P R A C E   O R Y G I N A L N E

położnictwo

Intra- and inter-observer variability of evaluation of uterine cervix elastography images during pregnancy

Zmienność wyników uzyskanych przez różnych badających i przez tego samego badającego w ocenie obrazów elastograficznych szyjki macicy ciężarnej

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Abstract

Objectives: *To evaluate reproducibility and repeatability of the assessment of elastography images of the uterine cervix using an Elastography Index.*

Material and methods: *Elastography images of the uterine cervix were obtained. Numeric scale called Elastography Index, previously published by the authors, was used to describe parts of the cervix. A total of 282 images were evaluated twice by an experienced and twice by an inexperienced operator.*

Results: *Reproducibility and repeatability of the evaluation of internal and external os and cervical canal were over 90%. Inter-assay coefficient of variation was 1.84%, 6.76% and 7.27% respectively, and 5.84% for anterior and 16.74% for posterior wall. Analysis of the second evaluation only of both operators revealed no significant difference for posterior wall as well (F-test; p=0.09).*

Conclusion: *Authors proved satisfactory reproducibility and repeatability of subjective assessment of elastography images of uterine cervix during pregnancy with the use of Elastography Index in the hands of experienced and inexperienced observer.*

Key words: **elastography** / **reliability** / **repeatability** / **reproducibility** / **uterine cervix** /

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Streszczenie

Cel pracy: *Ocena zmienności między badaczami i odtwarzalności oceny obrazów elastograficznych szyjki macicy ciężarnej przy użyciu Indeksu Elastograficznego.*

Materiał i metody: *W trakcie badania ultrasonograficznego szyjki macicy wykonywano dodatkowo zdjęcia elastograficzne. Do opisania uzyskanych zdjęć używano skali liczbowej opublikowanej wcześniej przez autorów nazwanej Indeksem Elastograficznym (EI). Każda z dwóch osób biorących udział w badaniu (jedna doświadczona w użyciu EI, jedna używając tej skali po raz pierwszy) dwukrotnie oceniła 282 zdjęcia.*

Wyniki: *Zmienność między oceniającymi nie przekraczała 10%, odtwarzalność była wyższa niż 90% dla ujścia wewnętrznego, środkowej części kanału szyjki i ujścia zewnętrznego. Zmienność między badaczami (inter-assay Coefficient of Variation – CV) wynosiła odpowiednio 1,84%, 6,76% i 7,27%, oraz 5,84% dla przedniej wargi szyjki macicy i 16,74% dla tylnej wargi szyjki macicy. W analizie obejmującej tylko drugą ocenę każdego z badających nie wykazano różnic istotnych statystycznie pomiędzy badaczami również w ocenie tylnej wargi szyjki macicy (test F; p=0,09).*

Wnioski: *Autorzy udowodnili zadowalająco niską zmienność między badaczami oraz satysfakcjonującą powtarzalność oceny obrazów elastograficznych szyjki macicy ciężarnej przy użyciu Indeksu Elastograficznego zarówno u osoby doświadczonej jak i dokonującej oceny po raz pierwszy.*

Słowa kluczowe: **elastografia** / **wiarygodność** / **powtarzalność** / **odtwarzalność** / / **szyjka macicy** /

Introduction

Ultrasound elastography has been presented as a new method of evaluating differences in tissue stiffness, allowing for a successful assessment of changes in cervical consistency before delivery [1-12].

The Elastography Index, a five-step numerical scale designed and published by Swiatkowska-Freund to describe areas of the cervix, enables a comparison of the results obtained in different patients or in the same patient at time intervals [11]. As in the case of every new method, intra- and inter-observer variability in image evaluation should be assessed to confirm reproducibility and repeatability of the generated scores.

Repeatability is an agreement between independent results obtained with the same method on identical test material and under the same conditions, whereas reproducibility is considered when conditions are different [13]. The two terms are used to measure the performance of a selected method of examination – good tests are characterized by good indices of reproducibility and repeatability.

Objectives

The aim of the study was to determine the reproducibility and repeatability of cervical consistency evaluation performed with the use of the EI by two independent observers.

Material and Methods

Images of the cervix using B-mode ultrasound in the sagittal section (Figure 1) were obtained with the use of a transvaginal probe (4-9Mhz). Dual mode displaying B-mode and elastogram was enabled. Elastography images of the uterine cervix were obtained using Elastoscan software in Medison Accuvix V10, color map number 2 coding hard as purple, soft as red (Figure 2). No pressure was applied to the cervix as arterial pulsation and breathing movements produced sufficient strain within the cervix to generate an image.

