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Regional practice variation in pelvic organ prolapse surgery in Tuscany, Italy: a retrospective cohort study on administrative health data

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ABSTRACT

Objectives To explore determinants of practice variation in both access, and quality and efficiency of surgical care for pelvic organ prolapse (POP).

Design and setting A retrospective cohort study employing administrative health data from the Tuscany region, Italy.

Participants All women over 40 years hospitalised for apical/multicompartmental POP reconstructive surgery (excluding anterior/posterior colporrhaphy without concomitant hysterectomy) from January 2017 to December 2019.

Outcomes We first computed treatment rates just for women residing in Tuscany (n=2819) and calculated the Systematic Component of Variation (SCV) to explore variation in access to care among health districts. Then, using the full cohort (n=2959), we ran multilevel models for the average length of stay and reoperations, readmissions and complications, and computed the intraclass correlation coefficient to assess the individual and hospital determinants of efficiency and quality of care provided by hospitals.

Results The 5.4-fold variation between the lowest-rate (56/100 000 inhabitants) and the highest-rate (302/100 000) districts and the SCV over 10% confirmed high systematic variation in the access to care. Higher treatment rates were driven by greater provisions of robotic and/or laparoscopic interventions, which showed highly variable usage rates. Both individual and hospital factors influenced quality and efficiency provided by hospitals, but just low proportions of variation were explained by hospital and patient characteristics.

Conclusions We found high and systematic variation in the access to POP surgical care in Tuscany and in quality and efficiency provided by hospitals. Such a variation may be mainly explained by user and provider preferences, which should be further explored. Also, supply-side factors may be involved, suggesting that wider and more uniform dissemination of robotic/laparoscopic procedures may reduce variation.

STRENGTHS AND LIMITATIONS OF THIS STUDY

- ⇒ This is the first study to explore regional variation in elective surgical practice for pelvic organ prolapse (POP) in Italy by using relatively inexpensive, easily accessible and high-quality administrative data, which allow gathering information about the entire population of interest.
- ⇒ Our data included all the ICD-9-CM (*International Classification of Diseases, 9th Revision, Clinical Modification*) diagnostic and procedural codes that allowed us to uniform our study population by selecting major POP surgical operations through a validated algorithm.
- ⇒ This study has the limitation of using regional administrative health data, which may lack non-clinical and functional outcomes and some potential confounding variables such as lifestyle and sociodemographic factors.
- ⇒ The POP stage according to the POP quantification system was missing and there was no information on the procedural characteristics such as the specific surgical technique used for each patient (eg, sacrocolpopexy).

INTRODUCTION

Pelvic organ prolapse (POP) can affect up to 40% of women, with a 7–11% lifetime surgical risk.[1 2] Transvaginal surgery, generally supported by concomitant hysterectomy, is the traditional and least invasive approach but has high recurrence rates in the presence of high-grade multicompartmental POP.[3 4] So, abdominal surgery (such as sacrocolpopexy, sacrohysteropexy or lateral suspension) is preferable for multicompartmental POP to achieve better anatomical outcomes.[5–7] Laparoscopic and robotic abdominal procedures offer shorter hospitalisations and fewer complications than traditional open laparotomy approaches, which should be avoided whenever possible.[8] Robotic surgery and laparoscopy provide similar objective outcomes, but, despite some advantages, robotic surgery is more costly and its superiority to laparoscopy is not proven.[9–11] So, laparoscopy remains the gold-standard approach for multicompartmental POP.[12]

The increasing adoption of robotic/laparoscopic interventions in elective gynaecological surgery has raised concerns over the contribution of such procedures to the matter of clinical practice variation. Variation is generally due to healthcare systems' failure in ensuring *effective care* to all patients, suboptimal use of *supply-sensitive care* in terms of resource availability or *preference-sensitive factors* involving patients and clinicians.[13] Variation is not per se a problem: from a patient-centred perspective, variation should be maintained when depending on patient preferences and needs but reduced when unwarranted, that is, driven by clinicians' attitudes and beliefs or resource allocation.[14] The need to reduce unwarranted variation also depends on its double link to healthcare costs: on one hand, excessively high treatment rates may result in unjustified costs to healthcare systems, especially public ones; on the other hand, as Wennberg noted,[15] people living in high-cost healthcare areas are more likely to receive visits, diagnostic tests and hospitalisations than people living in low-cost regions, but without substantial improvement in clinical outcomes.

As for elective surgery, variation is mainly driven by *supply-sensitive* and *preference-sensitive* factors, with clinicians' prescriptive behaviour being a major determinant of it.[16 17] Furthermore, novel technologies—such as robotic surgical systems—may amplify variation, as they disseminate before their cost-effectiveness is assessed, thus providing therapeutic alternatives not uniformly adopted by clinicians.[18] This is valid also for elective gynaecological surgery, with high variation in treatment rates observed for benign hysterectomy.[19] Like hysterectomy, POP surgery is a variation-prone kind of surgery, with potential risks of inappropriate under-treatment/over-treatment.[20] Several studies on practice variation are available.[20 21] However, poor evidence is available regarding POP surgery in Italy.

As for the Italian National Health Service, tackling variation is even more relevant, as variation is related to equity, one of the threefold missions of Beveridge-like healthcare systems.[22] Among the 21 regional health systems of Italy,[23] Tuscany provides health services to 3.7 million inhabitants, being one of the most performing regions according to the Italian Health Ministry. However, wide differences in elective surgical delivery occur within its districts.[24 25] Our hypothesis was that such practice variation could also be observed in the provision of POP surgery. Therefore, since no previous work exploring variations in POP surgery in Italy was available in the existing literature, we aimed to explore

1. Variation in the access to surgical services for POP surgery among Tuscan health districts.
2. Individual and hospital determinants of variation in care quality (in terms of reoperations, readmissions, complications) and efficiency (in terms of length of stay) provided by hospitals.

In doing so, we sought to follow the suggestion by Ward to go beyond the mere description of regional variation, trying to propose potential causes and solutions, which can be explored in future studies.[26]

METHODS

We conducted a retrospective cohort study on health administrative databases using individual data from Hospital Discharge Records of the Tuscany region. Provider hospitals routinely send the data of hospitalised patients to the Regional Health Information System Office of Tuscany for administrative purposes. The Regional Health Information System Office checks data quality and ensures data anonymisation by assigning to each patient an encrypted unique identifier. These data are shared with our research laboratory under a collaboration agreement with the Tuscany Region Health Authority (regional resolution 159/2019). As an observational study, it was reported according to the Strengthening the Reporting of Observational Studies in Epidemiology checklist.

