Research Article

Pelvic Organ Prolapse Quantification Accuracy for Elongasio Cervix Diagnose in Pelvic Organ Prolapse Patients

Akurasi Pelvic Organ Prolapse Quantification untuk Diagnosis Elongasio Serviks pada Pasien Prolaps Organ Panggul

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Abstract

Objective: To know sensitivity, specificity and accuracy of Pelvic Organ Prolapse Quantification (POP-Q) to measure cervical length for cervical elongation diagnose in Pelvic Organ Prolapse (POP) patients with gold standard was the anatomical cervical length from hysterectomy result.

Methods: Diagnosis research, cross-sectional, consecutive sampling. POP-Q was taken before the operation and the anatomical cervical length was from hysterectomy result.

Results: Sixty six subject, 1.5% 2nd stage POP, 45.5% 3rd stage POP, and 53.0 % 4th stage POP. Mean (± sd) age and body mass index consecutively 59.88 years (± 9.347) and 24.41 (± 3.67) kg/m². Median (min-max) cervical length POP-Q and anatomy consecutively 4 cm (1-12) and 5 cm (3-10). Sensitivity, Specificity dan Accuracy POP-Q consecutively 79%, 58% dan 68%.

Conclusions: POP-Q has good specificity (79%) but with less sensitivity (58%) with accuracy 68% to diagnose cervical elongation in POP.

Keywords: accuracy, cervical elongation, cervical length, pelvic organ prolapse, pelvic organ prolapse quantification (POP-Q), sensitivity, specificity.

Abstrak

Tujuan: Untuk mengetahui nilai sensitivitas, spesifisitas dan akurasi Pelvic Organ Prolapse Quantification (POP-Q) untuk menilai panjang serviks sebagai diagnosis elongasio serviks pada pasien POP dengan baku emas pengukuran anatomi serviks dari hasil histerektomi.

Metode: Uji diagnosis, potong lintang, consecutive sampling. Data diambil dari pemeriksaan POP-Q dan pengukuran anatomi serviks dari hasil histerektomi.

Hasil: Enam puluh enam subjek, 1,5% POP derajat 2, 45,5% POP derajat 3 dan 53,0 % POP derajat 4. Rerata(± sb)usia dan Indeks Massa Tubuh (IMT) berturut – turut 59,88 tahun (± 9,347) dan 24,41 (± 3,67) kg/m2. Median (min-maks) panjang serviks POP-Q dan anatomi berturut – turut 4 cm (1-12) dan 5 cm (3-10). Sensitivitas, spesifisitas, dan akurasi POP-Q berturut – turut 79%, 58% dan 68%.

Kesimpulan: Pemeriksaan POP-Q memiliki spesifitas yang baik (79%) tetapi dengan sensitivitas yang kurang baik (58%) dan akurasi 68% untuk diagnosis elongasio serviks pada prolaps organ panggul.

Kata kunci: akurasi, elongasio serviks, panjang serviks, prolaps organ panggul, pelvic organ prolapse quantification (POP-Q), sensitivitas, spesifisitas.

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INTRODUCTION

Pelvic Organ Prolapse (POP) is defined as a decrease in the pelvic organs which results in protrusion of the vagina and/or uterus/cervix and can be classified as anterior, posterior, apical or vaginal vault prolapse.[1]Studies conducted by the Women's Health Initiative in 27.342 menopausal women get POP prevalence of 41.1% for women who still have a uterus and 38% in women who have no uterus [2] POP rarely causes severe disability or death, but usually causes symptoms that can affect a woman's daily activities and quality of life.[3]POP is one of the diagnosis for hysterectomy in post-menopausal women and counts in 15-18% of measures for all age groups. [4]

In one study it was found that about 40% of women with anterior component POP had cervical elongation with the age of CE patients relatively younger than POP patients.[5] Cervical Elongation (CE) is an extension or hypertrophy of the cervix towards the introitus with other uterine supporting tissues still in good condition.[6]Cervical elongation can occur in both parts of the cervix, supravaginal and vaginal. Elongation of the supravaginal cervix is found in 18% of patients with pelvic organ prolapse while the elongation of the vaginal cervix almost always occurs congenitally[7,8] Cervical elongation is associated as one of the causes of infertility in 5-10% of couples.[9] The presence of cervical elongation will affect the management of hysterectomy for POP. Consideration needs to be made to choose the vaginal or abdominal approach, supravaginal or total hysterectomy, whether or not the uterus is maintained, or the choice of the apical suspension chosen. Undiagnosed cervical elongation before surgery will make surgery more difficult and at risk of failing to overcome symptoms even with the apical component already supported in patients who have surgery by maintaining the uterus.[5,10-12] Cervical elongation is also one of the factors associated with high rates of prolapse recurrence after suspension of the sacrospinous ligament. [13]

