



**UNIVERSIDADE ESTADUAL PAULISTA
“JÚLIO DE MESQUITA FILHO”
FACULDADE DE MEDICINA**

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Comparação da Resposta Sexual entre Gestantes Hiperglicêmicas e Normoglicêmicas

Dissertação apresentada à
Faculdade de Medicina, Universidade
Estadual Paulista “Júlio de Mesquita
Filho”, Campus de Botucatu, para
obtenção do título de Mestra em
Ginecologia, Obstetrícia e Mastologia.

Orientadora: Prof.^a Emérita Mariza Vieira Cunha Rudge
Coorientadora: Prof.^a Dr.^a Angélica Mércia Pascon Barbosa

**Botucatu
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Sthefanie Kenickel Nunes

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*“O correr da vida embrulha tudo.
A vida é assim: esquentada e esfria,
aperta e daí afrouxa,
sossega e depois desinquieta.
O que ela quer da gente é coragem”.*

Guimarães Rosa

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Contextualização

Cronologia do Grupo de Pesquisa

O Grupo de Pesquisa “Diabetes e Gravidez: Clínico e Experimental”, liderado por Rudge, junto ao Programa de Pós-Graduação em Ginecologia, Obstetrícia e Mastologia da Faculdade de Medicina de Botucatu-UNESP, realiza diferentes investigações relacionadas à gravidez complicada pelo diabetes desde 1980.

Em sua tese de livre-docência de 1984, Marilza Rudge deu início a investigações relacionadas com a hiperglicemia gestacional leve, direcionando o grupo a estudos com diferentes níveis glicêmicos, gestação e suas alterações. (1)

O estudo relacionado à associação da disfunção muscular do assoalho pélvico (DMAP) e à ocorrência da incontinência urinária (IU) em mulheres com Diabetes Mellitus Gestacional (DMG) evidenciada por Barbosa em sua tese de doutorado em 2006 foi o início da linha de pesquisa “Incontinência Urinária e Diabetes na Gestação”. A elevada ocorrência de IU específica da gestação (IUEG) no grupo com DMG foi de 50,8% *contra* 31,6% no grupo Normoglicêmico (NG) e dois anos após parto cesáreo. A IU no grupo com DMG foi de 44,8% *contra* 31,6% no grupo NG. A análise multivariada demonstrou que o DMG foi fator de risco independente (OR 2,26 IC 95%: 1,116-4.579) e aumentou significativamente a ocorrência de IUEG. A IUEG foi fator de risco para ocorrência de IU dois anos após parto cesáreo, e o DMG foi fator de risco para DMAP dois anos após parto cesáreo (OR 20.416; 95% CI: 3.5148-117.479). (2)

Esses resultados evidenciaram intrínseca relação entre DMG, “IUEG” e IU e DMAP dois anos após parto cesáreo, relação, entretanto, ainda não bem estabelecida na literatura.

Assim, a partir desses achados clínicos, decidiu-se pela pesquisa translacional, etapa *bedside to bench*, em que o grupo de pesquisa testou hipóteses sobre os mecanismos fisiopatológicos do binômio hiperglicemia gestacional e IU usando ratas prenhes com diabetes moderado e grave.

O estudo translacional inicial ocorreu na dissertação de mestrado de Marini (FAPESP n°. 2008/00989-4), 2010 e Piculo (FAPESP n° 2010/13303-3), 2013. Esses estudos demonstraram que, no músculo uretral de ratas prenhes com diabetes moderado e grave, houve alterações musculares estruturais caracterizadas por: adelgaçamento, atrofia, desorganização e rompimento de fibras, associados à perda da localização anatômica normal das fibras rápidas e lentas e à diminuição na proporção de fibras rápidas na uretra. Já no doutorado, Marini (FAPESP n°2010/10740-3) e Rudge (Auxílio Pesquisa FAPESP n°.2010/11703-4) analisaram em ratas prenhes com diabetes grave o músculo estriado uretral em conjunto com a Matriz Extracelular (MEC). Os resultados mostraram plasticidade das fibras musculares rápidas e lentas, desorganização das fibras musculares, aumento de tecido conjuntivo e colágeno entre as fibras musculares estriadas, aumento de vasos, acúmulo de mitocôndrias, gotas de lipídios e grânulos de glicogênio, indicando assim MEC mais rígida e consequente dificuldade de fechamento uretral (2,3) Toda essa etapa foi analisada em parceria importante com a *Case Western Reserve University (CWRU)* em *Cleveland Ohio-USA*. (3,4)

