |
| Experimental factors | Patients were surgically treated with prosthetic laparoscopic lateral suspension by using a V-mesh. |
| Experimental features | The aim of the study is to illustrate the outcomes of the laparoscopic lateral suspension with mesh technique in treating pelvic organ prolapse in a sample of Italian women by following patients after laparoscopic lateral suspension with mesh. |
| Parameters for data collection | PoP-Q stage, Baden and Walker Half-Way system, genital prolapse symptoms, some demographic characteristics, complications related to surgery, duration of surgery, any other concomitant surgery, King's General Health Perception Questionnaire scores (http://citeseerx.ist.psu.edu/ viewdoc/download?doi=10.1.1.1020.44\&rep=rep1\&type=pdf). |
| Description of data collection | Data were retrospectively collected by screening patients' charts and records of each follow-up. |
| Data source location | Azienda Ospedaliero-Universitaria S. Anna of Ferrara (Ferrara - Emilia Romagna - Italy) |
|  | Proctological Surgical Unit of the Policlinico of Abano Terme (Abano Terme - Veneto - Italy) |
| Data accessibility | With the article |
| Related research article | Martinello R et al. [1]. |
|  | Correction of pelvic organ prolapse by laparoscopic lateral suspension with mesh: a clinical series. European Journal of Obstetrics and Gynecology and Reproductive Biology https://doi.org/10.1016/j.ejogrb.2019.07.025 |

[^1]
## 1. Data

Forty-height patients were treated. Laparoscopic lateral suspension with mesh was performed alone in $65 \%$ ( 31 patients) of the cases, while $35 \%$ of women ( 17 cases) underwent a concurrent surgeries either gynecological (bilateral ovariosalpingectomy, salpingectomy) or urogynecologic (transobturator tape placement, Stapler trans-anal rectal resection, colpoperineoplasty, rectocele fascial repair) (Table 1). No severe intraoperative complications occurred. Early postoperative complications included 1 case of urinary tract infection, which was treated with intravenous antibiotics, and 1 case of bradycardia. Four cases of long-term complications were observed: 3 patients needed a mesh re-

Table 1
Descriptive statistics: data on surgery.

|  | All patients |
| :--- | :--- |
| Operative cohort $(\mathrm{n}=48)$ |  |
| Hysterectomy (prior hysterectomy), $\mathrm{n}(\%)$ | $7(14.5)$ |
| Type of mesh, $\mathrm{n}(\%)$ | $23(48)$ |
| Polypropylene | $25(52)$ |
| Titanium-coated polypropylene | $17(35.4)$ |
| Additional concomitant surgeries, $\mathrm{n}(\%)$ | $8(16.7)$ |
| Adnexectomy | $1(2.1)$ |
| Rectocele fascial repair | $4(8.3)$ |
| Adnexectomy and rectocele fascial repair | $1(2.1)$ |
| Salpingectomy | $1(2.1)$ |
| TOT | $2(4.2)$ |
| Stapler trans-anal rectal resection | $92.5(55-215)$ |
| Operating time (min), median (limits) | $3(2-7)$ |
| Days of hospital stay median (limits) | $6(12.5)$ |
| Postoperative complications (Clavien-Dindo grade), $\mathrm{n}(\%)$ | $42(87.5)$ |
| None | $1(2.1)$ |
| I | $1(2.1)$ |
| II | $4(8.3)$ |
| III | 0 |
| IV | 0 |
| V |  |
| Postoperative urinary tract complications, n (\%) | $47(97.9)$ |
| None | 0 |
| Retention | $1(2.1)$ |
| Cystitis | $3(6.3)$ |
| Reoperation for pelvic organ prolapse, n (\%) | $4(2-6)$ |

fixation to the vagina after 6 months, and 1 patient underwent a surgical removal of an abdominal wall stitch granuloma. According to Clavien-Dindo classification [2] of surgical complications, 1 2nd grade and 3 3rd grade complications were observed and treated (Table 1). No mesh exposures or extrusions were observed.