Until now there has been no consensus regarding the definition of cervical elongation even though the diagnosis is already listed in the ICD X with the code n88.4. [14]. Diagnosed cervical elongation with the cervical anatomical length of 5.0 cm (mean ± 1.96 standard deviation n =

119).[15] These results are similar to those revealed at 5.51 cm (3.84 cm ± 0.786 n = 20)[16] also by 5.18 cm (3.2 cm ± 0.99 n = 39) .[17] Different results were obtained in took the benchmark for cervical elongation 3.38 cm, 5 cm and diagnosed cervical elongation clinically 8 cm. The absence of a clear definition of elongation of the cervix makes the prevalence and incidence of cervical elongation data also unknown. [18]

There are several ways to diagnose cervical elongation, including uterine sondase, bimanual examination, Pelvic Organ Prolapse Quantification System (POP-Q), Transvaginal Ultrasonography (TV US) and Magnetic Resonance Imaging (MRI). Examination of the uterine sondase can be used to measure the length of the uterocervical canal. One of the causes of extending the uterocervical canal (≥ 8 cm) is the elongation of the cervix.[19] Bimanual examination is performed by palpating the protruding length of the cervix, if the cervix extends to the middle of the vagina or more with a well-supported apical component, this can express an elongation of the cervix.[12] TV US or MRI examination costs quite a lot. POP-Q is a clinical examination method, does not require additional costs, has been standardized by the International Urogynecological Association (IUGA) and International Continence Society (ICS), and has good interobserver and intraobserver reliability regardless of the experience of the examiner.[20,21]The difference in the difference in values at points C and D is related to the length of the cervix where a more positive value at point C than point D indicates a cervical elongation which can be either symmetric or eccentric. [12]

Examined the correlation between POP-Q examination, transvaginal ultrasound and direct anatomical measurements of cervical length. POP-Q examination correlated well with anatomic measurements (r = 0.3, p = 0.005), whereas transvaginal ultrasound examination was less correlated with anatomical measurements (r = 0.19, p = 0.14).[15] The correlation between cervical length examination on the apical component of POP-Q examination and MRI examination found a good correlation (r = 0.41-0.59, p <0.0001).[5]

Until now there have been no studies that examine sensitivity, specificity and accuracy POP-Q examination in measuring cervical length to diagnose cervical elongation in pelvic organ

prolapse patients. In this study, our purpose was to know sensitivity, specificity and accuracy of POP-Q examination as index test to assess cervical length for cervical elongation diagnosis in POP patients with reference standard measurement of cervical anatomy from the results of hysterectomy. Our hypothesis was the measurement of cervical length using Pelvic Organ Prolapse Quantification has good (>75%) sensitivity, specificity and accuracy.

METHODS

This was a cross-sectional study. Subjects were women with POP scheduled for hysterectomy that came to urogynecology polyclinic at Dr. Cipto Mangunkusumo, Persahabatan, Fatmawati Hospital in Jakarta and District Hospital Tangerang with timeline of Januari 2016 – June 2018. Samples were collected by consecutive sampling. The Intended sample size was 80 subjects with α=5%, research precission 15% and disease prevalence was 40%.

The inclusion criteria were subjects with suspected having cervical elongation by uterine sound age ≥ 8 cm, POPQ C-D point difference ≥ 5 and cervical length from US TV > 4 cm. The exclusion criteria were incomplete data.

All subjects were had POP-Q examination as an index reference taken before surgery in polyclinic by trainee that has been certified to perform POP-Q or urogynecology consultant. All subjects also had anatomical cervical length measurement from hysterectomy specimen as an standard reference taken right after surgery (Either by direct measurement from dissected hysterectomy specimen (Distance from Internal Ostium internal to External Ostium Eksternum or indirect measurement from undissected

hysterectomy specimen (Distance from Isthmus to External Ostium Eksternum) by residents in operating theatre. Each measurement was conducted independently and blinded to the results of the other. Each measurement is a rounding of 0.5 centimeters. Time interval between the index test and the reference standard was varied. Diagnosed cervical elongation as standard reference was made by anatomical cervical length ≥ 5 cm.

