CEOG Clinical and Experimental Obstetrics & Gynecology

Cervical breaking point; a phenomenon unveiled during continuous controllable balloon dilatation

P. Arsenijevic[1], A. Zivanovic[1], Z. Protrka[1], A. Dimitrijevic[1], M. Sorak[1], T. Vulovic[2], G. Vukcevic Globarevic[4], Z. Vilendecic[3], B. Andric[1], S. Arsenijevic[1]

[1]Department of Gynecology and Obstetrics, [2]Department of Anesthesiology and Reanimation, Faculty of Medical Sciences, University of Kragujevac, Kragujevac; [3]Department of Gynecology and Obstetrics, School of Medicine, University of Belgrade, Belgrade (Serbia); [4]Department of Gynecology and Obstetrics, Medical Faculty, University of Podgorica, Podgorica (Montenegro)

Summary

Introduction: Based on the characteristics of the internal cervical os and the cervix as a whole, during continuous controllable balloon dilatation, it can be said that the uterine cervix behaves as a sphincter, although it does not have the anatomical structure of a sphincter. *Material and Methods:* The system for continuous and controllable balloon dilatation is based on the hydraulic balloon dilator. The main advantage of the continuous and controllable balloon dilatation is that it provides the physician with the ability to monitor and control the process of cervical dilatation. This study included 42 patients, in whom the dilatation process was monitored and analysed prior to the termination of an unwanted pregnancy. Statistical analyses were performed using SPSS software. A normal distribution of continuous data was tested using the Kolmogorov-Smirnov test. The correlation between observed parameters was analysed using Pearson's and Spearman's correlation coefficients. *Results:* During dilatation with continuous and controllable balloon dilatation system, a sudden drop in pressure and volume of the fluid in the balloon extension occurred. This phenomenon was labelled as the breaking point of the cervix, or the point when the cervix stops resisting dilatation. There was no statistically significant correlation between the cervical breaking point and the number of previous births or the number of previous miscarriages or abortions. *Discussion:* The uterine cervix behaves as a sphincter during continuous and controllable balloon dilatation, which is verified by the existence of a cervical breaking point. The breaking point values did not vary with the number of previous cervical dilatations, whether artificial or physiological.

Key words: Continuous controllable balloon dilatation; Uterine cervix; Cervical breaking point.

Introduction

Anatomically, the cervix is part of the uterus, but functionally, it is a separate organ. The uterine cervix is primarily a barrier between the environment and internal genital organs. During pregnancy, the main role of the cervix is to keep the fetus inside the uterine cavity until birth, at which time it becomes a part of the delivery path [1, 2]. Therefore, the structural integrity of the uterine cervix is crucial for pregnancy maintenance and prevention of miscarriage [3, 4]. The integrity and mechanical properties of the uterine cervix derives from its extracellular matrix, constructed of a dense network of collagen fibres immersed in proteoglycans. The majority, 75%, of the uterine cervix, is composed of collagen and other connective fibres, while the remaining consists of smooth muscle cells and fibroblasts that secrete the extracellular matrix [5, 6]. The concentration of collagen fibres is constant along the cervical canal, while that is not the case with smooth muscle cells. In the external cervical os zone, muscle fibres are scattered and rare, while in the internal cervical os zone, they are packed into circular layers. The concentration of elastic fibres also decreases from the internal to the external cervical os, suggesting functional differences between the two ends of the cervix [7-9]. The centre of cervical resistance to dilatation, either natural or artificial, is located in the zone of the internal cervical os [10]. Based on the characteristics of the internal cervical os and the cervix as a whole, during dilatation, it can be said that the uterine cervix behaves as a sphincter, although it does not have the anatomical structure of the sphincter. Through the present research using the continuous and controllable balloon dilatation (CCBD) system, the authors attempted to demonstrate the sphincter-like quality of the uterine cervix.

