Bø, K., Hilde, G., Stær-Jensen, J., Brækken, I. H. (2011). Can the Paula method facilitate co-contraction of the pelvic floor muscles? : a 4D ultrasound study. I*nternational Urogynecology Journal, 22*, 671-676.

CAN THE PAULA METHOD FACILITATE CO-CONTRACTION OF THE PELVIC FLOOR MUSCLES? A 4D ULTRASOUND STUDY

Kari Bø, Professor, PhD, PT, Exercise scientist

Norwegian School of Sport Sciences, Department of Sports Medicine

Akershus University Hospital, Department of Obstetrics and Gynecology

Gunvor Hilde, PT, Exercise scientist, PhD candidate

Norwegian School of Sport Sciences, Department of Sports Medicine

Akershus University Hospital, Department of Obstetrics and Gynecology

Jette Stær- Jensen, consultant gynecologist, PhD candidate

Akershus University Hospital, Department of Obstetrics and Gynecology

Ingeborg Hoff Brækken, PhD, PT, Exercise scientist

Akershus University Hospital, Department of Obstetrics and Gynecology

Correpondent author:

Kari Bø, Professor, PhD

Norwegian School of Sport Sciences, Department of Sports Medicine

PO Box 4014, Ullevål stadion, 0806 Oslo, Norway

E-mail: kari.bo@nih.no

NO DISCLOSURES

ABSTRACT

Introduction and hypothesis. The aim was to compare constriction of the levator hiatus (LH) and reduction of pelvic floor muscle (PFM) length during instruction of the Paula method (contraction of ring musculature of the mouth) and contraction of the PFM.

Methods. Seventeen pregnant or postparum women, mean age 28.6 (range 20-35) participated. A Voluson E8 ultrasound machine with 4-8 MHz curved array 3D/4D transducer (RAB 4-7l/obstetric) was used. Measurements were performed in the axial plane of minimal hiatal dimensions. Muscle length was calculated as circumference of the LH minus the suprapubic arch. Differences between groups were analyzed using Wilcoxon Signed Ranks Test. Significance level was set to 0.05.

Results. There was a significant reduction of the LH area ($p<.001$) and muscle length ($p<.001$) during PFM contraction, but not during contraction according to the Paula method, $p=.51$ and $p=.31$, respectively.

Conclusions. The Paula method did not facilitate PFM contraction.

Key words: co-contraction, levator hiatus, Paula method, pelvic floor muscles, ultrasound

Brief summary: 4D ultrasound showed no significant co-contraction of the pelvic floor muscles during instruction to contract ring muscles of the mouth (Paula method).

Abbreviations:

LH: levator hiatus

PB: pubic bone

PFM: pelvic floor muscles

PFMT: pelvic floor muscle training

RCT: randomized controlled trial

SUI: stress urinary incontinence

INTRODUCTION

Kegel [1] was the first to report effect of pelvic floor muscle training (PFMT) to treat urinary incontinence and pelvic organ prolapse. Today, there is Level A evidence that pelvic floor muscle training (PFMT) can effectively treat stress (SUI) and mixed urinary incontinence, and it is recommended as first line treatment for these conditions [2-3]. Cure rates, measured as < 2 grams of leakage on pad testing varies between 44-80% in randomized controlled trials (RCTs) [4].

The evidence is based on specific strength training protocols for the PFM, and so far no RCTs have documented that the PFM can be trained indirectly by other muscle groups of the body [3]. In 1993, a training system named the “Paula method” was developed [5]. The theory behind this method is that all sphincters in the body work simultaneously, and that exercising the ring musculature of the mouth, eyes or nose will result in strengthening of the PFM. A pilot study showed that exercising according to the Paula method gave significant improvement in SUI measured by pad testing and Quality of life (QoL) comparing pre-and post test results within the Paula group [6]. No effect was found in improvement of PFM strength, neither after the Paula method nor the home PFMT.