The encrypted identifier does not allow tracing back the patient's identity and other sensitive data, in compliance with the Italian law on privacy 101/2018 (aligned with the European General Data Protection Regulation 2016/679). According to the Italian Data Protection Authority (*Garante per la protezione dei dati personali*), neither Ethical Committee approval, nor informed consent are required for carrying out observational studies based on health administrative data.[27] As a matter of fact, several previous articles using the same data source (regional health administrative databases) have been published by various Italian research groups, without needing informed consent or Ethical Committee approval.[19 28–36]

The analysis included all women aged 40 years or more who had a planned hospitalisation with primary ICD-9-CM (*International Classification of Diseases, 9th Revision, Clinical Modification*) codes of POP between 1 January 2017 and 31 December 2019. We excluded data after 2020 data to avoid the COVID-19 pandemic bias. Particularly, patients hospitalised for receiving POP surgery were included by using the following ICD-9-CM codes, which were chosen and validated with a team of gynaecologists who use them for internal performance monitoring and administrative purposes (online supplemental table S1):

- Diagnosis codes: 618.00, 618.09, 618.1, 618.2, 618.3, 618.4, 618.5, 618.01.
- Procedure codes: 69.22, 70.77, 68.31, 68.39, 68.59, 59.79, 00.39, 71.79, 70.50, 70.51, 70.52.

The cohort selection algorithm is shown schematically in online supplemental table S2, with all inclusion and exclusion criteria applied.

First, we excluded all patients receiving just transvaginal anterior/posterior colporrhaphy without concomitant hysterectomy (codes: 70.50, 70.51, 70.52). Indeed, such procedures are performed for low-grade and monocompartmental prolapses and do not require long hospitalisations. In contrast, our aim was to focus just on major surgical interventions with comparable indications and outcomes carried out for apical or multicompartmental POP requiring a reconstructive approach, such as abdominal surgery or transvaginal surgery with concomitant hysterectomy.

Secondly, we excluded patients belonging to the major diagnosis category of pregnancy and patients diagnosed with cancer or trauma.

Finally, despite having no information about the specific surgical technique, we identified the surgical procedure performed for each woman by employing the appropriate ICD-9-CM procedure codes. We thus obtained the following groups:

- Robot-assisted surgery (RAS), codes: 00.39.
- Laparoscopic surgery, codes: 54.21, 68.31, 68.41, 68.61.
- Transvaginal surgery, codes: 68.51, 68.59, 68.71, 68.79, 70.50, 70.51, 70.52.
- Open laparotomy surgery, codes: 69.22, 70.77 (when other codes were absent).

Data management and statistical analysis were performed by using both SAS (V.9.4) and Stata (V.15.1) software. Categorical variables were presented as percentages, while continuous variables as mean±SD. Statistical significance was set at a p value< 0.05.

Patient and public involvement

Since the study used administrative data, patients and members of the public were not involved.

Variation in the access to surgical care

To explore variation in the access to surgical services, we computed the 3-year treatment rates for POP surgery in Tuscan health districts (n=26) just among women aged 40 years or more and residing in Tuscany. Treatment rates were calculated by dividing the number of surgical procedures delivered to the women residing in each district from January 2017 to December 2019 by the sum of the female population of that district over the 3 years of analysis and multiplying it by 100 000. To derive treatment rates, we considered the hospitalisations for women residing in Tuscany regardless of where the provider hospital was located.

Furthermore, to examine what proportion of the variation among health districts is systematic variation over or above the expected random variation, we computed the Systematic Component of Variation (SCV) for surgical treatment rates in Tuscany. The SCV is a method of standardisation in which age grouping is assumed to change the risk of surgery by a fixed multiplicative factor. In our study, we applied a 5-year age grouping since the standard population we used, provided by the Tuscany region, was grouped this way—following the 2013 Eurostat guidelines.[37]

The SCV estimates the relative systematic component of variation between health districts by subtracting the random component of variance (variance within districts) from the estimate of the total variance. Therefore, the SCV represents the systematic variation considered to be beyond chance.[38] Considering I as the number of the health district (n=26) in Tuscany, y_i as the observed number of surgical procedures, and e_i as the expected number of procedures given the regional age-specific rates applied to the age distribution of each district, the SCV was calculated as follows:[39]

$$SCV = \frac{1}{I}\left(\sum \frac{(y_i - e_i)^2}{e_i^2} - \sum \frac{1}{e_i}\right)$$

Variation in quality and efficiency provided by hospitals

We sought to investigate the main determinants of variation both at the provider and user levels by exploring the effect of several covariates—available from administrative databases—on four specific performance outcomes. In this case, we used the full study cohort, regardless from where the patient resided and where the provider hospital was located. Particularly, our covariates were both patient features (age class, Elixhauser and Charlson Comorbidity Indexes,[40] education level, surgeon specialty, surgical approach, performance of concomitant hysterectomy) and hospital characteristics (total volumes of interventions and median waiting times from booking to hospital admission). Our outcomes were three quality indicators (complication, readmission and reoperation rates) and one efficiency indicator (length of stay). Perioperative complications were assessed by employing the ICD-9-CM codes shown in online supplemental table S3. Readmissions were computed by keeping duplicates and selecting those women who were hospitalised for any reason within 3 months post-intervention. Reoperations were identified by searching for patients those who underwent reoperation within 2 years.

First, we built two-level multilevel regression models, with level 1 referring to patients, and level 2 referring to the provider hospitals. We employed linear models for the continuous dependent variable and logistic models for dichotomous ones to measure the association between the dependent variables and the covariates at both levels for the length of stay and the occurrence of reoperations, readmissions and complications, respectively. Length of stay was included in the model as a natural logarithm. We adjusted for patients' sociodemographic and clinical features as well as for the above-mentioned hospital-level variables.[41]

Second, to assess the proportion of the variance explained by patient and hospital characteristics, we computed a postestimation analysis for each multilevel model of the intraclass correlation coefficient (ICC), which in two-level variance component models is equal to the variance partition coefficient, as also explained in online supplemental table S4.[42–44] The ICC was calculated as a ratio (variance of interest/total variance) and, therefore, allowed inferring to what extent the observed variance was explained by the various individual and hospital features included in our models.[45]

RESULTS

Variation in the access to surgical care

Out of the full study cohort, we selected just women residing in Tuscany. We thus obtained a population of 2819 women residing in 26 health districts who were