Em seguimento ao conhecimento da DMAP, o grupo de pesquisa deparou-se com dificuldade ética para verificar clinicamente nos músculos do assoalho pélvico os achados da pesquisa experimental. Dessa forma, em seu mestrado (FAPESP n° 2012/25053-7) com início em 2015, Vesentini investigou e realizou análise do músculo

reto abdominal de ratas prenhes com diabetes grave e moderado, uma vez que a literatura evidencia participação ativa dos músculos abdominais no mecanismo de continência urinária, confirmando desta forma a miopatia diabética. (5)

Estes achados experimentais direcionaram o grupo para a etapa *bench to bedside*, e entre 2016 e 2017, Sartorão Filho e Pinheiro em suas dissertações de mestrado avaliaram a biometria e a funcionalidade dos músculos do assoalho pélvico de gestantes diabéticas utilizando a ultrassonografia tridimensional como instrumento de avaliação, e os resultados foram expressivos. As gestantes com DMG apresentaram área hiatal significativamente menor na progressão da gestação, diminuição da contratilidade, distensibilidade e mobilidade do assoalho pélvico. (6,7) No mesmo período, Prudencio (Bolsa CAPES) em sua dissertação de mestrado analisou a evolução dos achados eletromiográficos dos músculos do assoalho pélvico de gestantes com DMG, e concluiu que o grupo de mulheres expostas ao DMG apresentou diminuição da resposta eletromiográfica e em repouso e na contração muscular tônica quando comparadas com o grupo de mulheres normoglicêmicas, demonstrando que o DMG diminui a atividade dos músculos do assoalho pélvico. (8)

Assim, a pesquisa translacional consolidou a miopatia diabética como a base fisiopatológica da DMAP e “IUEG” no DMG.

O grupo em tomada de decisão conjunta e respaldada nos achados experimentais e clínicos se propôs investigar ampla e profundamente os biomarcadores do DMG, miopatia diabética e IUEG nos aspectos morfológicos, clínicos, metabólicos, genéticos, imunológicos, moleculares e funcionais (Projeto Temático Fapesp, Processo 2016/01743).

Paralelamente aos estudos da miopatia gestacional e IUEG, ampliando o conhecimento sobre as repercussões da gestação, em sua dissertação de mestrado de 2007, Cibelee Rudge inicia os questionamentos sobre a falta de um questionário que avaliasse a sexualidade em gestantes, desenvolvendo assim o *Pregnancy Sexual Response Inventory* (PSRI) (Anexo 1). (9)

Ana Paula Machado de Almeida, em sua dissertação de mestrado (Processo 2012/25207-4), utilizou o questionário PSRI e calculou a pontuação para interpretação do questionário e verificou a possibilidade de usar o mesmo escore em diferentes trimestres gestacionais. O cálculo da pontuação "por domínio" e o escore "geral" foram obtidos, e foi concluído que o questionário PSRI pode ser aplicado em qualquer período de gestação. A pontuação detectou a influência negativa da gravidez na sexualidade feminina em 8/10 domínios. (10)

No contexto funcional, a presente dissertação de mestrado se insere a fim de investigar o efeito do DMG na função sexual, ou seja, considerou as questões do PSRI para analisar o comportamento sexual de gestantes normoglicêmicas e hiperglicêmicas e desta forma colaborar na elucidação dos achados anteriormente descritos sobre a alteração muscular do assoalho pélvico e sobre a influência do DMG na sexualidade.

O parecer consubstanciado do Comitê de Ética em Pesquisa referente a esta dissertação está apresentado no Anexo 2, assim como o Termo de Consentimento Livre no Anexo 3.

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Trajetória Acadêmica

Em 2012, ingressei como aluna de graduação no curso de Fisioterapia na Unesp, campus de Marília, onde me formei em 2015.