Table 2
Descriptive statistics: postoperative PoP-Q and symptoms.

|  | Postoperative cohort at 1month clinical follow-up $(\mathrm{n}=48)$ | Postoperative cohort at 12months clinical follow-up $(\mathrm{n}=24)$ | Postoperative cohort at 24months clinical follow-up $(\mathrm{n}=5)$ |
| :---: | :---: | :---: | :---: |
| Lower urinary tract symptoms and other symptoms, n (\%) |  |  |  |
|  |  |  |  |
| Prolapse ( $\mathrm{PoP-Q} \geq 1$ ) | 18 (37.5) | 17 (70.1) | 4 (80.0) |
| Urinary urgency | 4 (8.3) | 2 (8.3) | 1 (20.0) |
| Urinary frequency | 6 (12.5) | 1 (4.2) | 1 (20.0) |
| Stress urinary incontinence, persistent or de novo | 6 (12.5) | 4 (16.7) | 1 (20.0) |
| Urge incontinence | 3 (6.3) | 2 (8.3) | 1 (20.0) |
| Nocturia | 4 (8.3) | 4 (16.7) | 0 |
| Dysuria | 4 (8.3) | 2 (8.3) | 1 (20.0) |
| Incomplete voiding | 0 | 1 (41.7) | 0 |
| Bulging | 3 (6.3) | 3 (12.5) | 1 (20.0) |
| Constipation | 5 (10.4) | 4 (16.7) | 1 (20.0) |
| Sexual activity, n (\%) | 44 (91.7) | 20 (83.3) | 3 (60.0) |
| Dyspareunia, n (\% of sexually active) | 0 | 0 | 0 |
| Pelvic pain, n (\%) | 3 (6.3) | 2 (8.3) | 3 (60.0) |

One month after surgery, 18 women (18/48, 37.5\%) reported a PoP-Q equal to or greater than 1 . The same PoP-Q score was observed in 17 patients (17/24, 70.1\%) 12 months after surgery, and in 4 patients $(4 / 5,80 \%)$ after 24 months (per-protocol results) (Table 2 ). The per-protocol rates were calculated by excluding missing data, thereby providing an estimate of the anatomical outcome. Table 2 also provides raw data and descriptive statistics on symptoms associated to pelvic organ prolapse.


Fig. 1. Kaplan-Meier curves on urinary symptoms, anterior prolapse recurrence, posterior prolapse recurrence, bulging perception and constipation.

In the Kaplan-Meier curves (Fig. 1), anatomical repair of cystocele or rectocele along with improvement of some symptoms linked to the pelvic organ prolapse is reported. Kaplan-Meier curves provide probability of outcomes estimated in relationship with censored data. The urinary stress incontinence events were 6 at the 1 -month follow-up, 2 at the 3 -months follow-up, 2 at the 6 -months








Fig. 2. 7-items King's Health Questionnaire (http://citeseerx.ist.psu.edu/viewdoc/download?doi=10.1.1.1020.44\&rep= rep1\&type $=$ pdf) results. The score 0 and 1 mean that the symptoms have no or have a minimal impact of patient' quality of life. The score 2 and 3 mean that the symptoms affect moderately or severely the quality of life. Score $0-1,2$ and 3 are reported as rates in percentage scale. N.A.: not applicable (with regard to "personal relationship", because a proportion of patients was not sexually active).

Table 3
Crude numbers for King's Health Questionnaire scores.

|  | Pre-Surgery score (crude numbers) |  |  | 1-month score (crude numbers) |  |  | 12-months (crude numbers) |  |  | 24-months (crude numbers) |  |  |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
|  | 0-1 | 2 | 3 | 0-1 | 2 | 3 | 0-1 | 2 | 3 | 0-1 | 2 | 3 |
| General Health | 11 | 10 | 2 | 22 | 1 | 0 | 23 | 0 | 0 | 23 | 0 | 0 |
| Role Limitation | 14 | 7 | 2 | 22 | 1 | 0 | 21 | 0 | 2 | 18 | 0 | 5 |
| Physical Limitation | 13 | 8 | 2 | 22 | 1 | 0 | 21 | 0 | 2 | 18 | 0 | 5 |
| Personal Relationship | 7 | 6 | 2 | 20 | 0 | 0 | 21 | 0 | 0 | 23 | 0 | 0 |
| Emotion | 19 | 2 | 2 | 23 | 0 | 0 | 23 | 0 | 0 | 23 | 0 | 0 |
| Prolapse Impact | 12 | 7 | 4 | 23 | 0 | 0 | 21 | 2 | 0 | 18 | 0 | 5 |
| Sleep | 19 | 2 | 2 | 23 | 0 | 0 | 23 | 0 | 0 | 23 | 0 | 0 |