Materials and Methods

This research was conducted at the Gynaecology and Obstetrics clinic, Clinical Centre Kragujevac, Serbia. A total of 42 patients, who desired the termination of an unwanted pregnancy were enrolled in the research using the following criteria: age between 18 and 42 years, pregnancy was verified by an ultrasound, vital pregnancy, gestational age ≤ 10 weeks, uterus and cervix with normal findings, and absence of uterine contractions or bleeding. The study was approved by Ethical Committee of the Clinical Centre,

Revised manuscript accepted for publication June 1, 2017

7847050 Canada Inc.
www.irog.net

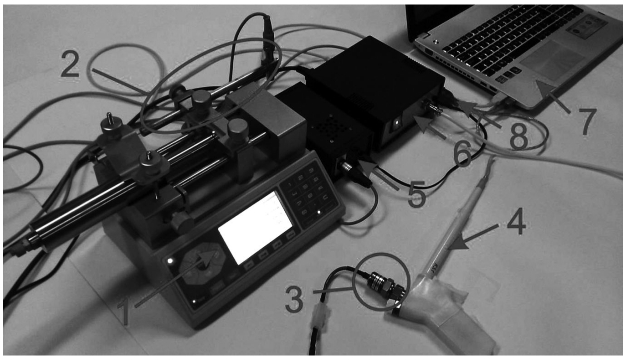

Figure 1. — System for continuous controllable balloon dilatation (CCBD). 1) Hydrostatic pump. 2) Motion sensor. 3) Pressure sensor. 4) Dilatation device. 5) Driver for pressure sensor 6) Acquisition card. 7) Laptop. 8) USB to PC converter.

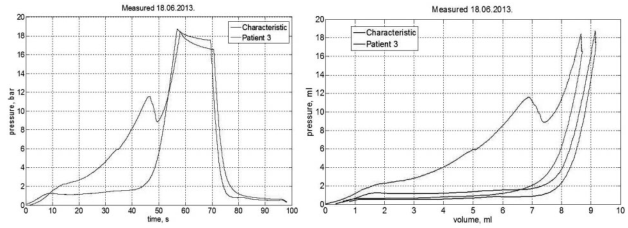

Figure 2. — Dilatation curves (DC). Blue DC: default curve of the dilatation process, green DC: curve obtained during dilatation of the cervix using CCBD. The graph on the left (a) shows the pressure change, while the graph on the right (b) shows the changes in the volume of balloon extension during the course of dilatation.

Kragujevac, Serbia (number of approval 01-4169). The experiments were undertaken with the understanding and appropriate informed consent of each patient. Before each experiment, the cervical dimensions (length, AP, and LL diameter) were determined by ultrasound and a medical history regarding previous births (by vaginal delivery) and abortions was gathered from every patient.

Dilatation of the cervical canal before suction and curettage was achieved by the CCBD system. The CCBD is a relatively new method of cervical dilatation based on the hydraulic balloon dilator. [11] CCBD is made of several interconnected hardware and software units which allow dilatation and real time monitoring of parameters (Figure 1). The basic elements of the CCBD system are as follows: (1) high pressure syringe hydrostatic pump with module for managing and monitoring operating parameters and execution of the dilation process, (2) linear variable differential transformer - LVDT motion sensor, (3) pressure sensor, (4) balloon dilator, (5) LVDT electronic unit (LVDT driver), (6) a data acquisition card and an integrated module for the analogue conversion of pressure into a voltage, (7) PC for control and data acquisition, and (8) a USB to RS_{232} port converter. A syringe hydrostatic pump type is shown in Figure 1; it is made of stainless steel for sterilization and allows for the filling of the balloon dilator with working fluid, which in this case was distilled water. The maximum allowable dilation pressure determined by the capacity of the hydrostatic pump as prescribed by the manufacturer is 20 bar, while the highest diameter of the balloon extension is 11 mm, achieved when the cervical canal is dilated. The pressure of the working fluid and the position of the piston hydro cylinder were monitored using a pressure sensor (3) and motion sensor (2). Signals obtained from these two sensors to the PC for managing and monitoring (7) are transmitted over the LVDT driver (5) and data acquisition card (6), whose function is to convert the resulting analogue signal into a digital signal. A specially developed software application was used to process the digital signals and parameters in real time following dilation. Also, a special software application called dilation curves (DC) were developed to manage the dilation process. The DC was developed using the programming language C#. The application has the ability to monitor the dilation process in real time by controlling the given mode of dilation.