Data were analyzed by 2x2 table to find out sensitivity, specificity and accuracy of POPQ. Data were processed with the help of Statistical Product and Service Solutions (SPSS) for Windows version 20.0.

RESULTS

From January 2016 to June 2018, 263 subjects with Pelvic Organ Prolapse that underwent elective surgery was collected. From there 92 subjects with elongation but 18 subjects underwent conservative surgery (not hysterectomy). Total population were 74 subjects with 8 subjects excluded due to incomplete data and 66 subjects available for analysis.
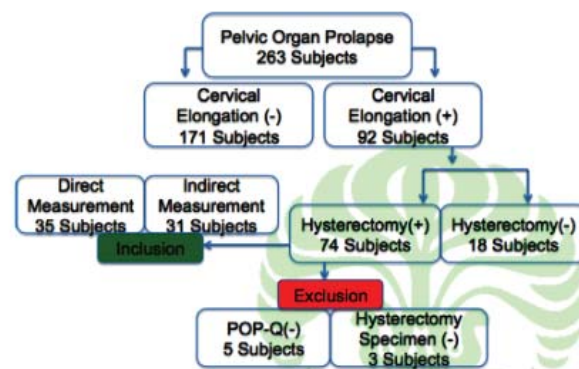

Figure 1. Flowchart of subject recruitment

Table 1. Categorical Data Characteristic

Variabel		n (%)	IK95%
Parity	Primiparity	4 (6.1)	3.3-11.8
	Multiparity	27 (40.9)	29.0-52.8
	Grandemultiparity	35 (53.0)	40.9-65.0
Obstetric History	Spontan	65 (98.5)	95.6-101.4
	Forcep/Vacum	1 (1.5)	1.4-4.4
	Caesarean	0 (0)	0
Body Mass Index	Underweight	2 (3.0)	1.1-7.1
	Normal	25 (37.9)	26.2-49.6
	Overweight	11 (16.7)	7.7-25.7
	Obesity	28 (42.4)	30.5-54.3
Menopause	Yes	48 (72.7)	61.9-83.4

	No	18 (27.3)	16.5-38.0
Medical Disability	Yes	21(31.8)	20.6-43.0
	No	45(68.2)	56.9-79.4
Hormonal History	Yes	4 (6.1)	3.3-11.8
	No	62 (93.9)	88.1-99.7
Smoking History	Yes	1 (1.5)	1.4-4.4
	No	65 (98.5)	95.6-101.4
Vaginal Discharge History	Yes	3 (4.5)	5.0-9.5
	No	63 (95.5)	90.5-100.5
Stage of POP	0	0 (0)	0
	1	0 (0)	0
	2	1 (1.5)	1.4-4.4
	3	30 (45.5)	33.5-57.5
	4	35 (53.0)	40.9-65.0
Cervical Elongation	Yes	33 (50)	37.9-62.0
	No	33 (50)	37.9-62.0

Most patients in this study with POP stage 3 or more, 45.5% (30 subjects) stage 3 POP and 53.0% (35 subjects) stage 4 POP and only 1.5% (1 subject) stage 2 POP. All patients underwent total vaginal hysterectomy and other reconstructive surgery for POP. When viewed from the predominant compartments of each POP, the dominant type of cystocele, uterine prolapse and symmetrical type were seen respectively, 6.1% (4 subjects), 47.0% (31 subjects), and 47.0% (31 subjects). There were no subjects with a prolapse type posterior component dominant.

Table 2. Numeric Data Characteristic

Variabel		Mean (s.d)	CI 95%	Median (min-max)
Age		59.88 (9.347)	57.58-62.18	
	Elongatio	58.58(9.135)	55.34-61.81	
	No	61.18(9.515)	57.81-64.56	
BMI		24.40 (3.675)	23.51-25.3	
CL POP-Q				4(1-12)
CL Anatomi				5(3-10)

The distribution numeric data of Cervical Length (CL) POPQ and Anatomy were abnormal and efforts to normalize the data are not successful, then the data is presented in the form of a median. While distribution numeric data for age and Body Mass Index (BMI) were normal, then the data is presented in the form of a mean respectively: 59.88 years (sd ± 9.347) and 24.4 (sd ± 3.675) kg / m^2.

