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Variations in pelvic floor thickness in relation to bony dimensions in South African women: using computed tomography scans

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SUMMARY

Pelvic floor disorders (PFDs) are a common reason for urogynaecological consultation around the world, especially in elderly women. These disorders have been associated with disruption to the structural integrity of the pelvic floor. This study explored whether there are variations in pelvic floor muscle (PFM) thickness in relation to parity, population group and age. Additionally, the study explored whether there were any correlations between PFM thickness and the bony pelvic parameters measured. This was a quantitative retrospective analysis of computerised tomography (CT) scans. A total of 125 CT scans of women belonging to black and white South African population groups were sampled from a tertiary hospital in Pretoria, South Africa. Statistical analyses were performed using Paleontological Statistics (PAST). A thicker pelvic floor was noted in black compared to white women. Pelvic floor thickness decreased with parity and age in both population groups. The intertuberous diameter, as well as the surface areas of the urogenital triangle and the perineum, were statistically significantly larger in white than in black women. Correlations between PFM thickness and bony dimensions were statistically significant for anteroposterior (AP) pelvic outlet diameter, where a greater AP outlet was associated with thinner PFMs in black women. Bony correlations with parity showed that the interspinous diameter in black women increased significantly with parity. The variations in bony pelvic dimensions and pelvic floor muscle thicknesses noted between population groups, in addition to the co-factors of parity and aging, will contribute to a better understanding of the anatomical reasons for incontinence.

Key words: Bony pelvic outlet – Clinical anatomy – Obstetrics and gynaecology – Pelvic floor – Pelvic floor disorders

INTRODUCTION

The pelvic floor is functionally important for the support of pelvic organs (García del Salto et al., 2014; Muro et al., 2024), as well as the maintenance of faecal and urinary continence (Miller et al., 2010; Betschart et al., 2014). Studies have shown that thicker pelvic floor muscles are relat-

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ed to stronger muscle strength and, consequently, stronger pelvic support (Brækken et al., 2010, 2014). Weakness of these supporting structures may lead to pelvic floor disorders (PFDs) such as pelvic organ prolapse, faecal and urinary incontinence (Fielding, 2008; Dufour et al., 2018; Law and Blomquist et al., 2020). The integrity of pelvic floor support structures has been found to be influenced by various factors such as age (Wente and Dolan, 2018), parity (Özdemır et al., 2015; Hwang et al., 2019) and population group (Handa et al., 2008).

Anatomical variations in the dimensions of the bony pelvic outlet linked to the incidence of PFDs have been reported (Handa et al., 2008). These variations have been noted between different population groups: white American compared with African American women (Handa et al., 2008) and between South African (SA) white compared with SA black women (Jagesur, 2022). These bony dimensions include subpubic angles, interspinous diameters and the anteroposterior (AP) pelvic outlet. The subpubic angles and interspinous diameters were reportedly greater in white SA when compared to black SA women (Jagesur et al., 2017) and in white American when compared to African American women (Handa et al., 2008). The AP pelvic outlet distance was smaller in white SA compared to black SA women (Jagesur et al., 2017) and in white American compared to African American women (Handa et al., 2008).

Other population variations contributing to the pathophysiology of PFDs have been reported. A study by Abdool et al. (2017) reported that there exist significant variations in levator hiatal area and pelvic organ mobility between South Asian, Black and those from western European ancestry, where black nulliparous women showed increased levator hiatal dimensions and pelvic organ mobility compared with other population groups. They also observed significant variations between populations in stages of pelvic organ prolapse, where South Asians had a lower levator ani avulsion rate than the other two population groups. This is the first study evaluating bony pelvic dimensions versus pelvic floor muscle thickness between population groups.

This study aimed to explore whether there is an association between bony pelvic outlet dimensions and the thickness of the pelvic floor, and to ascertain whether there is any variation with co-factors (age, population group or parity). Population group assignment was based on the patient's surname (Morales, 2021) and verified by photo identification, as population group is not routinely collected and was therefore not available in retrospective records. These relationships were investigated using computerised tomography (CT) scans. Computerised tomography scans have been reported to be sufficient for the illustration of pelvic floor anatomy (Jorge and Bustamante-Lopez, 2022).