Ao decorrer de 2014, iniciei pesquisas com a professora Angélica Barbosa e fui bolsista de iniciação científica do trabalho intitulado "Efetividade da eletroestimulação transcutânea do nervo tibial posterior unilateral e bilateral como propostas de intervenção fisioterapêutica da incontinência urinária por urgência".

Durante 2015, comecei a participar das reuniões do grupo de pesquisa as quais considero essenciais para o início da minha jornada acadêmica. Fazer parte de um grupo de estudos com tantos anseios em relação a pesquisa ampliou meus horizontes para um olhar na perspectiva científica. Em 2016, me mudei para Botucatu e iniciei como aluna regular no programa de mestrado.

Nesses dois anos, conquistei muita experiência: participei de *workshops* e capacitações de Eletromiografia e Ultrassonografia do assoalho pélvico, integrei-me à rotina de coleta hospitalar nos ambulatórios, enfermarias e laboratórios, participei na elaboração como coautora de cinco trabalhos apresentados em congressos nacionais e três internacionais (Anexos 4-10). Adquiri amplos conhecimentos científicos e principalmente, aprendi muito sobre trabalhar em equipe multidisciplinar com parceiros tão admiráveis e competentes.

Este é apenas o início de uma longa caminhada, mas já me sinto realizada pelos frutos alcançados e por todo o crescimento pessoal e profissional.

Sumários

Resumo

Nunes, S. K. Comparação da Resposta Sexual entre Gestantes Hiperglicêmicas e Normoglicêmicas, 2018. Dissertação (Mestrado) – Faculdade de Medicina de Botucatu, Universidade Estadual Paulista, Botucatu, Brasil.

Introdução: A nova ênfase no diagnóstico e tratamento da Diabetes Mellitus Gestacional (DMG) não é apenas para prevenir a morbidade e mortalidade perinatal, mas também representa a lacuna única de oportunidades para prover cuidados a longo prazo da mãe e do feto. Os efeitos de toda essa informação dada às mães sobre DMG no meio da gravidez e sua responsabilidade de gerenciar os fatores metabólicos intrauterinos por controle hiperglicêmico rigoroso enfrentam um estado de ansiedade e incerteza sobre problemas futuros atuais ou potenciais. Todos esses ajustes podem afetar a emoção, a mentalidade e a sexualidade aprovada pela declaração da Organização Mundial de Saúde como o direito fundamental para todas as pessoas. As dificuldades sexuais mais frequentes durante a gestação estão associadas a fatores psicológicos, físicos, relacionais, socioculturais e religiosos, bem como medos e mitos sobre a sexualidade feminina durante a gravidez. **Objetivos:** Este estudo foi projetado para investigar a função sexual usando índices de composição e pontuação específica do Inventário de Resposta Sexual de Gravidez (PSRI) em uma população bem categorizada de pacientes recentemente diagnosticados e sob tratamento de mulheres com Diabetes Mellitus Gestacional (GDM). **Método:** O presente estudo de coorte transversal foi composto por dois grupos, sendo um com 168 participantes no grupo de normoglicêmicas e outro com 108 participantes no grupo de hiperglicêmicas. Foi aplicado o questionário *Pregnancy Sexual Response Inventory* (PSRI) com a finalidade de avaliar a qualidade sexual das gestantes no terceiro trimestre gestacional. Foi analisado "por domínio" e a pontuação "geral" que variam de 0 (pior) até 100 (o melhor) e a pontuação final será proposta em categorização dividida em quartis como 0 <25 em "muito ruim", 25 <50 em "ruim", 50 <75 em "bom" e 75 a 100 em "excelente". **Análise de dados:** Ao término da coleta de dados, os resultados obtidos nos diferentes momentos foram compilados. A consistência interna e confiabilidade dos itens do PSRI de cada domínio foi avaliada por meio do coeficiente alfa de Cronbach. A comparação entre os valores de domínios classificados por trimestre foi avaliada pelo teste Wilcoxon e a comparação entre as médias foi avaliada pelo Teste-t. Para as variáveis quantitativas foi realizado o Teste t para dados com distribuição normal e com distribuição gama para variáveis com distribuição assimétrica. As associações entre as variáveis qualitativas serão feitas por meio de tabelas de contingência, com aplicação de teste qui-quadrado ou exato de Fisher. Todos os dados foram analisados usando o software estatístico SAS versão 9.2. Foi aplicado o cálculo para verificar o escore específico de cada um dos domínios. **Resultados:** A versão completa do PSRI em português brasileiro foi respondida por 276 mulheres grávidas, sendo 108 no grupo DMG e 168 no grupo não-DMG e os escores compostos de PSRI foram significativamente menores no grupo DMG em comparação com o grupo não-DMG ($41,2 \pm 17,3$ versus $54,5 \pm 15,0$, $P = <0001$). De acordo com esses resultados, o grupo DMG no terceiro trimestre da gravidez apresenta menores escores de função sexual do que o grupo não-DMG. **Conclusão:** Os resultados deste estudo fornecem evidências adicionais de que as gestantes do grupo DMG foram mais propensas a reportar disfunção sexual causada pelo impacto adicional de todos os aspectos que transformam a gravidez normal em importante e súbito prejuízo com grande sofrimento para a mãe e sua família.