Statistical analyses were performed using SPSS software version 22. All the data were numerical. A normal distribution of continuous data was tested using the Kolmogorov-Smirnov test. The correlation between observed parameters was analysed using Pearson's (parametric data) and Spearman's (non-parametric data) correlation coefficients. A linear regression model was used to determine predictors of cervical breaking point (CBP). A p value < 0.05 was required to reject the null hypothesis.

Results

Every experiment consisted of cervical dilatation using CCBD prior to suction and curettage. In each experiment, dilatation lasted 100 seconds with the breakdown as follows: the balloon filling lasted 60 seconds, the plateau 20 seconds, and discharging of the balloon extension lasted 20 seconds. Figure 2 shows graphs of the process of cervical dilation CCBD, or DC.

As seen in the DCs, there was a sudden drop in pressure and volume values in balloon extension, followed by a large increase in the maximum values. The sudden drop was labelled as the CBP, and it represented the moment when the cervical resistance to dilation ceased. The CBP values varied from 0.081 to 2.181 Joules (J), with an average of 0.641 ± 0.411 J. There was no statistically significant correlation between the CBP values and the number of previous births, miscarriages or abortions (Table 1). Furthermore, a significant correlation was not found between the CBP values and cervical dimensions, measured prior to dilatation. There was a positive statistical correlation between CBP values and the amount of energy required, as the values of CBP increased with the increase in the amount of energy required to achieve cervical dilatation (Tables 1 and 2). On the other hand, a multivariate linear regression analysis showed a statistically positive correlation between the values of CBP and the number of previous miscarriages ($p = 0.043^{B}$; B- standardized coefficient). On the basis of this result, the authors reached the controversial conclusion that patients with a higher number of previous miscarriages will have higher CBP values, which indicates that they will have a stronger response to cervical dilatation than patients without a history of previous miscarriages.

The charted area between two dilatation curves repre-

Table 1. — *Correlation between amount of energy required and other parameters of cervical dilatation.*

	Energy required	Significance
Number of births	ρ= -0,294	^{c}p = 0.062
Number of miscarriages	ρ= 0.063	^{c}p = 0.698
Number of abortions	ρ= -0.026	^{c}p = 0.872
Cervical length	r= -0.118	^{b}p = 0.463
Cervical LL diameter	r= -0.112	^{b}p = 0.486
Cervical AP diameter	r= -0.142	^{b}p = 0.377
Cervical breaking point	r= 0.397	^{b}p = 0.017*

*[b]Pearson correlation coefficient; [c]Spearman correlation coefficient. *p<0,05.*

Table 2. — *Correlation between the cervical breaking point and other parameters*

	Cervical breaking point	Significance
Number of births	ρ = -0.319	^{c}p = 0.058
Number of miscarriages	ρ= 0.221	^{c}p = 0.195
Number of abortions	ρ= -0.020	^{c}p = 0.907
Cervical length	r= -0.066	^{b}p = 0.701
Cervical LL diameter	r= -0.210	^{b}p = 0.220
Cervical AP diameter	r= -0.189	^{b}p = 0.270
Spent work	r= 0.397	^{b}p = 0.017*

*[b]Pearson correlation coefficient; [c]Spearman correlation coefficient. *p<0,05.*

sents the amount of energy required to achieve cervical dilatation. The minimal amount of energy required to achieve cervical dilatation was 2.736 J, while the maximum was 5.724 J with an average of 4.365 ± 0.787 J. There was no statistically significant correlations between the amount of energy required for cervical dilatation and number of previous births, or the number of miscarriages and abortions (Table 2). Also no significant correlation was found between the values energy required and the cervical dimensions. As mentioned before, the only statistically significant correlation was between the values of the CBP and amount of energy required to achieve cervical dilatation (Tables 1 and 2).