The results of this study are envisaged to provide crucial information towards a better understanding of the morphological factors influencing PFDs such as skeletal and muscular factors, with reference to parity, population group and aging.

MATERIALS AND METHODS

A total of 125 retrospectively collected pelvic CT scans of female patients were sampled from Steve Biko Academic Hospital, a tertiary hospital in Pretoria, South Africa. The sample was distributed according to parity and population group: 75 SA black women (28 nulliparous, 47 multiparous) and 50 SA white women (10 nulliparous, 40 multiparous). Parity subgroups were also considered where the sample was further categorised based on the number of children they had. The ages of women included in the study ranged between 18 years and 90 years. Patients that demonstrated any pelvic pathology, surgical alteration, skeletal abnormality or deformity were excluded.

Mevislab software (Heckel et al., 2009) was used to create 3D models of the imported CT scan data and to capture 3D points. The bony landmarks used for the parameters of interest were: tips of the ischial spine left (IS_L) and ischial spine right (IS_R), most inferior points of the ischial tuberosity left (IT_L) and ischial tuberosity right (IT_R), mid-ischiopubic ramus left (MIP_L) and mid-ischiopubic ramus right (MIP_R), pubic symphysis (PS), as well as the coccyx (C). The bony parameters that were measured were: 1) interspinous diameter between IS_L and IS_R; 2) intertuberous diameter between IT_L and IT_R; 3) subpubic angle (angle of

Fig. 1.- Horizontal section of computerised tomography (CT) scan showing pelvic floor muscle at the level of the urethra.

the subpubic arch), angle formed at inferior point of PS between MIP_L and MIP_R; 4) antero-posterior pelvic outlet (AP outlet), distance between the most inferior PS and tip of coccyx; 5) urogenital triangle, formed between PS and intertuberous diameter and lastly, 6) perineum, formed between PS and intertuberous diameter and tip of coccyx.

Distances between two 3D landmarks ($x_1y_1z_1$ and $x_2y_2z_2$) were calculated using the Pythagorean theorem (Katherine-Spradley and Jantz, 2016):