Palavras-chave: *Diabetes mellitus* gestacional, gestação, função sexual, *Pregnancy Sexual Response Inventory*.



Abstract

Nunes, S. K. **Comparison of Sexual Response Between Hyperglycemic and Normoglycemic Pregnant Women**, 2018. Thesis (Master) - São Paulo State University (Unesp), Medical School, Botucatu, Brazil.

Introduction: The new emphasis on the diagnosis and treatment of Gestational Diabetes Mellitus (GDM) is not only to prevent perinatal morbidity and mortality but also represents the unique gap in opportunities to provide long-term care for the mother and fetus. The effects of all this information given to mothers about GDM in the midst of pregnancy and their responsibility for managing the intrauterine metabolic factors for rigorous hyperglycemic control face a state of anxiety and uncertainty about current or potential future problems. All of these adjustments can affect the emotion, mentality and sexuality endorsed by the World Health Organization statement as the fundamental right for all people. The most frequent sexual difficulties during gestation are associated with psychological, physical, relational, sociocultural and religious factors, as well as fears and myths about female sexuality during pregnancy. **Objectives:** This study was designed to investigate sexual function using composite indexes and specific Pregnancy Sexual Response Inventory (PSRI) scores in a well-categorized population of newly diagnosed and under-treated women with GDM (Gestational Diabetes Mellitus). **Method:** The present cross-sectional cohort study consisted of two groups, one with 168 participants in the normoglycemic group and another with 108 participants in the hyperglycemic group. The Pregnancy Sexual Response Inventory (PSRI) questionnaire was applied to evaluate the sexual quality of pregnant women in the third trimester of pregnancy. It was analyzed by "domain" and the "general" score ranging from 0 (worst) to 100 (best) and the final score will be proposed in categorization divided into quartiles as 0 <25 in "rubbish", 25 <50 in "bad", 50 <75 in "good" and 75 to 100 in "excellent". **Data analysis:** At the end of the data collection, the results obtained in the different moments were compiled. The internal consistency and reliability of PSRI items in each domain was assessed using the Cronbach alpha coefficient. The comparison between the values of domains classified by quarter was evaluated by the Wilcoxon test and the comparison between the means was evaluated by the t-Test. For the quantitative variables, the t test was performed for data with normal distribution and with gamma distribution for variables with asymmetric distribution. The associations between the qualitative variables will be made by means of contingency tables, with application of chi-square test or Fisher's exact test. All data were analyzed using statistical software SAS version 9.2. The calculation was applied to verify the specific score of each of the domains. **Results:** The complete version of PSRI in Brazilian Portuguese was answered by 276 pregnant women, 108 in the DMG group and 168 in the non-DMG group, and the PSRI scores were significantly lower in the DMG group compared to the non-DMG group (41.2 ± 17.3 versus 54.5 ± 15.0 , $P = <10001$). According to these results, the DMG group in the third trimester of pregnancy has lower sexual function scores than the non-DMG group. **Conclusions:** The results of this study provide additional evidence that pregnant women in the DMG group were more likely to report sexual dysfunction caused by the additional impact of all aspects that make normal pregnancy an important and sudden injury with great suffering for the mother and her family.