Table 3. Table 2x2 of POPQ Accuracy for Diagnosis of Elongation of the Cervix in Pelvic Organ Prolapse Patients

		Reference (Hysterectomy)		
		Elongatio	No	Number
Index	Elongatio	19	7	26
(POPQ)	No	14	26	40
Number		33	33	66

Table 4. Analysis of POPQ Accuracy for Diagnosis of Elongation of the Cervix in Pelvic Organ Prolapse Patients

Parameter	P-value	n	CI 95% (Min-Max)
Sensitivity	0.58	33	0.41-0.75
Specificity	0.79	33	0.65-0.93
Positive Predictive Value	0.73	26	0.56-0.90
Negative Predictive Value	0.65	40	0.50-0.80
Positive Possibility Ratio	2.76	66	
Negative Possibility Ratio	0.53	66	0.41-0.65
Accuracy	0.68	66	0.57-0.79

Figure 2. Direct Measurement of Cervical Length(OUI – OUE)

Figure 3. Indirect Measurement of Cervical Length (Isthmus– OUE)

DISCUSSION

In this study, the number of subjects obtained was 66 people (82.5%) from the target of 80 subjects. The failure to achieve sample size is caused by several things, including rare cases of cervical elongation, hysterectomy is not the main choice of therapy for cervical elongation and examination of the length of the cervix using a ruler after hysterectomy according to the standards set by the researcher (uterus was dissected, and documentation) has not yet become a standard urogynecology procedure.

Although the number of samples in this study did not meet the minimum sample size set at the beginning of the study, the results in this study can still be used. This is because sensitivity and specificity in the 2 x 2 table are not too influenced by the sample size. The sample size only affects the accuracy rate in table 2 x 2. This is proofed in the initial analysis of the study with a sample of 41 subjects with 58% sensitivity, 80% specificity and 63% accuracy. After obtaining additional samples so that they reached 66 subjects, the sensitivity, specificity and accuracy respectively were 58%, 79% and 68%. This showed that sensitivity remains the same, specificity reduced but still good (> 75%) with an increased accuracy of 68%. Further research to obtain the minimum number of samples according to the calculation of the initial sample size is suggested in the hope of obtaining better accuracy.

Risk Factors of POP and Cervical Elongation

The exact cause of pelvic organ tissue losing its anatomical support and resulting in a decrease in pelvic organs into the vagina is still the subject of research. So that it is still thought the main cause is multifactorial with a variety of risk factors that have been studied, which are also examined in this study and presented the data in the form of numbers and percentages.

Obstetric factors such as parity and vaginal delivery are two things that are often studied and proven to be risk factors for POP. In this study it was found in the population of pelvic organ prolapse patients, most of 53.0% (35 subjects) had a history of grand multipara parity, followed by a multiparity of 40.9% (27 subjects) and primiparous 6.1% (4 subjects). Most 98.5% (65 subjects) gave birth vaginally with only 1 subject giving birth with the help of a tool. This is consistent with the study conducted involving 155 prolapse women from 1,964 women who underwent physical exams per 1 birth 1.2 (1.1-1.4) and vaginal delivery OR 2.9 (1.2 - 7.2). [22]

Lifestyle factors such as higher body mass index as categorical variables are real risk factors for POP. In this study, most subjects were 59.1% (39 subjects) had a higher body mass index (overweight and obesity) compared to 37.9% (25 subjects) with a normal body mass index and 3.0% (2 subjects) with a lack of body mass index (underweight). This is in accordance with Italian Study Group involving 410 prolapsed women from a total sample of 21,449 women who performed an examination obtained OR 1.6 (1.2-2.2) for BMI 23.8 - 27.2 while for BMI> 27.2 OR 1.8 (1.3 - 2.4)[13]

The status of menopause shows a tendency towards a positive relationship with POP. In this study, most POP patients were already in menopause 72.7% (48 subjects) compared to 27.3% (18 subjects) who still gets menstruation. This is consistent with research that states that menopausal women are at risk for POP with OR 1.3 (0.9 - 1.9). [23]

Medical complications such as constipation and lung disease are not significantly associated with POP.[24]This is in accordance with the results of this study which found that most of the 68.2% (45 subjects) in POP patients did not have medical complications and only 31.8% (21 subjects) with medical complications.