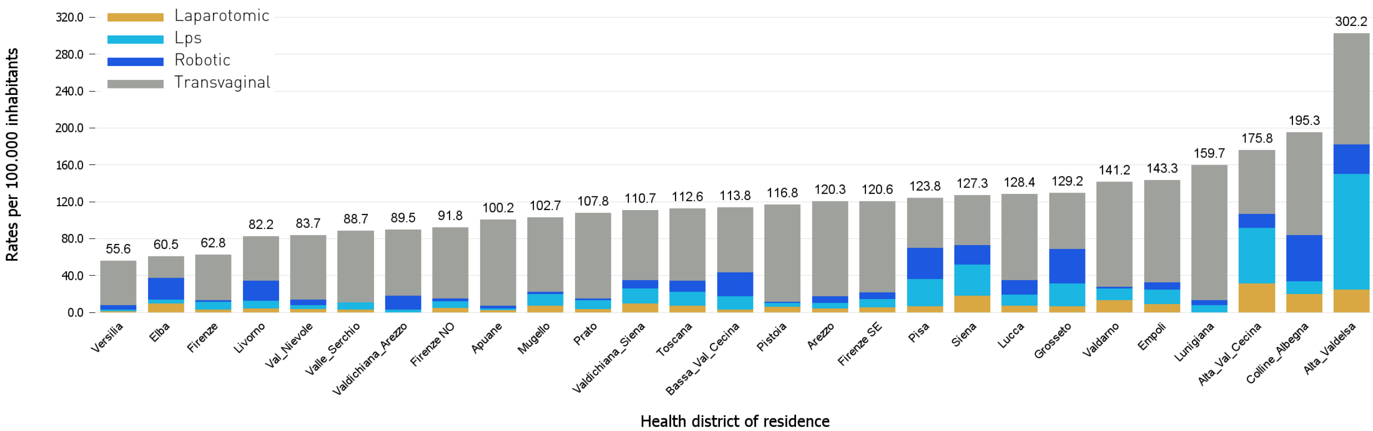

Figure 1 Treatment rates for POP surgery in each health district of Tuscany. Total treatment rates were also split into the specific treatment rates for each surgical procedure. Treatment rates were computed by dividing the number of POP interventions for the population of each health district regardless of where the intervention was provided. The Systematic Component of Variation was calculated to explore variation exceeding random variation, thus being systematic. Lps, laparoscopy; POP, pelvic organ prolapse.

hospitalised to receive POP surgery from 1 January 2017 to 31 December 2019 in any hospital. The overall 3-year treatment rate for POP in Tuscany was 112.6/100 000 inhabitants. However, treatment rates varied notably across the 26 health districts of Tuscany, ranging from 55.6/100 000 to 302.2/100 000, with a 5.4-fold difference between the highest-rate and lowest-rate districts (figure 1). Therefore, we quantitatively assessed such a level of variation by computing the SCV. After calculating standardised treatment rates by adjusting for age, we found an SCV of 18.6% (online supplemental table S5), suggesting very high variation.[46] It means that 18.6% of variation among health districts exceeds random variation, thus being systematic.

Variation in quality and efficiency provided by hospitals

We obtained a full study cohort of 2959 women, not necessarily residing in Tuscany, who were hospitalised for POP surgery from 1 January 2017 to 31 December 2019. Out of them, 140 (5%) did not reside in Tuscany, while 2688 (91%) received surgery in hospitals that provided more than 30 POP interventions during the 3 years of analysis (n=22). The patient sociodemographic and clinical features are shown in table 1, with also a comparison based on the surgical approach received by the women.

The mean age of our patients was 67.4±9.2 years. Most of them had a low education level and presented no or few comorbidities. Most women were operated on by gynaecologists and received concomitant hysterectomy. Transvaginal surgery was the prevalent approach. The average length of stay was 3.5±1.9 days. The overall reoperation, readmission and complication rates were 3.9%, 6.0% and 2.7%, respectively.

Different proportions of abdominal minimally invasive surgery usage were observed among hospitals performing more than 30 interventions during the study period (figure 2). Just five of them provided robotic surgery: among these five hospitals, the percentage of usage—computed as the number of robotic interventions out of the total number of interventions for each hospital—varied from 5% to 51%. Laparoscopic procedures were performed by all hospitals, and usage rates ranged from 1% to 56%. Eighteen hospitals still provided open laparotomy procedures, with usage rates from 1% to 20% and over 5% in seven hospitals. Furthermore, by comparing figure 1 and figure 2 we observed that higher treatment rates might be determined by the surgical procedure usage since rates over the regional average were found in districts where hospitals provided greater amounts of robotic/laparoscopic interventions. Therefore, we ran Pearson's correlation test and obtained a positive (r=0.122) and statistically significant (p<0.001) association between treatment rates and volumes of robotic/laparoscopic procedures delivered by hospitals providing more than 30 interventions during the study period.

As shown in figure 3 and online supplemental table S4, advanced age was a risk factor for longer hospitalisations. Besides, a longer length of stay was observed among women with a higher Elixhauser Comorbidity Index. Women operated on by general (ie, abdominal) surgeons or other specialists rather than gynaecologists experienced longer hospitalisations. Furthermore, laparoscopy ensured a shorter length of stay as compared with laparotomy surgery, while no difference emerged for robotic and transvaginal procedures. Receiving a concomitant hysterectomy was a risk factor for a longer hospitalisation. The ICC for the length of stay was 0.389, meaning that 38.9% of variation was explained by the patient and hospital-level features.

As shown in table 2, women aged 60–79 years and women with higher education were protected against reoperations. While transvaginal surgery decreased the risk of reoperation compared with open laparotomy, the performance of a concomitant hysterectomy increased