Discussion

The main role of the sphincter is to open and control the passage between two organs, or between an organ and the environment [12, 13]. Sphincters are constructed predominantly of smooth or skeletal muscle fibres and arranged transversally on the organ passage, while connective fibres are scarce and used only as suspension [14-16] As a result, sphincters can contract or dilate many times and always return to their original state.

Strictly anatomically, the uterine cervix as well as the tissue organization, are not like any other known sphincter in the human body. Observation of the cervix during physiological, and especially artificial, dilatation with CCBD led the present authors to believe that the uterine cervix behaves like a sphincter. The biophysical aspects of artificial cervical dilation, as opposed to natural dilation during childbirth, have not been sufficiently investigated, and the literature is limited. Research conducted by Petersen *et al.* on the cervical tissue samples obtained from non-pregnant women showed that cervical resistance to stretching is passive and directly proportional to the concentration of collagen fibres [17-19]. This indicates that the uterine cervix resists dilatation only to the point at which its specific structure is not disturbed and it can return to its original state. The purpose of this research was to determine that breaking point. CBP is defined as a sudden drop in pressure and volume in balloon extension, followed by a rapid increase to the maximum values, as can be seen in the results.

Statistical analysis showed only a positive correlation between CBP and the amount of energy required, while there was no significant correlation between the two parameters of cervical resistance and the number of previous births, miscarriages or abortions. There was also a somewhat controversial result from the multivariate linear regression analysis that demonstrates a statistically positive correlation between the CBP values and the number of previous miscarriages. These results are in direct conflict with previous results of studies concerning cervical resistance during artificial dilatation. Research conducted by Kiwi *et al.*, using specially designed balloons for cervical dilatation, showed that the elastic properties of the cervix decline with the number of previous miscarriages [20, 21]. Similar results were reached by Anthony *et al.* while trying to determine the cervical resistance index (CRI) in a patient with a history of miscarriages. Women with a history of previous miscarriages had much lower CRI values than those without [22, 23]. This contradiction is likely because previous studies were conducted in *ex vivo* conditions on patients who were not pregnant. The CCBD system allowed us to examine cervical dilatation under *in vivo* conditions, prior to the termination of an unwanted pregnancy. However, the number of patients enrolled in this research was insufficient to conduct a thorough analysis of the contradiction. Future research with a larger number of patients in multiple centres will give a definitive answer and perhaps additional insight into the problem of cervical incompetence.

Conclusion

The uterine cervix behaves as a sphincter during CCBD, which is verified by the existence of a CBP. The breaking point values did not vary with the number of previous cervical dilatations, whether artificial or physiological.

References

[1] Danforth, D.N: "Danforth's Obstetrics and Gynecology". Gibbs R.S. (ed). Philadelphia: Lippincott Williams & Wilkins, 2008, 25.
[2] Myers K.M., Paskaleva A.P., House M., Socrate S.: "Mechanical and

biochemical properties of human cervical tissue". *Acta Biomater.*, 2008, *4*, 104.

[3] House M., Kaplan D.L., Socrate S.: "Relationships between mechanical properties and extracellular matrix constituents of the cervical stroma during pregnancy". *Semin. Perinatol.*, 2009, *33*, 300.

[4] Owen J., Yost, N., Berghella V., Thom E., Swain M., Dildy G.A. III, McNellis, D. "Mid-trimester endovaginal sonography in women at high risk for spontaneous preterm birth". *JAMA*, 2001, *286*, 1340.

[5] Radulovic N.V., Ekerhovd E., Abrahamsson G., Norström A.: "Cervical tissue changes in women with miscarriage: a morphological and biochemical investigation". *Acta Obstet. Gynecol. Scand.*, 2010, *89*, 54.