The PFM surround the pelvic openings and during a voluntary contraction they constrict the urethra and increase urethral closure pressure, lift the pelvic organs inside the pelvis, stabilize and prevent descent during rise in intra-abdominal pressure [7-9] and constrict the levator hiatus (LH) [9-10]. Reduction of the LH area and muscle length can be used

to measure the effectiveness of a single PFM contraction as this has to be due to shortening of the muscle fibers. If the Paula method works, instruction of contracting the ring muscles of the mouth should give a significant constriction of the LH. Several studies have shown that > 30% of women with urinary incontinence are not able to perform a correct PFM contraction at their first consultation [11-13]. If contracting around the mouth gives a co-contraction of the PFM with constriction of the LH, it can be used as a training method in women who are not able to correctly contract the PFM.

The aims of the present study were:

1. To assess whether contraction of the muscles around the mouth (Paula method) gives a significant constriction of the LH and reduction of PFM length
2. To compare the Paula method with ordinary instruction of PFM contraction to assess which method gives the most significant reduction of LHarea and muscle length.

METHODS

Design

This was an experimental study with the participants being their own controls. Consecutive women attending an ongoing cohort assessing changes in the PFM from gestational week 20 till 12 months postpartum and a RCT assessing effect of PFMT postpartum were recruited for the study. Inclusion criteria were ability to perform a correct PFM contraction evaluated by vaginal palpation. Exclusion criterion was inability to understand instructions given in Scandinavian language.

The data examined for this project were obtained in the context of the ongoing cohort and RCT of postpartum PFMT. The study followed the Helsinki declaration and was approved by the Regional Medical Ethics Committee and the Norwegian Social Science Data Services. All subjects gave written informed consent to participate.

Sample size calculation

Power calculation was based on a previously published study comparing the effect of contracting abdominal muscles with voluntary PFM contraction on the LH [14]. In that study 13 participants was a sufficient sample size showing statistically significant differences with a power of 80% and a significance level of < 0.05.The difference in constriction of LH area was 3.3 cm^2 (95% CI: 1.35-5.25) in favour of the PFM contraction [14]. To allow for possible missing data we decided to include at least 15 participants within a timeframe of 2 months in the present study.

Instruction of PFM contraction and contraction of the ring muscles of the mouth.

The participants were instructed and taught to perform a correct PFM contraction. Correct PFM contraction was defined as an inward lift and squeeze around the pelvic openings and assured with vaginal palpation in crook-lying position [1]. Contraction of the ring muscles of the mouth was taught according to Liebergall-Wischnitzer et al [6], and a correct contraction was assessed by the gynaecologist and the physical therapist.

Measurement of PFM strength

PFM strength was evaluated by a vaginal balloon catheter (ballon size 6.7 x 1.7 cm) connected to a high precision pressure transducer (Camtech AS, Sandvika, Norway) [15-17]. Maximum voluntary contraction (MVC) was calculated as the strongest of three attempts. This method has been found to be reliable and valid if used with simultaneous observation of inward movement of the catheter/ perineum during PFM contraction [16]. PFM endurance was defined as a sustained maximal contraction and was quantified during the first 10 seconds as the area under the curve (cmH_2Osec) [18].

Ultrasound assessment

A Voluson E8 ultrasound machine (GE Healthcare, Oslo, Norway) with 4-8 MHz curved array 3D/4D transducer (RAB 4-7 l/obstetric) was used. The field of view angle was set to its maximum of 70 º in the sagittal plane and volume acquisition angle to 85 º in the coronar plane (frame rate was approximately 2 Hz).

Procedure

Participants were instructed to void before the examination. Ability to contract the PFM was assessed by vaginal palpation and visual observation of inward movement of the perineum by the physical therapist (PT) (GH) [16].