$$distance = \sqrt{(x_2 - x_1)^2 + (y_2 - y_1)^2 + (z_2 - z_1)^2}$$

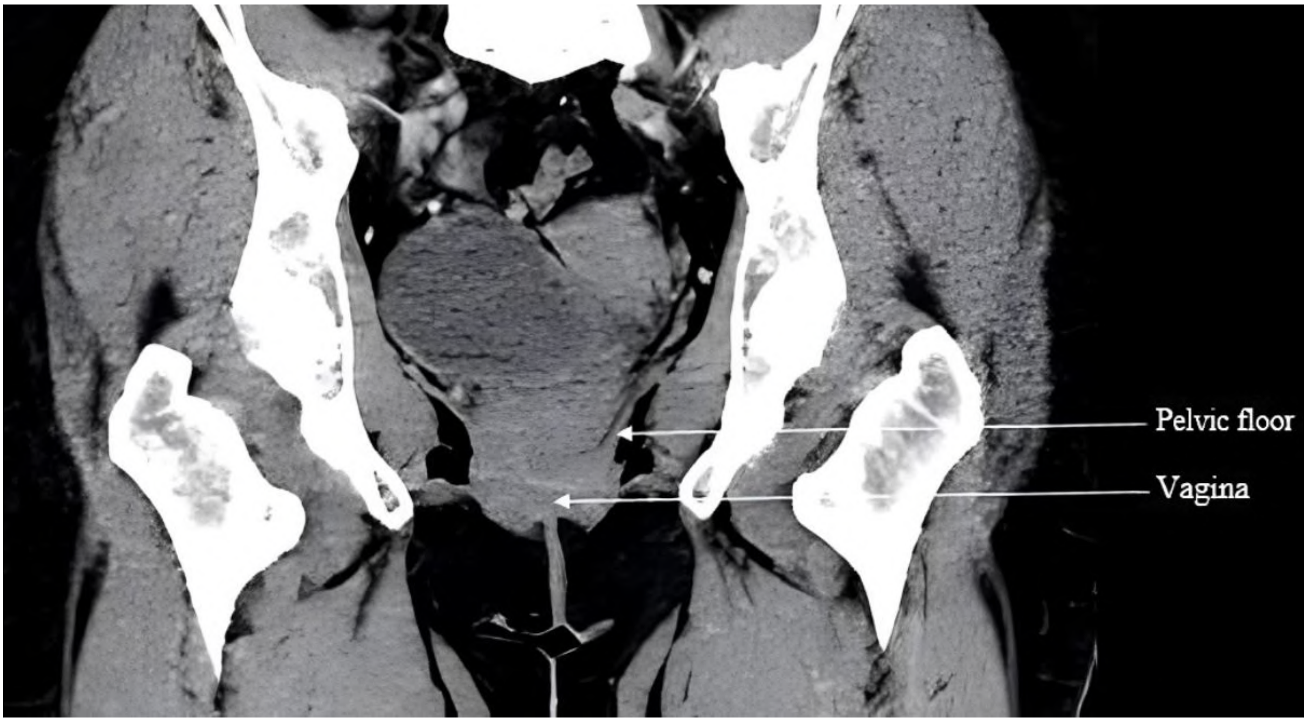

Fig. 2.- Coronal section of computerised tomography (CT) scan showing pelvic floor muscle at the level of the vagina.

The dot product formula (see annexure A1) was used to determine the angle between three 3D landmarks ($x_3y_3z_3$, $x_2y_2z_2$ and $x_1y_1z_1$) (Dumas, 2008). The surface area of the perineum was calculated as a composite of the urogenital triangle and the anal triangle, using the cross-product formula (Kuchel et al., 2021) (see annexure A2).

The thicknesses of the pelvic floor muscles from the CT scans were measured on Mevislab software (in millimetres). On a horizontal section, the thicknesses were measured at the level of the urethra (Fig. 1) and coronally at the level of the vagina (Fig. 2). The measurements were taken perpendicularly at the shortest distance across.

Statistical analyses were performed using Paleontological Statistics (PAST) (Hammer et al., 2001). Firstly, descriptive analysis was performed on all data, after which tests for normality were performed. To determine the extent of variation between groups, ANOVA, followed by Tukey's pairwise tests, were performed when samples were normally distributed, while the non-paramet-

Table 1. Univariate analysis of bony dimensions and pelvic floor thicknesses and statistical significance between group comparisons.