follow-up, 1 at the 12 -months follow-up. The urinary urge incontinence events were 4 at the 1 -month follow-up, 2 at the 3 -months follow-up, 5 at the 6 -months follow-up, 1 at the 12 -months follow-up. The cystocele recurrences were 2 at the 1 -month follow-up, 2 at the 3 -months follow-up, 1 at the 6months follow-up, 1 at the 12 -months follow-up. The rectocele recurrences were 1 at the 1 -month follow-up, 3 at the 3 -months follow-up, 3 at the 6 -months follow-up, 1 at the 12 -months follow-up. Constipation occurred in 5 cases at 1-month follow-up, in 3 cases at the 3 -months follow-up, in 1 case at the 6 -months follow-up, in 2 cases at the 12 months follow-up. Bulging symptom occurred in 3 cases at the 1 -month follow-up, in 6 cases at the 3 -months follow-up, 1 at the 6-months follow-up, 0 at the 12 -months follow-up. At the 24 -months follow-up, none of the above mentioned symptoms or prolapses recurrences were registered.

Fig. 2 illustrates the 7-items King's Health Questionnaire (http://citeseerx.ist.psu.edu/viewdoc/ download?doi=10.1.1.1020.44\&rep=rep1\&type=pdf) administered to 23 women before the surgical treatment and at each follow-up evaluation. Table 3 summarizes raw data illustrated in Fig. 2.

## 2. Experimental design, materials, and methods

Data were retrospectively collected between May 2016 and April 2018 at the Azienda OspedalieroUniversitaria S. Anna of Ferrara and at the Proctological Surgical Unit of the Policlinico of Abano Terme among patients suffering of pelvic organ prolapse and treated by laparoscopic lateral suspension with mesh. Medical charts and surgical records were screened and reviewed. The follow-ups check-ups were screened and reviewed as well. The anatomical degree of prolapse was assessed both with the PoPQ staging system and with the Baden and Walker Half-way system presurgically, along with symptoms of prolapse and, in 23 patients, even King's Health Questionnaire (simplified in 7-items) (http://citeseerx. ist.psu.edu/viewdoc/download?doi=10.1.1.1020.44\&rep=rep1\&type=pdf) was administered for assessing the general health perception. At each follow-up, patients were checked for any kind of symptoms and for the degree of prolapse. To the same 23 patients underwent to the King's Questionnaire presurgically, the 7-items King's Health Questionnaire was administered again at each follow-up (http:// citeseerx.ist.psu.edu/viewdoc/download?doi=10.1.1.1020.44\&rep=rep1\&type=pdf).

The data were collected aiming to have only a descriptive value, without planning a comparison with a control group.

Data were reported in a OpenOfficeOrg Calc 3.3 file. Data were processed by using both KyPlot 2.0 and OpenOffice tools.

## Conflict of interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

## References

[1] R. Martinello, G. Scutiero, A. Stuto, U. Indraccolo, F. Cracco, C. Borghi, F. Sorrentino, L. Nappi, P. Greco, Correction of pelvic organ prolapse by laparoscopic lateral suspension with mesh: a clinical series, Eur. J. Obstet. Gynecol. Reprod. Biol. 240 (2019) 351-356. https://doi.org/10.1016/j.ejogrb.2019.07.025.
[2] D. Dindo, N. Demartines, P.-A. Clavien, Classification of surgical complications: a new proposal with evaluation in a cohort of 6336 patients and results of a survey, Ann. Surg. 240 (2004) 205-213. https://doi.org/10.1097/01.sla.0000133083.54934. ae.


[^0]:    DOI of original article: https://doi.org/10.1016/j.ejogrb.2019.07.025.

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[^1]:    Value of the data

    1. Why are these data useful.

    The present data, along with what reported in the companion article, show that the laparoscopic lateral suspension with mesh is a safe and reproductable technique for pelvic organ prolapse repair.
    2. Who can benefit from these data.

    Basing on such findings, laparoscopic surgeons can evaluate the likelihood to perform laparoscopic lateral suspension with mesh for prolapse repair
    3. How can these data be used for further insights and development of experiments.

    To further validate the laparoscopic lateral suspension with mesh surgery, the data are provided in a meta-analyzable format or can be used to calculate power size for hypothetical randomized trials.
    4. What is the additional value of these data.

    Efforts to provide more detailed information than already reported have been done.