Table 1 Sociodemographic and clinical characteristics of women

	Total	Laparotomy	Laparoscopy	Robotic surgery	Transvaginal surgery	
	n=2959	n=175 (5.9%)	n=393 (13.3%)	n=337 (11.4%)	n=2054 (69.4%)	P value
Age, mean (SD)	67.4 (9.2)	66.1 (10.2)	64.1 (9.4)	65.4 (9.4)	68.5 (8.9)	<0.001
Age class						<0.001
40–59 years	571 (19.3%)	43 (24.6%)	114 (29.0%)	85 (25.2%)	329 (16.0%)	
60–79 years	2133 (72.1%)	117 (66.9%)	271 (69.0%)	233 (69.1%)	1512 (73.6%)	
80 years or more	255 (8.6%)	15 (8.6%)	8 (2.0%)	19 (5.6%)	213 (10.4%)	
Education						<0.001
Elementary/ middle school	1624 (54.9%)	101 (57.7%)	218 (55.5%)	180 (53.4%)	1125 (54.8%)	
High school	594 (20.1%)	30 (17.1%)	90 (22.9%)	85 (25.2%)	389 (18.9%)	
University	159 (5.4%)	9 (5.1%)	32 (8.1%)	35 (10.4%)	83 (4.0%)	
Not reported	582 (19.6%)	35 (20.0%)	53 (13.5%)	37 (11.0%)	457 (22.2%)	
Elixhauser comorbidity index						0.42
0	2844 (96.1%)	163 (93.1%)	378 (96.2%)	326 (96.7%)	1977 (96.3%)	
1	95 (3.2%)	9 (5.1%)	11 (2.8%)	9 (2.7%)	66 (3.2%)	
2	18 (0.6%)	3 (1.7%)	4 (1.0%)	2 (0.6%)	9 (0.4%)	
3	2 (0.1%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.1%)	
Surgical unit						<0.001
ObGyn	2585 (87.3%)	98 (56.0%)	295 (75.1%)	223 (66.2%)	1968 (95.8%)	
Urology	147 (5.0%)	23 (13.1%)	16 (4.1%)	62 (18.4%)	46 (2.2%)	
General surgery	210 (7.1%)	53 (30.3%)	76 (19.3%)	48 (14.2%)	33 (1.6%)	
Other	18 (0.6%)	1 (0.6%)	6 (1.5%)	4 (1.2%)	7 (0.3%)	
Concomitant hysterectomy	2319 (78.4%)	9 (5.1%)	157 (39.9%)	99 (29.4%)	2054 (100.0%)	<0.001
Length of stay, mean (SD)	3.5 (1.9)	3.4 (1.8)	2.8 (1.6)	2.6 (0.9)	3.8 (2.0)	<0.001
Reintervention	114 (3.9%)	11 (6.3%)	28 (7.1%)	25 (7.4%)	50 (2.4%)	<0.001
Readmission	179 (6.0%)	12 (6.9%)	29 (7.4%)	15 (4.5%)	123 (6.0%)	0.40
Complication	79 (2.7%)	4 (2.3%)	13 (3.3%)	11 (3.3%)	51 (2.5%)	0.69

To explore between-group differences, we used the Kruskal-Wallis or analysis of variance tests for continuous variables and Pearson's χ^2 test for categorical variables.

it. Advanced age and not being operated on by gynaecologists were risk factors for readmissions. The risk of complications was mainly related to the presence of more comorbidities. The ICCs for reoperations, readmissions and complications were 0.031, 0.035 and 0.302, respectively, showing that 3.1% of variation for reoperations, 3.5% of variation for readmissions and 30.2% of variation for complications could be explained by the different individual and hospital characteristics.

DISCUSSION

Main findings

We found that overall 3-year POP treatment rates in Tuscany were 112.6/100 000, in line with the literature.[20 47 48] We observed high-grade variation in the access to POP surgical care in Tuscany in terms of treatment rates. Indeed, we detected a 5.4-fold variation between the highest-rate and lowest-rate health districts, with treatment rates ranging from 56 to 302/100 000 inhabitants. These findings are in line with previous studies from other countries:[20 47 49] for instance, high practice variation emerged in The Netherlands in 2010, with surgical rates varying from 55 to 363/100 000 women. Moreover, the SCV over 10% confirmed high systematic variation in surgical rates among health districts.[46]

As for POP surgery provision, the different outcomes in the efficiency and quality of POP surgical care depended on both patient and hospital features, but just small

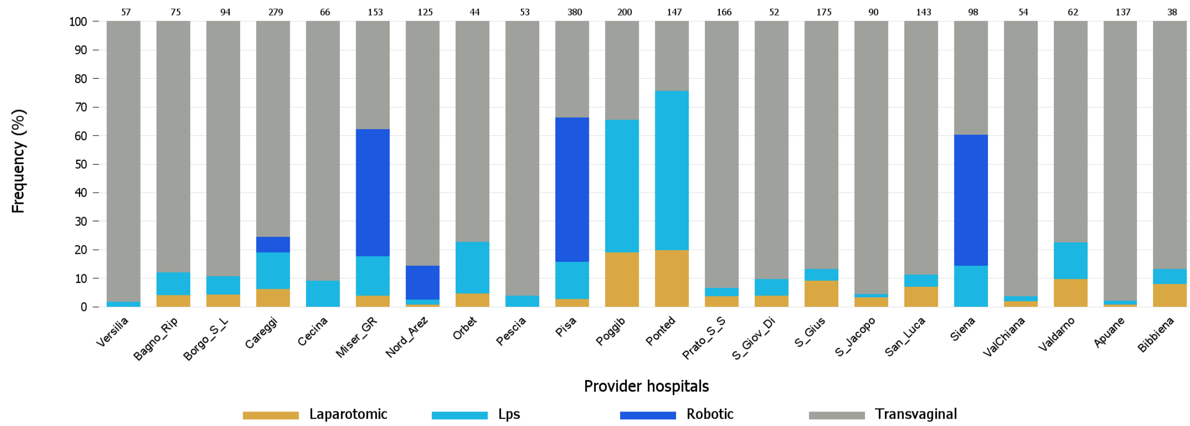

Figure 2 The overall number of pelvic organ prolapse interventions provided by hospitals (regardless of where the patient resided) and classified according to the surgical procedure. In this figure we have only shown hospitals that provided more than 30 interventions during the 3 years of analysis to allow for better visualisation. Lps, laparoscopy.

proportions of variance were explained by the covariates used in the models. In line with the literature, an older age increased the risk of readmissions and longer hospitalisations, while decreased the risk of reoperation. Also, patients with comorbidities were at greater risk of complications.[50 51] Being operated on by gynaecologists reduced the length of hospital stay and the risk of readmission, as previously suggested.[52]

Receiving a concomitant hysterectomy was a risk factor for longer hospitalisation and reoperation. Moreover, laparoscopy offered shorter hospitalisations compared with open laparotomy surgery, as already shown.[9] Surprisingly, reoperation rates were lower for transvaginal procedures than for laparotomy ones, in contrast with most of the literature.[53] Although few previous studies did find a lower risk of reintervention after transvaginal surgery than after abdominal surgery,[54] we believe that our result was related to the limit that we considered reinterventions within 2 years after the first surgery because we had no data available after 2021. Finally, we observed no statistical difference for robotic surgery, probably because few robotic interventions are performed every year in Tuscany, and just in five hospitals, so this study may lack the power to determine a real difference, if any exists.