After instruction of PFM contraction and constriction of the mouth in a crook lying position, one gynaecologist (JSJ) performed the ultrasound examinations. One PT (GH) gave instructions to all the participants and supervised the test procedure. The ultrasound transducer was covered with a condom and directed cranially on the perineum. The ring muscles of the mouth and the PFM were contracted in random order. Three contractions of each maneuver were undertaken. The strongest contraction, defined as the one with the smallest anterior-posterior LH length on ultrasound, was used for statistical analysis.

Ultrasound analyses

Analyses of 4D real time volumes were conducted offline on a laptop by one investigator (JSJ) using the software “4D View v 6.2” (GE Healthcare, Oslo, Norway). Measurements were performed in the axial plane of minimal hiatal dimensions (Fig 1). The area of LH was measured as the area bordered by the pubovisceral muscle, symphysis pubis and inferior pubic ramus. The plane of minimal hiatal dimensions was identified as the minimal distance between the hyperechogenic posterior aspect of the pubic bone (PB) and the hyperechogenic anterior border of the puborectal muscle at the anorectal angle [9,19]. Muscle length was calculated as circumference of the LH minus the suprapubic arch [9,19]. Intra-tester reliability of constriction of LH area during PFM contraction has

been found to be very good to good [9]. Measurements of the muscle length demonstrated good reliability at rest and fair reliability during contraction [9].

Statistical analysis

Background variables are reported as frequencies or means with standard deviation (SD). Reduction in LHarea and muscle length during contraction of PFM and during contraction of the ring muscles of the mouth (Paula method) are given as means with 95% CI. Differences in reduction of LHarea and muscle length when comparing PFM contraction and the Paula, method are reported as means with 95% confidence intervals (CI). Wilcoxon Signed Ranks Test is used to test differences between the two maneuvers. P-value is set to < 0.05.

RESULTS

Seventeen women (8 nulliparous pregnant women at gestational week 22 and 9 primiparous women at 6 weeks postpartum) participated in the study. All were able to perform correct PFM contraction. Mean age of the participants was 28.6 years (range 20-35) and mean BMI 25.8 (SD 2.8). Mean PFM strength and endurance was 25.8 cm H_2O (SD 11.7) and 188.7 cmH_2Osec (SD 78.9), respectively.

LH area and muscle length at rest and when performing contraction of the ring muscles of the mouth and contraction of the PFM, respectively and the difference between the two maneuvers are shown in Table 1. A statistically significant mean constriction of the LH area of 2.4 cm^2 (95% CI: - 3.4- -1.5), was shown during PFM contraction ($p<0.001$), but not during the Paula method ($p= 0.51$). The LH area was significantly more constricted during PFM contraction compared to the Paula method (Table 1).

Muscle length was significantly reduced by mean 1.7 cm (95% CI: -2.3- -1.2) during PFM contraction ($p<0.001$), but not during the Paula method ($p= 0.31$). There was a statistically significant difference between the two maneuvers in favour of instruction to contract the PFM (Table 1).

DISCUSSION

This experimental study explored narrowing of the LH area and reduction of muscle length during instructed contraction of the ring muscles around the mouth (Paula method) versus instructed PFM contraction, using 4D transperineal ultrasound. No effect of contracting the ring muscles was found. Instruction to contract the PFM gave an expected statistically significant narrowing of the LH area and a reduction of muscle length.

The strengths of the present study were that all women were thoroughly taught how to perform the contractions, and all participants were examined whether they could perform both maneuvers. The two maneuvers were done in random order, and measurements were done with a perineal ultrasound method with high face validity measuring the actual response of the PFM inside the pelvis. The method has shown to be reproducible [9,19,20,21] and valid [22]. Possible limitations were non-blinding of the observer and that assessment of the Paula method was limited to only one of more possible muscle groups.