Key words: Pelvic floor, Pregnancy, Pregnant women, Sexuality

Artigo

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A case-control study of sexual function evaluated by the Pregnancy Sexual Response Inventory (PSRI) among women who received guidance and treatment for a gestational diabetes mellitus diagnosis and the long-lasting influence on mother and offspring

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Running title: Sexuality on Gestational Diabetes

Précis: Gestational diabetes mellitus decreases women sexual function in the third trimester.

Abstract

Objective: To compare PSRI composite and specific scores between women who recently were diagnosed and under treatment for GDM and women who were not.

Design: Case-control study.

Setting: Brazilian Perinatal Diabetes Research Centre-Unesp.

Patient(s): Pregnant women.

Intervention(s): None.

Main Outcome Measure(s): Specific and composite PSRI scores before and during pregnancy in the case group (GDM) compared to the control group (non-GDM) to detect the conjoint impact of GDM diagnosis, treatment and long-lasting maternal and offspring guidance on sexual function.

Result(s): Compared with non-GDM women, women who did develop GDM had lower specific and composite PSRI scores (41.2 ± 17.3 versus 54.5 ± 15.0 , $P < .0001$) and higher prevalence of pregnant sexual dysfunction (PSD) in the third trimester (66.7% versus 33.9%).

Conclusion(s): A specific and composite decrease in PSRI score and an increase in sexual dysfunction provide evidence that pregnancy and GDM are a adverse combination.

Key Words: Gestational Diabetes Mellitus, Pregnancy, Pregnancy Sexual Response Inventory, Sexual function.

Introduction

Introduction

The new emphasis in the universal diagnoses on strict glycemic control for gestational diabetes mellitus (GDM) is intended not only to prevent perinatal morbidity and mortality but also to present an opportunity to provide long-term maternal and offspring care. To optimize gestational outcomes and reduce the risk of maternal and perinatal complications, women with GDM should change their habits and undergo rigorous medical follow-up until delivery. Recommendations include maintenance of an adequate and controlled diet to ensure control of weight gain, an active lifestyle, continuous monitoring of glucose level and, sometimes, daily insulin injections. In addition, as part of their follow-up, these patients receive information about the risks of GDM and possible fetal complications associated with the disease, such as polyhydramnios, macrosomia, preterm delivery and tocotrauma (11). Health-care professionals are encouraged by the Federation International Gynecology and Obstetrics (FIGO) to educate and advise the pregnant woman and her family on the different approaches to prevent or delay the negative outcomes of GDM for herself and her offspring (12).

The substance of these reports may affect maternal emotional, mental and sexual health as endorsed by the World Health Organization declaration, which asserts that these are the fundamental right of all persons (3-6). Sexual health is defined as “a state of physical, emotional and social well-being in relation to sexuality” and “not merely the absence of disease dysfunction or infirmity” (3, 7). The female sexual response cycle proposed by Basson (13) starts from a neutrality phase, and the rewards of emotional closeness serve as the motivational factors that will activate the cycle next time. The burden of GDM diagnosis and treatment and its negative long-term

consequences may unsettle the emotional intimacy of the partners and, as a consequence, affect the sexual lives of both partners (13,14).

Although there are studies on emotional disorders such as anxiety and stress (15) in women diagnosed with GDM, there is a lack of investigations assessing the sexual function of these women (16). It is well-established in the literature that during pregnancy, most women experience a decline in sexual activity and function (17,18) and a decrease in the sexual activity frequency and sexual function during the third trimester of pregnancy (19,20). If pregnancy and GDM are a prejudicial combination detrimental to female sexual function, there are insufficient data in the literature on this topic, and the studies assessing the sexual function in GDM women are still controversial. Conflicting results were found in five recent articles using FSFI (Female Sexual Function Index) as a validated questionnaire either in web-based or paper-based versions to evaluate sexual function (21,22). Two of them showed no difference in FSFI scores, either in current GDM patients compared to healthy women or in previous GDM women (16,23). Another one showed that GDM women had a higher incidence of sexual dysfunction and lower scores of FSFI for all domains compared with low-risk pregnant women (24). The association of overweight women with GDM showed lower FSFI scores than normal-weight women with the same disorder (25).

Taken together, the interactions among pregnancy, concerns of GDM diagnosis and treatment, lifestyle adaptations, and biological changes create a burden of long-lasting effect for both women and their offspring and affect the woman's central role in the family and healthy community. Our hypothesis, based on this premise, is that the sexual function in women with GDM will be compromised compared to the pre-pregnancy period.