Our analyses also showed that the robotic/laparoscopic surgery usage rates are still low (almost 26%) and vary widely among hospitals providing less than 30 interventions during the study period. Indeed, robotic

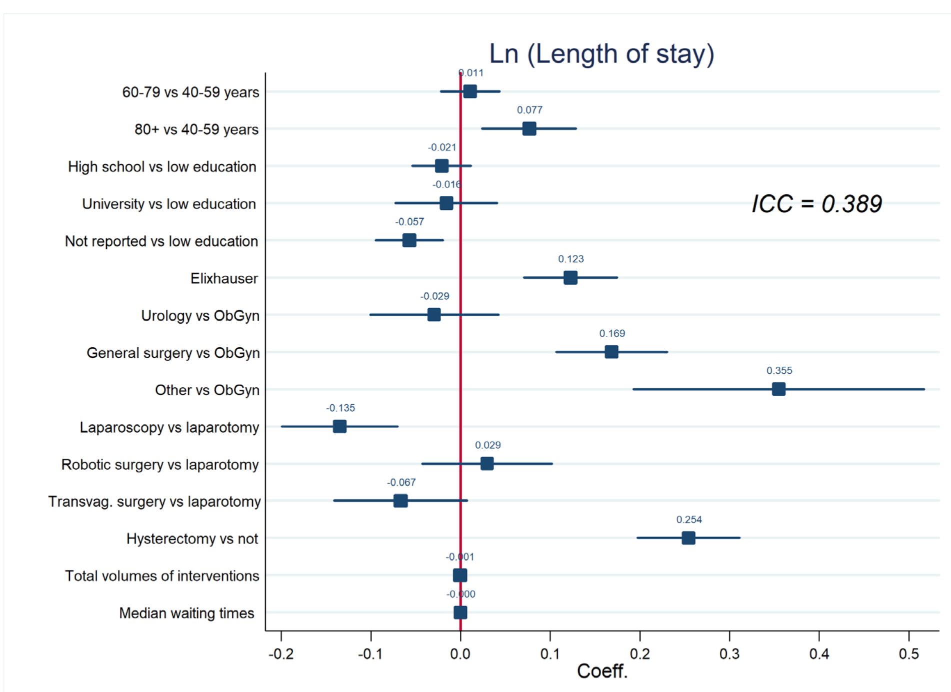

Figure 3 Risk factors emerged from multilevel regression models for the length of stay (expressed as a natural logarithm). The intraclass correlation coefficient (ICC) was computed to infer to what extent variance was explained by individual/hospital features. See online supplemental table S4 for further details on the regression coefficients and on the ICC calculation.

Table 2 Risk factors emerged from multilevel regression models for reinterventions, readmissions and complications

	Reintervention				Readmission				Complication*			
	OR	P value	95% CI		OR	P value	95% CI		OR	P value	95% CI	
Age class												
60–79 vs 40–59 years	**0.612**	**0.032**	0.390	0.959	**1.728**	**0.024**	1.074	2.780	0.964	0.911	0.505	1.839
≥80 vs 40–59 years	0.517	0.134	0.218	1.226	**2.869**	**0.001**	1.540	5.344	2.230	0.064	0.954	5.210
Education												
High school vs elementary/middle school	**0.562**	**0.043**	0.322	0.981	0.784	0.287	0.501	1.227	1.613	0.110	0.898	2.899
University vs elementary/middle school	0.684	0.371	0.298	1.571	1.500	0.192	0.815	2.761	1.302	0.605	0.479	3.542
Not reported vs elementary/middle school	0.840	0.522	0.492	1.434	1.004	0.985	0.662	1.523	0.835	0.610	0.418	1.668
Elixhauser Comorbidity Index	1.346	0.377	0.696	2.604	0.598	0.190	0.278	1.289	**2.456**	**0.002**	1.395	4.323
Surgical unit												
Urology vs ObGyn	0.720	0.565	0.235	2.206	1.382	0.440	0.609	3.137	0.330	0.311	0.039	2.814
General surgery vs ObGyn	0.476	0.114	0.189	1.195	1.650	0.143	0.844	3.225	2.533	0.050	0.999	6.421
Other vs ObGyn	0.693	0.731	0.086	5.603	**5.083**	**0.009**	1.511	17.104	2.180	0.348	0.429	11.085
Surgical approach												
Laparoscopy vs laparotomy	0.697	0.370	0.317	1.535	0.988	0.975	0.454	2.150	1.431	0.574	0.410	4.996
Robotic surgery vs laparotomy	0.499	0.115	0.210	1.184	0.596	0.251	0.246	1.441	0.948	0.939	0.241	3.726
Transvaginal surgery vs laparotomy	**0.171**	**0.000**	0.073	0.401	0.578	0.209	0.246	1.359	0.568	0.418	0.144	2.234
Concomitant hysterectomy vs not	**2.162**	**0.012**	1.189	3.932	1.811	0.081	0.930	3.526	1.230	0.653	0.498	3.041
Total volumes of interventions	1.002	0.097	1.000	1.005	1.001	0.520	0.998	1.003	1.003	0.417	0.996	1.009
Median waiting times	0.998	0.182	0.994	1.001	1.002	0.153	0.999	1.005	1.002	0.577	0.995	1.009
ICC	0.031				0.035				0.302			

Bold values represent statistically significant coefficients.
*The IC9 diagnosis codes for complications are shown in online supplemental table S3.
ICC, intraclass correlation coefficient.

interventions were provided by just five hospitals with usage rates ranging from 5% to 51%, while laparoscopy was adopted by all hospitals with usage rates varying from 1% to 56%. On the other hand, seven hospitals provided more than 5% open laparotomy interventions, which seem not to be justified by contraindications to minimally invasive surgery. Finally, we found that the surgical procedure is likely to influence treatment rates since treatment rates were associated with wider usage of robotic and/or laparoscopic surgery.

Limitations

Our study presents several limitations related to its intrinsic observational design, which does not allow inferring causation. Moreover, it employs administrative data, which may lack potential confounding variables such as the POP stage according to the POP quantification system, lifestyle and sociodemographic factors and procedural characteristics. Non-clinical and functional outcomes are missing as well. As another limitation, we considered reoperations just within the first 2 years after the first intervention as we had no data after 2021, and we did not consider whether patients in our cohort had previously undergone surgery in the same anatomical compartment because the procedure coding before 2017 was not regionally standardised. Finally, no information was available about the specific surgical technique (eg, sacrocolpopexy, sacrohysteropexy, lateral suspension) used for each patient.

However, administrative data are relatively inexpensive and easily accessible and allow gathering information about the entire population of interest. They have been widely adopted by healthcare authorities to evaluate hospital performance. A strength of this paper is the use of high-quality regional administrative data, such as Hospital Discharge Records, which are routinely checked by the Regional Health Information System Office of Tuscany and, therefore, are well-validated and reliable. We employed such data to explore, for the first time, regional variation in elective surgical practice for POP in Italy. Despite having no information on the surgical technique, we tried to uniform our study population by selecting major POP surgical operations through the appropriate ICD-9 codes using a validated algorithm. We thus included all abdominal interventions and all transvaginal interventions with concomitant hysterectomy.