Former studies using the same ultrasound assessment methodology have demonstrated a statistically significant constriction of the LH and reduction of muscle length during instruction of PFM contraction in asymptomatic women [9] and in women with pelvic organ prolapse [23]. An expected variance between different populations in these parameters has been found. Our study included both nulliparous pregnant women and postpartum women, but was not powered to compare differences between these two groups. With only 8 and 9 pregnant and postpartum women, respectively, our data can

not serve as normative values for these two populations of women. It may, however, be used for power calculations for important future studies to establish normal values for these groups. The aims of the present study were to assess whether there was a co-contraction of the PFM when the participants were instructed to contract the ring muscles of the mouth (Paula method) and to investigate the magnitude of a PFM response between these two maneuvers. Since there was no knowledge whether instruction of the Paula method would affect the pelvic floor before starting the study, we based the included number on a previous study on abdominal contraction. A postpriori power calculation based on our results, showed that, with a difference between the two methods of 2.3 (SD 1.5) and 1.6 (SD 0.9) for LH area and muscle length, respectively, the power to detect differences in both variables is >99%.

The Paula method is developed and used by midwifes [6], and our population was selected to match one of the target groups for interventions using the Paula method. By including both nulliparous pregnant and postpartum women, our study sample covers women with very weak, but also presumably non-injured stronger muscles. The high standard deviation of muscle strength and endurance confers the heterogeneity of the group. However, a huge variation in PFM strength confers with results of other studies in this area [3,18,23]. The fact that there was no significant effect on any of the participants following the Paula method, support some ability to generalize our results. However, if future RCTs are planned in this area, it may be interesting to assess a possible effect in pregnant and postpartum women separately. In addition, we have not assessed whether

instruction of the Paula method can facilitate a co-contraction in women unable to contract the PFM.

Data from a published RCT showed statistically significant improvement in quality of life and reduction of leakage in SUI women after both the Paula method and home PFMT [6]. However, in this trial the group randomized to the Paula method also did PFMT, which may explain that some improvement was found from pre- to posttest. No comparisons between the groups were reported, and the true effect of the Paula method is therefore still unknown. The present study cast doubt that the Paula method can be effective in facilitating PFM contraction as no reduction of the LHarea or muscle length was found. If the Paula method is effective it may therefore be mediated by other factors than the PFM. However, this needs to be shown in high quality RCTs comparing the results between, and not within, groups.

Our aim was to evaluate the theoretical background for the Paula method. We chose contraction of the ring muscles of the mouth as we consider this a stronger stimulus than contracting the muscles around the eyes. We did not find any support for the theory that contracting the ring muscles of the mouth facilitates co-contraction of the PFM, using a reliable method to assess LH area constriction and reduction of muscle length [9,19]. Former studies have found that instruction to contract the PFM is significantly more effective than instruction to contract other muscles such as the abdominals [14,24], and that the PFM are not significantly co-contracting during yoga and Pilates exercise [25]. This is in line with general strength training theory [26-27].

PFMT has shown to be effective to treat SUI and mixed incontinence in several high quality RCTs, systematic reviews and meta-analysis, and PFMT is recommended first line treatment for SUI and mixed incontinence [2-3] In spite of this there seem to be some interest in exploring alternative exercise programs to improve pelvic floor function [28-29,6]. To date there are two rationales for PFMT; 1. voluntary co-contraction of the PFM before and during increase in intra-abdominal pressure [30] and strength training [31,23]. Both these theories have strong evidence from experimental anatomy studies and have proven to be effective in RCTs [2-3]. They can therefore be used interchangeably or one by one according to the patients' aims, needs and abilities.

In conclusion, assessment with 4D perineal ultrasound showed that contracting the ring muscles of the mouth (Paula method) did not constrict the LH area or change muscle length. The results of the present study cast doubt that the Paula method can facilitate PFM contraction and does not support the use of the method in clinical practice.

ACKNOWLEDGEMENT: This study was supported financially by the Norwegian Research Council, Program for Clinical Research and Helse Sør-Øst.