	Interspinous diameter (mm)	**Intertuberous diameter (mm)**	**AP pelvic outlet (mm)**	**Subpubic angle (˚)**	**Urogenital triangle mm^2**	**Perineum mm^2**	**Left Axial thickness (mm)**	**Left coronal thickness (mm)**
SAB **N = 75**	**109.67** *8.49* (74.60-135.26)	**123.55**^{a} *10.88* (95.13-152.91)	**112.04** *11.60* (80.83-139.17)	**89.49** *7.32* (75.25-106.38)	**3847.97**^{a} *514.11* (2429.30-4966.13)	**8117.65**^{a} *1113.74* (4562.81-11040.18)	**4.87**^{a} *0.91* (3.05-6.97)	**4.92**^{a} *0.93* (3.22-7.28)
SAB0 **N = 28**	**107.34**^{a} *9.21* (74.60-120.16)	**124.02**^{b} *12.53* (95.13-144.29)	**108.44** *13.00* (80.83-131.83)	**90.82** *6.16* (79.75-103.81)	**3784.06**^{b} *555.1545* (2429.298-4860.127)	**7956.71**^{b} *1237.86* (4562.81-9652.97)	**5.53**^{bcdefg} *0.78* (4.13-6.97)	**5.56**^{bcdef} *0.78* (4.11-7.27)
SABm **N=47**	**111.06** *7.80* (97.30-135.26)	**123.26**^{c} *9.90* (99.84-152.91)	**114.19** *10.24* (94.21-139.17)	**88.70** *7.90* (75.25-106.38)	**3886.05**^{c} *490.227* (2827.993-4966.135)	**8213.53** *1034.86* (5984.05-11040.18)	**4.47**^{bh} *0.74* (3.05-6.54)	**4.53**^{bg} *0.79* (3.22-7.12)
SAB1,2 **N = 16**	**109.13**^{b} *6.12* (98.61-120.95)	**122.96** *8.50* (110.46-135.56)	**114.44** *8.55* (98.82-128.08)	**90.03** *9.67* (78.53-106.38)	**3774.92** *374.546* (2997.42-4500.33)	**8213.02** *810.46* (6822.81-9720.46)	**4.94**^{eij} *0.72* (3.98-6.54)	**4.95**^{h} *0.82* (3.90-7.12)
SAB3 **N=16**	**109.05**^{c} *5.86* (98.98-116.51)	**123.10** *6.27* (110.69-132.00)	**111.69** *7.35* (94.21-125.74)	**87.33** *6.30* (77.36-99.56)	**3969.08** *364.75* (3345.67-4576.31)	**8051.32** *661.13* (6892.30-9123.76)	**4.35**^{fi} *0.57* (3.55-5.54)	**4.38**^{e} *0.67* (3.22-5.79)
SAB4+ **N=15**	**115.28**^{abc} *9.75* (97.30-135.26)	**123.75** *14.21* (99.84-152.91)	**116.59** *13.97* (96.96-139.17)	**88.75** *7.60* (75.23-103.66)	**3916.03** *688.35* (2827.99-4966.14)	**8387.11** *1511.41* (5984.05-11040.18)	**4.11**^{gj} *0.71* (3.05-5.91)	**4.24**^{fh} *0.73* (3.23-5.79)
SAW **N = 50**	**109.36** *12.14* (48.32-135.05)	**130.37**^{a} *17.32* (48.32-161.33)	**111.93** *11.58* (83.18-141.42)	**91.44** *6.97* (76.22-106.72)	**4213.07**^{a} *604.39* (3084.10-5737.72)	**8739.8**^{a} *1283.25* (6409.77-12160.12)	**3.52**^{a} *0.94* (1.90-5.64)	**3.56**^{a} *0.91* (1.88-5.22)
SAW0 **N = 10**	**106.51** *7.79* (95.44-117.56)	**128.70** *16.02* (109.93-161.33)	**108.03** *13.37* (92.84-129.35)	**93.63** *6.65* (85.13-106.72)	**3850.32**^{d} *603.2742* (3146.752-4938.189)	**8466.29** *1672.08* (6816.48-12160.12)	**4.33**^{cqklm} *0.56* (3.10-4.94)	**4.38**^{cijk} *0.56* (3.12-5.00)
SAWm **N=40**	**109.36** *12.14* (48.32-135.05)	**130.37**^{b,c} *17.32* (48.32-161.33)	**111.93** *11.58* (83.18-141.42)	**91.44** *6.97* (76.22-106.72)	**4303.76**^{b,c,d} *576.8728* (3084.103-5737.716)	**8808.19**^{b} *1183.13* (6409.77-11149.50)	**3.10**^{dhq} *0.84* (1.90-5.00)	**3.15**^{dgi} *0.82* (1.88-5.22)
SAW1,2 **N= 21**	**112.16** *10.50* (96.61-135.05)	**132.34** *13.22* (105.45-158.21)	**114.61** *9.25* (83.18-127.02)	**90.72** *7.56* (76.22-105.68)	**4312.68** *627.01* (3398.95-90566.25)	**8984.55** *1265.06* (6409.77-11149.50)	**3.69**^{kno} *0.86* (2.23-5.64)	**3.78**^{lm} *0.77* (2.88-5.22)
SAW3 **N=11**	**109.61** *6.12* (101.76-122.59)	**133.19** *12.48* (116.92-155.12)	**104.52** *9.52* (92.158-122.90)	**91.46** *7.24* (80.14-102.64)	**4319.39** *545.50* (3084.10-47513.23)	**8425.05** *1225.32* (6799.88-10966.95)	**3.01**^{ln} *0.79* (2.00-5.00)	**2.98**^{jl} *0.81* (1.86-4.90)
SAW4+ **N= 8**	**112.16** *3.59* (106.59-117.43)	**131.12** *10.89* (115.27-152.39)	**113.87** *11.29* (99.87-127.42)	**90.56** *6.01* (80.35-99.22)	**4258.87** *550.2753* (3651.93-5143.51)	**8872.06** *867.63* (7327.91-10062.64)	**2.74**^{mo} *0.77* (1.90-4.01)	**2.93**^{km} *0.62* (2.01-4.00)
Alphabet letters in the superscript indicate statistical significant differences (p value < 0.05) between groups per column								

number of women = N; mean values are indicated in bold standard deviation is indicated in *italics*; range is shown within the round (brackets)