Interpretation

Regional practice variation can be explained by several factors. Warranted factors such as patient preferences and needs should be promoted by policymakers, while unwarranted factors not related to patient needs must be reduced. We sought to analyse the extent and the main determinants of regional variation in POP elective surgery in Tuscany in terms of access to care and performance level. We focused on POP requiring major interventions with comparable indications and outcomes, thus excluding procedures for monocompartmental or low-grade prolapse, such as colporrhaphy without concomitant hysterectomy. We carried out our analyses until December 2019 to avoid the COVID-19 bias.

The observed variation in the access to POP surgical services could not be explained just by different patient needs across districts and was not completely explained by the hospital-level features.[55] Also, although other studies have shown that the surgical training and background of surgeons, and the resulting preferences, were one of the determinants of practice variations,[18 56] operative guidelines and training in surgical gynaecology are uniform throughout Tuscany. Supply-sensitive conditions—such as the robotic surgical system availability—may partly contribute to such differences in treatment rates and therefore need further evaluation. For instance, the low rates observed in the Elba Island district are due to evident demand-supply gaps. Additionally, the availability of operating rooms—not explored in this study—may reflect problems in terms of internal resource allocation among different procedures: the very low rates observed in the Versilia district might be explained by higher numbers of operating rooms in the neighbouring (eg, Pisa and Florence) districts.

However, we believe that preference-sensitive factors involving both users and providers are the leading determinants of regional variation in POP surgical practice. For instance, patients could choose to be operated on in hospitals offering surgical services which are perceived to be of higher quality, such as the performance of large numbers of minimally invasive interventions. On the other hand, the positive correlation between treatment rates and the usage rates of robotic/laparoscopic procedures may imply several underlying causes, such as excessive enthusiasm for operative interventions in units possessing the robotic surgical system, referral-in from other units or specialists, instructions from Health Authorities to mitigate the costs of robotic surgery (where present) or underusage of surgical interventions at the other centres.

Therefore, to define the observed variation as unwarranted, all these factors should be further analysed to assess the main determinants of clinicians' attitudes and patients' choices. Such analyses could enrich the existing literature, which shows that both physician[57 58] and user[59 60] preferences are determinants of practice variation. However, with respect to previous studies that more often compared preferences between surgical techniques,[57 60 61] it would also be interesting to investigate the factors influencing the choice of surgery vs conservative treatment, such as pelvic floor muscle training.[62]

For instance, discrete choice analyses on regional administrative data could be carried out through the proper methodology to investigate how travel distances, waiting times and the provision of minimally invasive surgery influence patients' choices in Tuscany.[33 63] Also, discrete choice experiments could be performed as quasi-experimental studies to intercept individual preferences by administering—after a randomisation process—surveys to patients and/or clinicians in which they are invited to choose between different hypothetical scenarios according to several attributes considered and identified as the main determinants of their choices.[64 65]

As for POP surgery provision, we detected high variation in quality and efficiency provided by hospitals and in robotic/laparoscopic surgery use. As previously said, we also found a positive correlation between treatment rates and robotic/laparoscopic surgery use. It is unclear whether variation is driven by overusage of robotic/laparoscopic procedures in some health districts, or underusage of those procedures in others. Overusage may be due to excessive surgical enthusiasm in hospitals where robotic/laparoscopic surgery is available. Underusage may be due to a lack of surgical skills or to the absence of robotic surgical systems in most hospitals. In our opinion, the implementation of laparoscopy and/or wider dissemination of robotic surgical systems may positively impact variation by reducing the use of open laparotomy surgery and levelling more treatment rates across the region.

Therefore, to encourage wider use of minimally invasive abdominal procedures, we developed and included in the Performance Evaluation System of Sant'Anna School of Advanced Studies[66] a new indicator tracking the annual usage rates of robotic/laparoscopic interventions in Tuscany. However, robotic surgery and laparoscopy provide comparable outcomes, so policymakers need further elements for allocating resources. For example, robotic surgery is more expensive but offers some technical advantages and a shorter learning curve compared with laparoscopy. So, detecting further elements that might indirectly mitigate the higher costs of RAS becomes fundamental. This information could be obtained, for instance, by launching a patient-reported outcome measure collection programme[67] to explore a potential subjective superiority of one procedure over the other.

Furthermore, our model showed that the length of stay was not influenced by the overall number of interventions delivered by each hospital. This would not justify the centralisation of most interventions in medical centres providing higher overall numbers of interventions. It rather suggests that all hospitals, even the most peripheral, should enhance the expertise of medical staff on POP surgery, for instance by organising training courses for young surgeons, by creating multidisciplinary surgical teams and by promoting the continuous dialogue between healthcare professionals on the various POP surgical alternatives to align their recommendations towards patients. As a result, the entire care pathway would benefit from a reduction of practice variation in both access and quality of health services.

CONCLUSION

We explored the differences in the access to surgical care for POP by comparing treatments rates among Tuscan health districts and in the performance ensured by the providers by comparing several outcomes (length of stay, reoperations, readmissions and complications) among hospitals. Preference-sensitive factors may be the main determinants of regional variation and, therefore, must be further analysed by exploring patients' and clinicians' decision-making processes. Additionally, the use of robotic/laparoscopic surgery seems to drive treatment rates but remains too variable, thus suggesting—in our opinion—that the implementation of laparoscopy and/or the introduction of robotic surgical systems might also fill supply-side gaps, furtherly reducing variation. This would require resource allocation and investments by policymakers and healthcare managers, based on a deeper awareness of the patient's point of view. For such a purpose, the collection of patient-reported data may help to assess possible patient preferences for specific surgical procedures and align healthcare targets with patient needs.

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Contributors AF was responsible for the overall content of this work as a guarantor, developed the study design and plan, collected and managed the data, assessed the methodology, performed the statistical analysis and wrote the manuscript. AG contributed to the interpretation of the results and drafting of the manuscript. CS gave her contribution in the choice of statistical models, data analysis and revising the drafts of the article. TS and MV coordinated the collaboration between the two research groups, reviewed the drafts of the article and approved the final version of the manuscript.