Legend to figures:

Fig.1: Ultrasound measurements in the axial plane of minimal hiatal dimensions The levator hiatus area (LHarea) is bordered by the black line. The pubovisceral muscle length is drawn as a white dotted line. PB= pubic bone, U= urethra, V= vagina, R= rectum

References

1.Kegel AH (1948) Progressive resistance exercise in the functional restoration of the perineal muscles. American Journal of Obstet Gynecol 56:238-249

2.Hay-Smith J, Dumoulin C (2006) Pelvic floor muscle training versus no treatment, or inactive control treatments, for urinary incontinence in women. The Cochrane Database Syst Rev 25: Issue 1

3.Hay-Smith J, Berghmans B, Burgio K, Dumoulin C., Hagen S, Moore K et al (2009) Adult conservative management. In: Abrams P, Cardozo L, Khoury S, Wein A (Editors): Incontinence. 4th International Consultation on Incontinence (4th Edition). Health Publication Ltd:1025-1120

4.Bø K (2007) Pelvic floor muscle training for stress urinary incontinence. In: Bø K, Berghmans B, Mørkved S, Van Kampen M (eds). Evidence based physical therapy for the pelvic floor: bridging science and clinical practice. Elsevier Ltd, Churchill Livingstone, pp 171–187

5.Yom-Tov S, Golani I (1993) Oscillators in the human body and circular-muscle gymnastics. Med Hypotheses, 14,2: 118-122

6.Liebergall-Wischnitzer M, Hochner-Celnikier D, Lavy Y, Manor O, Arbel R, Paltiel O (2005) Paula method of circular muscle exercises for urinary stress incontinence - a clinical trial. Int Urogynecol J, 16: 345-351

7.DeLancey JO (1994) The anatomy of the pelvic floor. Curr Opin Obstet Gynecol 6,4:313-316

8. Thompson JA, O'sullivan PB, Briffa K, Neumann P, Court S (2005) Assessment of pelvic floor movement using transabdominal and transperineal ultrasound. Int Urogynecol J Pelvic Floor Dysfunct 16, 4:285-292

9.Brækken IH, Majida, M, Engh ME, Bø K (2009a) Test-retest reliability of pelvic floor muscle contraction measured by 4D ultrasound. Neurourol Urodyn 28: 68-73

10. Guaderrama NM, Liu J, Nager CW, Pretorius DH, Sheean G, Kassab G et al (2005) Evidence for the innervation of pelvic floor muscles by the pudendal nerve. Obstet Gynecol 106, 4:774-781

11.Benvenuti F, Caputo GM, Bandinelli S, Mayer F, Biagini C, Somavilla A (1987) Reeducative treatment of female genuine stress incontinence. American Journal of Physical Medicine 66, 4:155-168

12.Bø K, Larsen S, Oseid S, Kvarstein B, Hagen R, Jørgensen J (1988) Knowledge about and ability to correct pelvic floor muscle exercises in women with urinary stress incontinence. Neurourol Urodyn 7, 3:261-262

13.Bump R, Hurt WG, Fantl JA, Wyman JF (1991) Assessment of Kegel exercise performance after brief verbal instruction. Am J Obstetet Gynecol 165:322-329

14.Bø K, Brækken IH, Majida M, Engh ME (2009). Constriction of the levator hiatus during instruction of pelvic floor or transversus abdominis contraction: a 4D ultrasound study. Int Urogynecol J 20: 27-32

15.Bø K, Kvarstein B, Hagen R et al (1990a) Pelvic floor muscle exercise for the treatment of female stress urinary incontinence, I: reliability of vaginal pressure measurements of pelvic floor muscle strength. Neurourol Urodyn 9:471-477

16.Bø K, Kvarstein B, Hagen R et al (1990b) Pelvic floor muscle exercise for the treatment of female stress urinary incontinence, II: validity of vaginal pressure measurements of pelvic floor muscle strength and the necessity of supplementary methods for control of correct contraction. Neurourol and Urodyn 9:479-487

17.Bø K (1992) Pressure measurements during pelvic floor muscle contractions: the effect of different positions of the vaginal measuring device. Neurourology and Urodynamics 11:107-113

18.Braekken IH, Majida M, Ellstrøm Engh M, Holme IM, Bø K (2009b). Pelvic floor function is independently associated with pelvic organ prolapse. BJOG 116, 13: 1706-1714

19. Dietz H, Shek K, Clarke B (2005) Biometry of the pubovisceral muscle and levator hiatus by three-dimensional pelvic floor ultrasound. Ultrasound Obstet Gynecol;25:580-585.