SAB refers to South African Black women and SAW refers to South African white women, the number following refers to the number of live births and *m* refers to multiparous ric test, Kruskal-Wallis, followed by Mann Whitney test were performed when samples were not normally distributed (Neideen and Brasel, 2007). Comparisons between black and white women, between nulliparous versus multiparous, as well as between stepwise parity groups within population groups were performed. This was followed by correlations between continuous variables, i.e. the bony dimensions versus the pelvic floor thicknesses, and age versus the pelvic floor thicknesses. A Pearson's correlation coefficient r was determined, where a value of +1 indicates perfect positive association and a value of –1 indicates perfect negative association, while a value of 0 indicates no linear association (Schober et al., 2018).

Intra- and inter-observer tests for measurement accuracy were run by two observers. Twenty individuals were randomly selected from the entire sample, and analysed twice by the principal researcher in order to assess the intra-observer reliability and once by co-author, SJ, for the inter-observer reliability. Intraclass correlations were performed on the analysis of these 20 cases.

RESULTS

The mean age in years for the entire sample was 51.35 ± 15.44. The mean parity for the entire sample was 1.95 ± 1.72. The mean age in years and mean parity in black women were 47.87 ± 14.78 and 1.92 ± 1.87, respectively, while the mean values for age in years and parity in the white women were 56.58 ± 15.06 and 2 ± 1.48, respectively.

For each patient, the pelvic floor muscle thickness was measured on both the left and right sides (for both the axial and coronal sections). As the data had a normal distribution, ANOVA tests were performed between left and right sides and no statistically significant differences between sides were observed (left axial versus right axial, p = 0,804; left coronal versus right coronal, p = 0,909). The measurements for the left side of the pelvic floor are tabulated in Table 1 (since there were no statistically significant differences between the left and right sides). Intraclass correlation coefficients (r) for intraobserver and interobsever repeatability approached 1, indicating excellent agreement for all the measurements taken on the left side (Table 2).

Table 2. Intraclass correlation coefficients.

Parameters	**Intraobserver repeatability**	**Interobserver repeatability**
Interspinous diameter	0.992	0.940
Intertuberous diameter	0.961	0.910
AP pelvic outlet	0.966	0.925
Subpubic angle	0.988	0.930
Urogenital triangle	0.993	0.937
Perineum	0.952	0.981
Left Axial thickness	0.981	0.976
Left coronal thickness	0.993	0.989

A1:

$$angle = \cos^{-1}\left(\frac{(x_2-x_1)(x_3-x_1)+(y_2-y_1)(y_3-y_1)+(z_2-z_1)(z_3-z_1)}{\left(\sqrt{(x_2-x_1)^2+(y_2-y_1)^2+(z_2-z_1)^2}\right)\left(\sqrt{(x_3-x_1)^2+(y_3-y_1)^2+(z_3-z_1)^2}\right)}\right)$$

A2:

$$area = \frac{\sqrt{((y_2-y_1)(z_3-z_1)-(z_2-z_1)(y_3-y_1))^2+((z_2-z_1)(x_3-x_1)-(x_2-x_1)(z_3-z_1))^2+((x_2-x_1)(y_3-y_1)-(y_2-y_1)(x_3-x_1))^2}}{2}$$

Annexure A1 y A2

Table 1 describes the comparison between population groups, bony pelvic outlet and pelvic floor thickness measurements. Alphabet letters in the superscript indicate statistically significant differences (p-value < 0.05) between groups per column. The intertuberous diameter, as well as the surface area of the urogenital triangle and the perineum, were statistically significantly larger (p: 0.0003; p: 0.0004 and p: 0.0047 respectively) in the entire sample of white women (N=50) compared to black women (N=75). The subpubic angle was larger in white women, while the interspinous and AP outlet diameters were larger in black women but they did not reach statistical significance.