To study the potentially conjoint effect of all these variables in previously normal pregnant women, this study was designed to assess whether PSRI composite and

specific scores vary significantly between women who were recently diagnosed and under treatment for GDM and those who did not receive this challenging diagnosis to identify if pregnancy and GDM are a prejudicial combination.

Materials and Methods

Study Design

This case-control study was developed among pregnant women at the Brazilian Perinatal Diabetes Research Centre (PDRC) of University Hospital-Unesp, a tertiary referral unit in southeast Brazil, between 2016-2017. Approval for the study was given by the local Institutional Research Bureau- IRB (Botucatu Medical School Unesp, Brazil) under the protocol number (CAAE: 73305517.5.0000.5411). The study adhered to the tenets of the Declaration of Helsinki. Pregnant women were recruited at the time of antepartum screening for GDM. The protocol was explained to each participant, voluntary participation was emphasized, and privacy was assured. Written informed consent was obtained from all subjects according to Declaration of Helsinki principles. This study was part of Project (Proc. 563808/2010- Pregnancy complicated by mild gestational hyperglycemia and GDM as a window of susceptibility, identified by maternal, placental and cord blood biomarkers for the prevention of Type 2 DM) with financial support from CNPq/Brazil Health Ministry (MCT/CNPq/CT-Saúde/MS/Decit nº 42/2010).

Sample size estimation

Sample size was calculated based on the estimated prevalence of 40% sexual dysfunction in pregnant women (19) and an absence of confounders; type I errors=0.10 and II=0.05. It was estimated that to detect differences greater than or equal to 10%

size, the minimum sample size was 92 participants per group.

Case Group Assessment

The case group included women who developed GDM and received full guidance related to the deleterious influence on perinatal outcome, the need for awareness of the strict glycemic control during pregnancy to avoid these complications and the severe short- and long-term effects on her own health and that of her offspring. The diagnostic protocol in PRDC for GDM has two steps: universal screening with fasting glucose ≥ 90 mg/dL and risk factors (personal, obstetric and family) (26). All positive-screened women were followed after the diagnostic phase with a 75 g-Oral Glucose Tolerance Test (OGTT) and a glycemic profile. GDM was diagnosed by a 75-g glucose tolerance test (75-gGTT), recommended by the American Diabetes Association (27), and with the glucose profile (GP) test, as recommended by Rudge (20), between the 24th and 28th gestational weeks. Patients with a positive screening and negative diagnosis of gestational hyperglycemia (normal OGTT and glycemic profile) were classified as non-GDM (27).

All mothers with GDM received glucose-lowering treatment consisting of dietary and lifestyle counselling aiming to achieve glycemic control; insulin therapy was introduced when necessary. Glycemic control and management of diabetes were evaluated by 24-h GP glycemic profile (fasting, pre- and post-prandial glycemic levels) performed at 2-week intervals until week 32 and weekly until delivery.

The sample consisted of pregnant women with GDM (case group) and without GDM (control group) diagnosis and under rigorous treatment. Inclusion criteria were literacy, 18 years or older, gestation age higher than 28 weeks, stable heterosexual relationship for almost the last 6 months and out of labor. Exclusion criteria were clinical and/or obstetric complications that contraindicated sexual activity (such as placenta

previa, premature rupture of membranes and preterm labor), pregnancy resulting from rape, twin pregnancy, regular use of alcohol and/or illicit drugs, arterial hypertension and use of psychoactive drugs.

The groups were composed considering the inclusion and exclusion criteria and classified according to hyperglycemia exposure (case group n=108) or non-diabetic exposure (control group n=168) (Figure 1).