[6] Radulovic N.V., Ekerhovd E., Abrahamsson G., Norström A.: "Cervical priming in the first trimester: morphological and biochemical effects of misoprostol and isosorbide mononitrate". *Acta Obstet. Gynecol. Scand.*, 2009, *88*, 43.

[7] Danforth D.N.: "The morphology of the human cervix". *Clin. Obstet. Gynecol.*, 1983, *26*, 7.

[8] Leppert P.C., Yu S.Y.: "Three-dimensional structures of uterine elastic fibers: scanning electron microscopic studies". *Connect. Tissue Res.*, 1991, *27*, 15.

[9] Leppert P.C.: "Anatomy and physiology of cervical ripening". *Clin. Obstet. Gynecol.*, 1995, *38*, 267.

[10] Mazza E., Nava A., Bauer M., Winter R., Bajka M., Holzapfel G.A.: "Mechanical properties of the human uterine cervix: an in vivo study". *Med. Image Anal.*, 2006, *10*, 125.

[11] Arsenijevic S., Vukcevic-Globarevic G., Volarevic V., Macuzic I., Todorovic P., Tanaskovic I., Jeremic B. "Continuous controllable balloon dilation: a novel approach for cervix dilation". *Trials*, 2012, *13*, 1.

[12] Sivarao D.V., Goyal R.K.: "Functional anatomy and physiology of the upper esophageal sphincter". *Am. J. Med.*, 2000, *108*, 27.

[13] Jung J., Ahn H.K., Huh Y.: "Clinical and functional anatomy of the urethral sphincter". *Int. Neurourol. J.*, 2012, *16*, 102.

[14] Yucel S., Baskin L.S.: "An anatomical description of the male and female urethral sphincter complex". *J.Urol.*, 2004, *171*, 1890.

[15] Chandrasoma P.T., Der R., Ma Y., Dalton P., Taira M. "Histology of the gastroesophageal junction: an autopsy study". *Am. J. Surg. Pathol.*, 2000, *24*, 402.

[16] Fritsch H., Brenner E., Lienemann A., Ludwikowski B.: "Anal sphincter complex". *Dis. Colon Rectum*, 2002, *45*, 188.

[17] Petersen L.K., Uldbjerg N. "Cervical collagen in non-pregnant women with previous cervical incompetence". *EJOG*, 1996, *67*, 41.

[18] Petersen L. K., Oxlund, H., Uldbjerg, N., & Forman, A. "In vitro analysis of muscular contractile ability and passive biomechanical properties of uterine cervical samples from nonpregnant women". *Obstet. Gynecol.*, 1991, *77*, 772.

[19] Petersen L.K., Vogel I., Oxlund H., Forman A., Uldbjerg N.: "No effects of human relaxin on the active and passive biomechanical properties of isolated cervical specimens from nonpregnant women". *EJOG*, 1997, *73*, 183.

[20] Kiwi R., Neuman M.R., Merkatz I.R., Selim M.A., Lysikiewicz A.: "Determination of the elastic properties of the cervix". *Obstet. Gynecol.*, 1988, *71*, 568.

[21] Kiwi R. "Recurrent pregnancy loss: evaluation and discussion of the causes and their management". *Cleve. Clin. J. Med.*, 2006, *73*, 913.

[22] Anthony G.S., Calder A.A., MacNaughton M.C.: "Cervical resistance in patients with previous spontaneous mid-trimester abortion". *BJOG*, 1982, *89*, 1046.

[23] Anthony G.S., Walker R.G., Robins J.B., Cameron A.D., Calder A.A.: "Management of cervical weakness based on the measurement of cervical resistance index". *EJOG*, 2007, *134*, 174.

Corresponding Author:
P.S. ARSENIJEVIC, M.D.
Department of Gynecology and Obstetrics
Faculty of Medicine, University of Kragujevac
69 Svetozara Markovica Street
Kragujevac 34000 (Serbia)
e-mail: petar.arsenijevic@yahoo.com