20.Brækken IH, Majida M, Engh ME, Dietz HP, Umek W, Bø K (2008)Test- retest and intra-tester reliability of two-, three- and four dimensional perineal ultrasound of pelvic floor muscle anatomy and function. Int Urogynecol J 19:227-235

21.Majida M, Brækken IH, Umek W, Bø K, Benth JS, Engh ME (2009) Inter-observer repeatability of three – and four-dimensional perineal ultrasound of pelvic floor muscle anatomy and function. Ultrasound Obstet Gynecol 33, 5:567-573

22.Majida M, Brækken IH, Bø K, Benth JS, Engh ME (2009) Validation of three dimentional perineal ultrasound and magnetic resonance imaging measurements of the pubovisceral muscle at rest. In press Ultrasound Obstet Gynecol

23.Brækken IH, Majida M, Engh ME, Bø K (2010) Morphological changes after pelvic floor muscle training mesaured by 3-dimensional ultrasonography. A randomized controlled trial. Obstet Gynecol 115, 2, part 1: 317-324

24.Bø K, Sherburn M., Allen T (2003) Transabdominal measurement of pelvic floor muscle activity when activated directly or via a transversus abdominis muscle contraction. Neurourol Urodyn 22: 582-588

25.Baessler K, Junginger B (2010) Gymnastics for urinary incontinence – destroying the myth. Neurourol Urodyn, 29, 6: 1052-1053

26.Folland JP Williams AG (2007) The adaptations to strength training : morphological and neurological contributions to increased strength. Sports Med 37:145-168

27.Bø K, Aschehoug A (2007) Strength training. In: Bø K, Berghmans B, Mørkved S, Van Kampen M (eds). Evidence based physical therapy for the pelvic floor: bridging science and clinical practice. Elsevier Ltd, Churchill Livingstone, pp:119-131

28.Sapsford R (2004) Rehabilitation of pelvic floor muscles utilizing trunk stabilization. Manual Therapy 9:3-12

29.Savage AM (2005) Is lumbopelvic stability training (using the Pilates model) an effective treatment strategy for women with stress urinary incontinence? A review of the literature and report of a pilot study. Jass Chart Physiother Women's Health 97: 33-48

30.Miller, JM, Ashton-Miller JA, DeLancey JOA (1998) Pelvic muscle precontraction can reduce cough-related urine loss in selected women with mild SUI. J Am Geriatr Soc 46:870-874

31.Bo, K (2004) Pelvic floor muscle training is effective in treatment of female stress urinary incontinence, but how does it work? Int Urogynecol J Pelvic Floor Dysfunct 15:76-84

Table 1: Levator hiatus area and muscle length at rest, during pelvic floor muscle (PFM) contraction and contraction of the ring muscles of the mouth (Paula method) measured by 4D ultrasound. N = 17. Mean values 95% confidence interval (CI). P-values refer to differences between the two maneuvers.

	Rest	PFM contraction	Paula method	Mean difference with 95% CI between PFM and Paula method	p-value
Levator hiatus area (cm^2)	12.7 (11.4-14.1)	10.3 (9.1-11.5)	12.6 (11.4-13.9)	-2.3 (-3.1- -1.6)	0.000
Muscle length (cm)	9.6 (8.9-10.3)	7.8 (7.1-8.5)	9.5 (8.8-10.2)	1.6 (-2.1- -1.2)	0.000