When considering the stepwise parity groups as set out in Table 1, the bony dimensions (interspinous diameter, AP outlet diameter, surface areas of urogenital triangle and perineum) increased slightly with increasing parity in both population groups, and were statistically significant when considering the interspinous diameter in black women.

Comparative analyses showed statistically significantly thinner pelvic floor measurements (p< 0.0001) in white when compared to black women throughout, as indicated by the superscript ^{a} in the last two columns of Table 1.

The black nulliparous women (SAB0 on Table 1) displayed statistically significant thicker mean values for the pelvic floor muscles than white nulliparous women (SAW0). The black multiparous women (SAB*m*) displayed statistically significant thicker mean values for the pelvic floor muscles when compared to white multiparous women (SAW*m*). Pelvic floor thinning was observed as parity increased in the stepwise population group comparisons (became thinner with increasing parity in both population groups) and many of these comparisons were statistically significant (see Table 1).

Ordinary least square regressions performed between pelvic floor thickness and age showed that the thickness of the pelvic floor decreased with age in nulliparous women of both population groups, even though age correlations within the white nulliparous group were not significant. The pelvic floor also became significantly thinner with increasing age in multiparous women of both population groups. Hard tissue correlations with the PFM thickness were not significant, except PFM correlations with AP pelvic outlet and surface area of the perineum. Weak, but statistically significant negative relationships for the entire sample of black women were noted when correlating the AP pelvic outlet dimensions with the pelvic floor thickness on both the coronal and horizontal sections. Significant but negative correlation was noted in the small group of eight white women who had given birth to four or more live babies when correlating the surface area of the perineum with the coronal section of the pelvic floor.

DISCUSSION

Main findings and interpretation (in light of other evidence)

Despite the fact that population group was not indicated in the patient's records and assignments were based on surnames and photographic identification, very clear population group variations were noted in the measurements taken. The trends observed in the variations of the bony dimensions include a longer AP outlet diameter in the entire sample of black women when compared to the entire sample of white women, as well as a greater surface area of the urogenital triangle and the perineum, subpubic angle and the intertuberous diameter in the entire sample of white women than in the entire sample of black women. The only significant observations were those of the intertuberous diameter, as well as the surface areas of the urogenital triangle and the perineum. Similar findings were reported in African- American versus white-American women concerning the AP pelvic outlet diameter (Handa et al., 2008).

These variations in the pelvic diameters between population groups were not entirely unexpected (Jagesur, 2022). It is well known that populations who originated in colder climates, as noted in the white South African population group in this study, have relatively wider pelves in order to reduce heat loss. Narrower pelves associated with populations that originated in tropical climates, as noted in black South Africans, would help reduce heat stress (Weaver and Hublin 2009; Sharma et al., 2016). The variation in the shape of the pelvis reflects genetic diversity based on ancient demographic events, as explained by neutral phenotypic evolution and are therefore useful in population history (Stull et al., 2014; Betti, 2017).

This was the first study to evaluate relationships between pelvic floor muscle thickness and pelvic bony dimensions, and between population groups with respect to the effect of age and parity on the measurements. Variations in the bony dimensions based on parity have been noted in an older study (Russell, 1969). For instance, similar to our study, the interspinous diameter increased with parity in a study performed by Russell (1969); however, the population group was not specified in their study. The mechanism of this increase was explained by the backward movement of the lower part of the sacroiliac joint occurring during childbirth, consequently leading to a separation of the ischial spines.

White American women have been reported to be at a higher risk for pelvic floor disorders (PFDs) compared to African American women (Graham and Mallett, 2001). Increased risk for PFDs could be explained by the observed thinner pelvic floor in white women as compared to African American women (Hoyte et al., 2005), as also noted in our groups, since thinner pelvic floors have been associated with weakness and as such, may be more susceptible to PFDs (Brækken et al., 2010, 2014;).