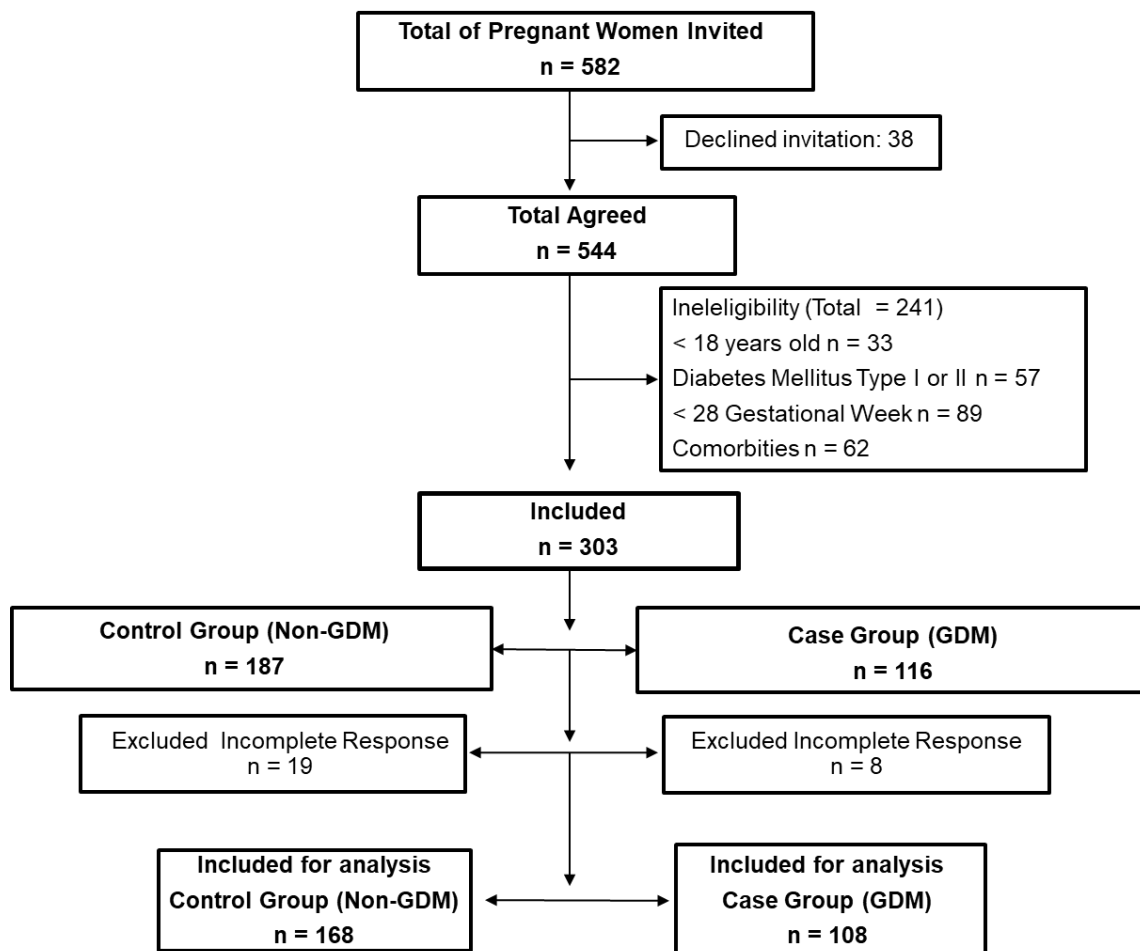


Figure 1. Flowchart of individuals enrolled in the study.

Data Collection

Details of the questionnaire

All participants answered the Pregnancy Sexual Response Inventory (PSRI) Portuguese version (28), a semi-structure designed and validated questionnaire with good internal consistency and reliability over its entire scale (Cronbach's alpha coefficient=0.79) to evaluate sexual function during pregnancy. The PSRI is a 38-item questionnaire (12 demographic characteristics and 26 items about sexual behavior/activity before and during pregnancy). The PSRI (supplemental material) was applied during the third-trimester and suitable for use in assessing sexual function during pregnancy in obstetric clinical samples (37).

To evaluate sexual function, the composite and specific scores measured by domains of the PSRI were categorized into quartiles by sexual response as 0 <25 in "rubbish", 25 <50 in "bad", 50 <75 in "good" and 75-100 in "excellent", for "Before pregnancy" and "During pregnancy" (28). The turn point was established at ≥ 50 (without sexual dysfunction) and < 50 (with sexual dysfunction) based on PSRI quartiles to detect sexual dysfunction.