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REFERENCES

1 Caretto M, Giannini A, Russo E, *et al*. Pelvic floor reconstructive surgery in ageing women: tailoring the treatment to each woman's needs. *Pre-Menopause, Menopause and Beyond* 2018:303–16.
2 Jelovsek JE, Maher C, Barber MD. Pelvic organ prolapse. *Lancet* 2007;369:1027–38.
3 Giannini A, Caretto M, Russo E, *et al*. Advances in surgical strategies for prolapse. *Climacteric* 2019;22:60–4.
4 Fritel X, de Tayrac R, de Keizer J, *et al*. Serious complications and recurrences after pelvic organ prolapse surgery for 2309 women in the VIGI-MESH registry. *BJOG* 2022;129:656–63.
5 Maher C, Feiner B, Baessler K, *et al*. Surgical management of pelvic organ prolapse in women. *Cochrane Database Syst Rev* 2013;2013:CD004014.
6 Russo E, Giannini A, Guevara MM, *et al*. Medium-term outcomes after robotic-assisted lateral suspension with mesh for advanced multi-compartmental prolapse. *Int Urogynecol J* 2019.
7 Mereu L, Tateo S, D'Alterio MN, *et al*. Laparoscopic lateral suspension with mesh for apical and anterior pelvic organ prolapse: A prospective double center study. *Eur J Obstet Gynecol Reprod Biol* 2020;244:16–20.
8 Mannella P, Giannini A, Russo E, *et al*. Personalizing pelvic floor reconstructive surgery in aging women. *Maturitas* 2015;82:109–15.
9 De Gouveia De Sa M, Claydon LS, Whitlow B, *et al*. Robotic versus laparoscopic sacrocolpopexy for treatment of prolapse of the apical segment of the vagina: a systematic review and meta-analysis. *Int Urogynecol J* 2016;27:355–66.
10 Roh HF, Nam SH, Kim JM. Robot-assisted laparoscopic surgery versus conventional laparoscopic surgery in randomized controlled trials: A systematic review and meta-analysis. *PLoS One* 2018;13:e0191628.
11 Hudson CO, Northington GM, Lyles RH, *et al*. Outcomes of robotic sacrocolpopexy: a systematic review and meta-analysis. *Female Pelvic Med Reconstr Surg* 2014;20:252–60.
12 Serati M, Bogani G, Sorice P, *et al*. Robot-assisted sacrocolpopexy for pelvic organ prolapse: a systematic review and meta-analysis of comparative studies. *Eur Urol* 2014;66:303–18.
13 Nuti S, Bini B, Ruggieri TG, *et al*. Bridging the gap between theory and practice in integrated care: the case of the diabetic foot pathway in tuscany. *Int J Integr Care* 2016;16:9.
14 Mulley A, Trimble C, Elwyn G. *Patients' preferences matter: stop the silent misdiagnosis*. King's Fund, 2012: 1–64.
15 Wennberg JE. Practice variations and health care reform: connecting the dots: A focus on medical error is preventing sufficient focus on improving the quality of patient decision making to reduce practice variations (and costs) in today's health care system. *Health Aff* 2004;23.
16 Cafagna G, Seghieri C, Vainieri M, *et al*. A turnaround strategy: improving equity in order to achieve quality of care and financial sustainability in italy. *Int J Equity Health* 2018;17:169.
17 Wennberg JE. Time to tackle unwarranted variations in practice. *BMJ* 2011;342:bmj.d1513.
18 Birkmeyer JD, Reames BN, McCulloch P, *et al*. Understanding of regional variation in the use of surgery. *Lancet* 2013;382:1121–9.
19 Lungu DA, Foresi E, Belardi P, *et al*. The impact of new surgical techniques on geographical unwarranted variation: the case of benign hysterectomy. *Int J Environ Res Public Health* 2021;18:6722.
20 van IJsselmuiden MN, Detollenaere RJ, Kampen MY, *et al*. Practice pattern variation in surgical management of pelvic organ prolapse and urinary incontinence in the Netherlands. *Int Urogynecol J* 2015;26:1649–56.
21 Enklaar RA, van IJsselmuiden MN, IntHout J, *et al*. Practice pattern variation: treatment of pelvic organ prolapse in the Netherlands. *Int Urogynecol J* 2022;33:1973–80.
22 Nuti S, Seghieri C. Is variation management included in regional healthcare governance systems? some proposals from italy. *Health Policy* 2014;114:71–8.
23 Ferre F, de Belvis AG, Valerio L, *et al*. Italy: health system review. *Health Syst Transit* 2014;16:1–168.
24 Lungu DA, Grillo Ruggieri T, Nuti S. Decision making tools for managing waiting times and treatment rates in elective surgery. *BMC Health Serv Res* 2019;19:369.
25 Nuti S, Daraio C, Speroni C, *et al*. Relationships between technical efficiency and the quality and costs of health care in Italy. *Int J Qual Health Care* 2011;23:324–30.
26 Ward MM. Regional variation in surgical procedure rates: going beyond description. *JAMA Surg* 2022;157:91–2.
27 Italian Data Protection Authority. General authorisation to process personal data for scientific research purposes. 2012. Available: www.garanteprivacy.it/home/docweb/-/docweb-display/docweb/1884019#
28 Cegolon L, Mastrangelo G, Maso G, *et al*. Determinants of length of stay after cesarean sections in the friuli venezia giulia region (north-eastern italy), 2005-2015. *Sci Rep* 2020;10:19238.
29 Seghieri C, Mimmi S, Lenzi J, *et al*. 30-day in-hospital mortality after acute myocardial infarction in tuscany (italy): an observational study using hospital discharge data. *BMC Med Res Methodol* 2012;12:1–11.
30 Cafagna G, Seghieri C. Educational level and 30-day outcomes after hospitalization for acute myocardial infarction in italy. *BMC Health Serv Res* 2017;17:18.
31 Orlando V, Rea F, Savaré L, *et al*. Development and validation of a clinical risk score to predict the risk of SARS-cov-2 infection from administrative data: a population-based cohort study from italy. *PLoS One* 2021;16:e0237202.
32 Calovi M, Seghieri C. Using a GIS to support the spatial reorganization of outpatient care services delivery in italy. *BMC Health Serv Res* 2018;18:883.
33 Seghieri C, Calovi M, Ferrè F. Proximity and waiting times in choice models for outpatient cardiological visits in italy. *PLoS One* 2018;13:e0203018.
34 Lenzi J, Avaldi VM, Hernandez-Boussard T, *et al*. Risk-adjustment models for heart failure patients' 30-day mortality and readmission rates: the incremental value of clinical data abstracted from medical charts beyond hospital discharge record. *BMC Health Serv Res* 2016;16:473.
35 Ferrari A, Pirrotta L, Bonciani M, *et al*. Higher readability of institutional websites drives the correct fruition of the abortion pathway: a cross-sectional study. *PLoS One* 2022;17:e0277342.
36 Ferrari A, Bonciani M, Corazza I, *et al*. Reduced abortion rates and improved provision of counseling and contraception services: analysis of a regional campaign for young women in Italy. *NEJM Catalyst* 2022;3.
37 Pace M, Lanzieri G, Glickman M, *et al*. *Revision of the european standard population: report of eurostat's task force*. Publ Off Eur Union, 2013.
38 Murthy BN, Jabbar S, Venkatarao T, *et al*. Components of small area variation in fertility rates among married women in South India. *Int J Epidemiol* 2003;32:639–44.
39 Ibáñez B, Librero J, Bernal-Delgado E, *et al*. Is there much variation in variation? revisiting statistics of small area variation in health services research. *BMC Health Serv Res* 2009;9:1–12.
40 Austin SR, Wong Y-N, Uzzo RG, *et al*. Why summary comorbidity measures such as the Charlson comorbidity index and Elixhauser score work. *Med Care* 2015;53:e65–72.
41 Wei W, Gruebner O, von Wyl V, *et al*. Variation of preoperative chest radiography utilization in switzerland and its influencing factors: a multilevel study with claims data. *Sci Rep* 2018;8:17475.
42 Merlo J, Chaix B, Yang M, *et al*. A brief conceptual tutorial of multilevel analysis in social epidemiology: linking the statistical concept of clustering to the idea of contextual phenomenon. *J Epidemiol Community Health* 2005;59:443–9.
43 Pianori D, Adja KYC, Lenzi J, *et al*. The contribution of case mix, skill mix and care processes to the outcomes of community hospitals: a population-based observational study. *Int J Integr Care* 2021;21:25.
44 Rabe-Hesketh S, Skrondal A. *Multilevel and longitudinal modeling using stata*. 2nd edn. Coll Station TX Stata Press, 2012.
45 Murante AM, Seghieri C, Vainieri M, *et al*. Patient-perceived responsiveness of primary care systems across europe and the relationship with the health expenditure and remuneration systems of primary care doctors. *Soc Sci Med* 2017;186:139–47.
46 Murphy ME, Bennett K, Fahey T, *et al*. Geographical variation in anti-diabetic prescribing in Ireland in 2013 and 2014: a cross-sectional analysis. *Fam Pract* 2017;34:587–92.
47 Lisonkova S, Geoffrion R, Sanaee M, *et al*. Regional variation and temporal trends in surgery for pelvic organ prolapse in canada, 2004-2014. *J Obstet Gynaecol Can* 2020;42:846–52.
48 Ferrari A, Seghieri C, Giannini A, *et al*. Driving time drives the hospital choice: choice models for pelvic organ prolapse surgery in italy. *Eur J Health Econ* 2023:1–12.