The history of hormonal drug use in this study was only found in 4 subjects (6.1%) out of 66 total subjects. History of use of hormonal drugs is considered because in the study conducted, It was stated that patients with cervical elongation had more estrogen and progesterone receptors than patients with normal cervices. [18]

The history of smoking in this study was only found in 1 subject (1.5%) of the total of 66 subjects. The history of smoking is thought because cigarette smoke can inhibit the peptidyl lysine oxidase enzyme. Where the enzyme is needed to unite the dominant type I and III collagen as connective tissue in the cervix. The absence of the peptidyl lysine oxidase enzyme will naturally cause collagen matrix metalloproteinase splitting, causing the cervix to lose its supporting tissue.[18]

There is a hypothesis about the mechanism of cervical elongation in the vaginal part where there is chronic congestion which results in hyperplasia and hypertrophy of the fibromusculoglandular component. This leads to the enlarged and narrowed part of the vagina. Additional infections make the emergence of fluid from the ulcer which can be a whitish, purulent liquid to blood. [25]In this study most subjects (95.5%, 63 subjects) did not experience vaginal discharge. This can be

caused by the elongation that occurred in this study mostly supravaginal.

In this study, the age of pelvic organ prolapse subjects who experienced cervical elongation had a younger average (mean 58.58 sb 9,135) compared to women who had pelvic organ prolapse alone (mean 61.18 sb 9,515). This is consistent with the study. But in contrast to the study which stated that there was no age difference between elongated patients and those who did not. [5,18]

Pelvic Organ Prolapse Quantification Accuracy for Elongasio Cervix Diagnose in Pelvic Organ Prolapse Patients

This study was the first study to look for sensitivity, specificity, and accuracy of POPQ examination for the diagnosis of cervical elongation in pelvic organ prolapse patients. Previous research was limited to the conformity test between the length of the cervix measured using POP-Q, US, MRI and hysterectomy specimen. [5,15]

In this study, there were 33 POP patients with cervical elongation and 33 POP patients without cervical elongation. The results of the 2 x 2 table analysis revealed that POPQ examination had good specificity (79%) to diagnose cervical elongation in pelvic organ prolapse patients but with poor sensitivity (58%) and 68% accuracy.

Because this study is a diagnostic study, the value of good specificity (79%) indicates that POPQ examination can be used to diagnose cervical elongation in pelvic organ prolapse patients. In clinical practice, this is especially beneficial in pelvic organ prolapse patients who are planning conservative surgery therapy (maintaining the uterus). In patients with pelvic organ prolapse with POPQ examination does not show elongation of the cervix, the examiner can be sure that the patient does not experience cervical elongation so that the operative actions performed on patients with pelvic organ prolapse with conservative surgery therapy can still be carried out without additional action generally performed on patients with elongation cervix such as amputation of the cervix.

While poor sensitivity (58%) must cause caution for the examiner in deciding good operative actions on the patient. In pelvic organ prolapse patients with POPQ examination showing cervical elongation, cervical elongation can not be found in 42% of patients. So that in patients when planned for operative action related to the cervical elongation such as cervical amputation alone, it should be explained the possibility of a repeat examination at the time of the patient under anaesthesia, and the possibility of surgery to extend to removal of the uterus if it is found that elongation of the cervix is not found.

The results of accuracy of 68% showed the accuracy of POPQ to correctly diagnose cervical elongation in patients with pelvic organ prolapse by 68%. In clinical practice, this is useful in preparing operators, related to the difficulties that will be faced when performing TVH surgery in patients with cervical elongation, example the presence of remote peritoneal access in 68% of patients diagnosed with cervical elongation from POPQ examination.

Cervical length measurement by POPQ as a CD point difference can be done as a standard examination because based on numerical comparative analysis t paired test 2 groups repeated measurements of abnormal data distribution of Wilcoxon, the results of examination of POPQ cervical length compared with the results of examination of anatomic cervical length showed no significant differences (p 0.076) with a difference of 1,777. This is different from the research conducted which obtained mean POPQ cervical length (5.6 ± 2.91) compared to anatomical cervical length (3.2 ± 0.99) after being compared with paired t-test showed a significant difference (p <0.0001).[17] This can be caused because the sample in this study is more homogeneous (prolapsed patients with cervical elongation plan to have surgery vs all prolapsed patients who will be operated either with elongation or without elongation) and different measurement methods (measurement of anatomic length from results of surgery vs measurement results anatomical length of pathological specimens).