The image was deemed to be of good quality when:

1. the cervix occupied at least 1/3 of the image area;
2. the internal and external os and cervical canal were visible in B-mode;
3. amniotic fluid and urine were coded as red, if visible, fetal scull as purple, if visible.

A numeric scale (0 – purple, 1 – blue, 2 – green, 3 – yellow and 4 – red) was used [9-11]. The internal os was defined as a round area of 3 mm in diameter, free of amniotic fluid or fetal parts; the external os – area of the same size, not including the vaginal wall; the cervical canal as the softest part of the canal excluding orifices and walls of the cervix as the softest part of them.

The images were evaluated by assigning EI scores to each part of the cervix to determine their maximum softness values. A total of 282 images were evaluated twice by an experienced operator (MSF), at a one-week interval at least. Then, an inexperienced operator (ZP) was instructed once how to assess the elastogram and evaluated the same images twice as well.

The images were taken from 89 patients of the Department of Obstetrics, Medical University of Gdansk, between 16 and 42 weeks of gestation. The Local Ethics Committee approved of the study protocol. All participants were scanned every time there was an indication for a vaginal examination but with no particular indication for an ultrasound assessment of the cervix. Both operators performed the second evaluation of the images seven days after the first assessment to blind themselves to their first analysis.

The results were recorded in Microsoft Office 2010 Pro Excel Worksheet. Variability in points and Coefficient of Variation (CV) and repeatability (100%-CV) of the cervix evaluation were calculated using Statistica 7.0.

Results

In a cohort of 282 images, all of the designated parts were described using the EI twice by both operators, with no missing data. The EI values were not normally distributed. Medians and Standard Deviations of the EI are presented in Table I.

Table II presents inter-assay CV for every part of the cervix.

Table I. EI values for different parts of uterine cervix – Standard Deviations for all the evaluations together and separately for each observer.

Part of the cervix	Median	SD	SD for MSF	SD for ZP
Internal os	1	1.17	1.15	1.19
Cervical canal	1	1.36	1.34	1.36
External os	1	1.33	1.34	1.32
Anterior wall	1	1.02	1.02	1.03
Posterior wall	1	1.02	1.09	0.93

SD – Standard Deviation; MSF – first operator; ZP – second operator

Table II. Inter-assay coefficient of variation of EI for parts of the uterine cervix.

Part of the cervix	Variability (points)	Coefficient of Variation (%)
Internal os	0,10	1,84
Cervical canal	0,49	7,27
External os	0,44	6,76
Anterior wall	0,29	5,84
Posterior wall	0,78	16,74
TOTAL	**0,37**	**8,92**

Table III. Difference in EI distribution for the first (MSF) and second (ZP) operator.

Part of the cervix	F-test for MSF	F-test for ZP
Internal os	0.75	0.01
Cervical canal	0.70	0.86
External os	0.97	0.79
Anterior wall	0.39	0.18
Posterior wall	0.67	0.08

Table IV. Difference between operators in EI distribution for the first and second series.

Part of the cervix	F-test for first series	F-test for second series
Internal os	0.12	0.49
Cervical canal	0.91	0.76
External os	0.89	0.66
Anterior wall	0.33	0.21
Posterior wall	0.0001	0.09

Images which generated discrepant interpretations were analyzed to uncover reasons for diverse opinions of both operators. The cause turned out to be different interpretations of the definitions of the cervical areas to be assessed, e.g. incorporating amniotic fluid funneling to the cervical canal into the region evaluated as the internal os resulted in an increase of the EI score assigned to that part of the cervix (amniotic fluid is always soft with EI=4). The biggest differences were found in defining the posterior wall (Figure 3).

F-test comparing results number 1 and number 2 for each operator was performed. Differences in result distribution for the experienced operator (MSF) were not significant for all cervical areas. The p-value for the inexperienced operator (ZP) was significant only for the first evaluation of the internal os (p=0.01), and was not significant for other areas (Table III).

The F-test was performed also to compare first evaluations of MSF and ZP. The p-value was not significant, except for the posterior wall (p=0.0001), confirming the above mentioned problems with defining the area of the posterior wall.

The analysis of the second evaluation of both operators revealed no significant differences, suggesting improved performance of ZP (Table IV).