The thinning of the pelvic floor with increasing parity (Özdemır et al., 2015) and aging (Alperin et al., 2016) has been documented. In the stepwise population group comparisons, we observed that the pelvic floor became thinner with increasing parity in both population groups where many of these comparisons were statistically significant. Possible mechanisms influencing the thinning of the pelvic floor with parity may be explained by micro-architectural distortion of the pelvic floor muscles and elevated intra-abdominal pressure experienced by the pelvic floor during pregnancy and labour (Mørkved et al., 2004). It is plausible that vaginal birth might, over time, have an effect on the pelvic floor and might therefore not be distinguishable from the effect that aging would have. In our study, nulliparous groups in both population groups demonstrated a thinning of the pelvic floor with aging. This, however, was not significant in white nulliparous women, perhaps due to the small sample number (N=10).

Although no studies were found which directly correlated the pelvic bony dimensions measured with pelvic floor thicknesses, greater dimensions of interspinous and intertuberous diameters, subpubic angles, as well as smaller dimensions in AP pelvic outlets were reportedly associated with PFDs (Handa et al., 2003). In our study, increasing AP pelvic outlet diameter was associated with thinner PFMs (in the entire group of black women). A possibility exists that the increased risk for PFDs noted when certain pelvic dimensions were increased could be linked to population group differences in pelvic dimensions rather than the differences in the dimensions themselves. For instance, a greater intertuberous dimension as noted in the white population group may be associated with an increased chance for PFD, while a greater AP outlet dimension as noted in the black population group may be associated with a smaller risk for PFD. Finally, South African white women may be particularly disadvantaged early on for possible PFDs, as they have greater bony dimensions and thinner pelvic floors, compounded by structural distortion of pelvic floor musculature by childbirth and aging.

Limitations

Possible limitations of this study are the factors that could have contributed to the variations in the pelvic floor thicknesses other than those noted with parity, population group and aging. These factors include the type of childbirth (vaginal or caesarean), body mass index (BMI), patient involvement in high impact physical activity or genetic factors. None of these factors were known in this retrospectively studied scan sample. It is crucial to recognise that the findings of this study, which are derived from Black and White patients at a Pretoria hospital, should be interpreted with an awareness that interethnic differences may exist in other regions of South Africa and beyond (Sapo, 2021).

CONCLUSION

This study has demonstrated that there exist population group variations between pelvic floor thickness and bony pelvic dimensions, in addition to the co-factors of age and parity. Black nulliparous women displayed statistically significant thicker mean values for the pelvic floor muscles than white nulliparous women. Ordinary least square regressions performed between pelvic floor thickness and age showed that pelvic floor thickness decreased with age in nulliparous women of both population groups, although age correlations within the white nulliparous group were not significant. The intertuberous diameter, as well as the surface area of the urogenital triangle and the perineum were statistically significantly greater in the entire sample of white women compared to black women. Bony correlations with parity were significant for the interspinous diameter, which increased with parity in black women. Bony pelvic correlations with pelvic floor muscle thickness were significant for AP pelvic outlet, where the increasing diameter of the AP pelvic outlet was associated with thinner PFMs in the entire sample of black women. It is therefore important in clinical practice to consider the variations noted in pelvic bony dimensions and pelvic floor muscles between women of varying populations groups, ages and parity in association to pelvic floor disorders. These conditions affect quality of lives, and therefore better understanding of mechanisms involved can lead to advancement of treatment options or even prevention where possible. The results of this study add to the paucity of data on the effect of population group on pelvic floor morphology.

Recommendations

Future research using greater sample sizes could confirm or disprove the non-significant relationships noted. Data where the mode of childbirth is known, e.g. vaginal or caesarean section, could be helpful to ascertain whether mode of delivery has any effect on the bony dimensions and the thickness of the pelvic floor.

Details of ethics approval

This study was approved by the University of Pretoria (UP) as well as the National Health Research Database (NHRD) and finally by Sefako Makgatho Health Sciences University (SMU). Reference number: 54/2020. Committee: University of Pretoria Faculty of Health Sciences Research Ethics Committee. Approval date: 24 March 2020.

NHRD: Reference number: GP_202005_037. Committee: Steve Biko Hospital Research Committee. Approval date: 05 June 2020.

SMU: Reference number: SMUREC/M/326/2020. Committees: Sefako Makgatho University Research Ethics Committee (SMUREC). Approval date: 14 December 2020.

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