Although POP-Q is considered the standard of examination of POP patients, its ability to correctly estimate preoperative cervical length is limited, along with the large stage of prolapse. It was

stated that the suitability of the cervical length that was measured preoperatively with POPQ with the measured cervical length postoperatively from the hysterectomy specimen decreased with increasing stages of prolapse. From the preoperative cervical length in the study 56.93% were found in the agreed-upon conformity range ± 2 cm but only 36.4% were different ± 1 cm. [26]In this study prolapse stage was found most at stage 4 (53.0%) and 3 (45.5%). This can be one explanation of the low sensitivity and accuracy of POPQ for the diagnosis of cervical elongation in POP patients in this study. Further research was suggested on prolapse stage two and more.

POPQ examination can be used in general to predict the length of the cervix but cannot provide a definite number. It is possible for anatomical differences in the length of the cervix to be measured with POPQ from the C-D point and measurement of the cervical length from the internal uterine os to the external. This can be caused by the use of point C in POPQ as the most distal part of the cervical part of the vagina, which may add C length significantly while actually not entering the cervical canal. Furthermore, anatomical variation from the cervical portion of the relationship angle to the vaginal axis can cause a marked variation in point C, which may not be measured anatomically after hysterectomy. [15]

The reduced ability of POPQ to detect elongation of the cervix along with the large stage of prolapse is thought to be due to changes in point D from the proximal position to a more distal position so that examination of POPQ cervical length is below estimates in patients with advanced POP. [26] In the original description of the POPQ system, point D is defined as an attachment to the sacrouterine ligament to the proximal cervix. In patients with severe stage prolapse, the sacrouterine ligament changes depending on the stage of prolapse. The sacrouterine ligament may still depend on the position of the cervix, but it may be that the site of attachment is no longer exactly where we are measuring the D point. In other words, measured from the posterior cul de sac in patients with a changed sacrouterine ligament may not reflect the proximal cervix, making estimates of the length of the cervix inaccurate. [17]

Measurement of the stage of POP with POPQ has been known to be different if POPQ is examined when the patient is in the clinic and before surgery when the patient is under anaesthesia. It was found that Bp, C and D points were significantly more prolapsed when preoperatively measured in anaesthesia than when in the polyclinic. As for points Aa, Ap and Ba are not very influential. Some explanations of these differences include the effect of anesthesia, the effect of traction on anesthesia compared to the valsalva maneuver in the polyclinic, the long-time measurements (average of 3 months from patients in the polyclinic to surgery) and measurement variability. An explanation of the effects of anesthesia is that both regional and general anesthesia are known to relax pelvic floor muscles so as to provide less resistance to the decline of pelvic floor organs. [27]

The POPQ examination in this study was carried out by trainees who had been validated beforehand to do POP-Q and / or by urogynecology consultants in multicenter hospitals. We did not examine POP-Q examinations based on individuals who examined. Although the interobserver and intraobserver bias for POPQ assessment is low, not depend from the experience of the examiner and has good reproducibility research, differences can still be possible in daily practices that cannot be generalized.[28]

The strength of this study is that the research was conducted in a multicentre hospital. Data for anatomical cervical length was taken from uterus right after the hysterectomy procedure. The uterus can be positioned slightly in accordance with the conditions in the body with the hanging ligament so that the length of the cervix is more suitable. The examination is also carried out before the tissue is fixed into formalin solution and sent to the anatomical pathology section. Data on the percentage of tissue shrinkage in gynaecological specimens after exposure to formalin is limited. However, in a study that specifically looked at cervical tissue, the shrinking rate of the formalin specimens was around 2.7%.[26] Until now there is no standard or clinical practice guide for diagnosing elongation of the cervix. The existence of this study can be used as a guideline for the operation of POP patients to assess whether there is a cervical elongation with POPQ examination.

The weakness in this study was POPQ measurement had varied experience ranges and were not carried out by inter-observer reliability or intra-observer reliability. From the data taken by indirect measurement method from specimen photographs, the identification of the researcher with the isthmus can be subjective and affect the measurement results.

In this study there were no adverse events from performing the index test of the reference standard. There were no parties involved in financing this research. This research already has ethical approval from the Medical Faculty University as Indonesia.

CONCLUSIONS

POPQ examination has good specificity (79%) to diagnose cervical elongation in pelvic organ prolapse patients but with poor sensitivity (58%) and 68% accuracy.

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