Discussion

The uterine cervix undergoes changes leading to delivery at the end of pregnancy. Its stiffness decreases before labor, and the Bishop score is the tool for subjective assessment of the cervical ripening [14]. Cervical maturation is a sign of threatened preterm delivery (if observed too early in pregnancy), or a sign of approaching labor (if observed at term). The Bishop score, as a subjective feature, is very difficult to interpret and its predictive value is limited. Introduction of the ultrasound measurements of the internal os dilatation and cervical canal length increased the sensitivity and specificity of prediction of preterm delivery and success of labor induction, but it is still far from ideal [15-19].

Elastography may help to evaluate the consistency of the cervix and has a positive correlation with labor induction success [8-12]. Every diagnostic tool ought to be reliable and reproducibility of each new method should be studied to prove it is fully repeatable [20].

Analyses of the repeatability of evaluation of the Elastoscan image of the uterine cervix during pregnancy with the use of EI, generated satisfactory results, with the exception of the posterior wall. Results for the other areas of the cervix had CV of <10% – a value accepted by most clinicians.

Assessment of the same images by the experienced operator revealed no unacceptable variations between the first and second evaluation. A learning curve was suggested in the two series of evaluations performed by the inexperienced operator. After the initial problems with defining the internal os area and assigning 4 points of EI in cases where the amniotic fluid was present in funneling of the cervical canal, the second series evaluations were similar to the results of the experienced operator.

Conclusions

The results of our study suggest that EI is a tool which can be easily applied, even by sonographers unfamiliar with this new method of visualization [9-11]. Also, it does not require a long training to be reliable. Discrepancies between EI scores assigned in the independent assessments resulted from differences in the identification of the cervical parts. Thus, assessment of the B-mode image of the cervix by the operator is essential in the EI evaluation, similarly to the measurements of the internal os and cervical canal. The question how to define the evaluated area of the cervix to achieve the best results in predicting preterm delivery and cervical maturity at term remains to be addressed by future studies.

Oświadczenie autorów

1. Małgorzata Świątkowska-Freund – autor koncepcji i założeń pracy, wykonanie części badań, przygotowanie manuskryptu i piśmiennictwa, przechowywanie dokumentacji –autor zgłaszający i odpowiedzialny za manuskrypt..
2. Zofia Pankrac – wykonanie części badań, zebranie materiału, analiza statystyczna wyników.
3. Krzysztof Preis – współautor założeń, interpretacja wyników, współautor tekstu pracy, korekta i akceptacja ostatecznego kształtu manuskryptu.

Figure 1. Image of uterine cervix in B-mode.

Figure 2. Elastography of uterine cervix with cervical canal and both orifices softer than cervical walls.
A – internal os (red, Elastography Index = 4 points)
B – external os (red, Elastography Index = 4 points)
C – cervical canal (from blue to yellow, Elastography Index = 3 points)
D – anterior wall of the cervix (purple, blue and yellow, Elastography Index = 3 points)
E – posterior wall of the cervix (purple and blue, Elastography Index = 2 points)
Difference in stiffness of cervical parts is visualized as different colors in elastography. Elastography Index is evaluated as the color representing the softest tissue visible in the chosen part of the cervix.

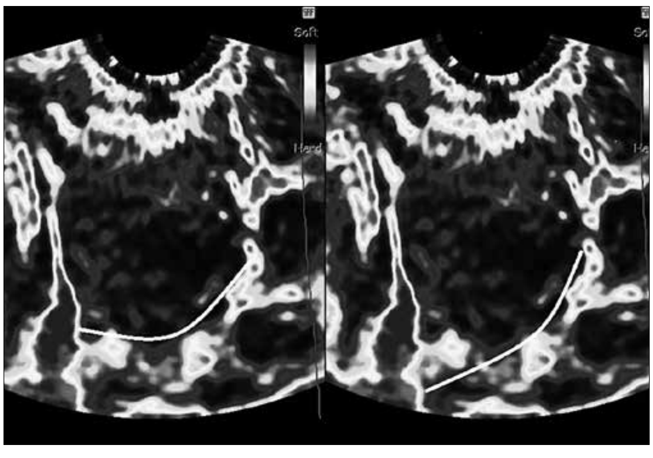

Figure 3. Posterior wall of the uterine cervix defined by two operators.
White lines define posterior outlineation of posterior wall of the cervix. In the image on the right it included the yellow patch into the posterior wall, in the image on the left it was excluded.

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Autorzy nie zgłaszają konfliktu interesów oraz nie otrzymali żadnego wynagrodzenia związanego z powstawaniem pracy.

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