49 Husby KR, Lose G, Klarskov N. Trends in apical prolapse surgery between 2010 and 2016 in Denmark. *Int Urogynecol J* 2020;31:321–7.
50 Richter HE, Goode PS, Kenton K, *et al*. The effect of age on short-term outcomes after abdominal surgery for pelvic organ prolapse. *J Am Geriatr Soc* 2007;55:857–63.
51 Jelovsek JE, Chagin K, Lukacz ES, *et al*. Models for predicting recurrence, complications, and health status in women after pelvic organ prolapse surgery. *Obstet Gynecol* 2018;132:298–309.
52 Anger JT, Mueller ER, Tarnay C, *et al*. Robotic compared with laparoscopic sacrocolpopexy: a randomized controlled trial. *Obstet Gynecol* 2014;123:5–12.
53 Clark AL, Gregory T, Smith VJ, *et al*. Epidemiologic evaluation of reoperation for surgically treated pelvic organ prolapse and urinary incontinence. *Am J Obstet Gynecol* 2003;189:1261–7.
54 Zhang C-Y, Sun Z-J, Yang J, *et al*. Sacrocolpopexy compared with transvaginal mesh surgery: a systematic review and meta-analysis. *BJOG* 2021;128:14–23.
55 Tran AHL, Liew D, Horne RSC, *et al*. Sociodemographic associations of geographic variation in paediatric tonsillectomy and adenoidectomy. *Sci Rep* 2021;11:15896.
56 Adams-Piper ER, Guaderrama NM, Chen Q, *et al*. Impact of surgical training on the performance of proposed quality measures for hysterectomy for pelvic organ prolapse. *Am J Obstet Gynecol* 2017;216:588.
57 Enklaar RA, Essers BAB, Ter Horst L, *et al*. Gynecologists' perspectives on two types of uterus-preserving surgical repair of uterine descent; sacrospinous hysteropexy versus modified Manchester. *Int Urogynecol J* 2021;32:835–40.
58 Anglim B, O'Sullivan O, O'Reilly B. How do patients and surgeons decide on uterine preservation or hysterectomy in apical prolapse? *Int Urogynecol J* 2018;29:1075–9.
59 Frick AC, Barber MD, Paraiso MFR, *et al*. Attitudes toward hysterectomy in women undergoing evaluation for uterovaginal prolapse. *Female Pelvic Med Reconstr Surg* 2013;19:103–9.
60 Schulten SFM, Essers B, Notten KJB, *et al*. Patient's preference for sacrospinous hysteropexy or modified Manchester operation: a discrete choice experiment. *BJOG* 2023;130:99–106.
61 Notten K, Essers BA, Weemhoff M, *et al*. Do patients prefer mesh or anterior colporrhaphy for primary correction of anterior vaginal wall prolapse: a labelled discrete choice experiment. *BJOG* 2015;122:873–80.
62 Hagen S, Stark D, Glazener C, *et al*. Individualised pelvic floor muscle training in women with pelvic organ prolapse (poppy): a multicentre randomised controlled trial. *Lancet* 2014;383:796–806.
63 Sivey P. The effect of waiting time and distance on hospital choice for English cataract patients. *Health Econ* 2012;21:444–56.
64 de Bekker-Grob EW, Ryan M, Gerard K. Discrete choice experiments in health economics: a review of the literature. *Health Econ* 2012;21:145–72.
65 Corazza I, Pennucci F, De Rosis S. Promoting healthy eating habits among youth according to their preferences: indications from a discrete choice experiment in tuscany. *Health Policy* 2021;125:947–55.
66 Nuti S, Vola F, Bonini A, *et al*. Making governance work in the health care sector: evidence from a " natural experiment " in Italy. *Health Econ Policy Law* 2016;11:17–38.
67 Black N. Patient reported outcome measures could help transform healthcare. *BMJ* 2013;346:bmj.f167.