Outcome Measures

The current primary outcomes of this study were the PSRI composite and specific scores for each domain before and during pregnancy in the case group compared with the control groups of pregnant women in order to detect the conjoint, long-lasting impact of guidance about GDM diagnosis and treatment on the mothers and offspring and to diagnose sexual dysfunction. The secondary outcomes were the PSRI composite and specific scores for each domain before and during pregnancy in both the case and control groups to detect changes in sexual function induced by pregnancy.

Statistical Analysis

The results are presented descriptively, and the collected data were manually transcribed on previously printed forms and later digitally included in an electronic database. Student's *t*- and chi-square tests were used to compare continuous and categorical sociodemographic variables of the case group and control group. Comparison means of the domains values between the groups and before and during pregnancy, classified by both analyzed periods, were assessed by paired *t*-test. All data were analyzed using SAS statistical software version 9.3, and the statistical significance was set at 0.05 for all the tests.

Results

During the study period, the PSRI was answered by 108 GDM women who formed the case group; 168 women who did not develop GDM were randomly selected as the control group. The demographic features of our full sample are presented in Table 1. There were no differences between the case and control groups in almost all these characteristics. Most women in our sample (74.1 and 79.2) were married or living together and had studied until elementary school (55.6% and 53.0%). From our sample, 62.0% and 54.8% were of Catholic denomination, 35.2% and 41.7% were Brazilian Protestants, and the rest answered another or no religion. Higher proportions of the respondents were students and unemployed (49.1% and 36.3%). A higher percentage (86.1% and 88.9%) reported either nonsmoking habits or not drinking alcohol even socially (91.7% and 93.5%). A history of illicit drug use was seen in 2.8% and 1.8% of all respondents. A high prevalence of our sample (62.8% and 63.7%) declared that pregnancy was unplanned, and 55.6% and 67.3% did not use a condom. GDM women

were older ($P<.0001$), (28.9 ± 4.7 and 25.1 ± 5.31), and the majority were first gestation (71.3% and 76.8%) and answered the questionnaire one week later (34.1 ± 2.8 and 33.0 ± 3.3).

Table 1. Descriptive demographic characteristics of pregnant women collected by Pregnancy Sexual Response Inventory (PSRI).

Variable	GDM (n=108)		non-GDM (n=168)		P-value
	Mean	SD	Mean	SD	
1 - Maternal Age (years)	28.9	± 4.7	25.1	± 5.3	<.0001
2 - Gestational Age (weeks)	34.0	± 2.7	33.0	± 3.2	.0063
	n (%)		n (%)		
3- Partnership status					
(1) (1) married/living together	80	(74.0)	133	(79.1)	0.5098
(2) (2) single	18	(16.6)	25	(14.8)	
(3) (3) other	10	(9.2)	10	(5.9)	
4 - Education level					
(1) (1) basic level	60	(55.5)	89	(52.9)	0.9153
(2) (2) high school	40	(37.0)	66	(39.2)	
(3) (3) college/university	8	(7.4)	13	(7.7)	
5 – Religion					
(1) (1) catholic	67	(62.0)	92	(54.7)	0.4876
(2) (2) evangelical	38	(35.1)	70	(41.6)	
(3) (3) others	3	(2.7)	3.57	(3.5)	
6- Do you work?					
(1) (1) no	53	(49.0)	61	(36.3)	0.1016
(2) (2) yes, and I have a job	26	(24.0)	47	(27.9)	
(3) (3) yes, but now I am unemployed	29	(26.8)	60	(35.7)	
7- Do you have children?					
(1) (1) no	77	(71.3)	129	(76.7)	0.3063
(2) (2) just one	31	(28.7)	39	(23.2)	
(3) (3) two or more					
8 – Do you smoke?					
(1) (1) yes, often or very often	10	(9.2)	10	(5.9)	0.5683
(2) (2) yes, but just sometimes	5	(4.6)	7	(4.1)	
(3) (3) no	93	(86.1)	151	(89.8)	
9 – Do you drink?					
(1) (1) yes, often or very often	3	(2.7)	9	(5.3)	.0689
(2) (2) yes, but just sometimes	6	(5.5)	0.72	(1.1)	
(3) (3) no	99	(91.6)	157	(93.4)	
10 – Do you use illicit drugs?					
(1) (1) yes, often or very often	0	(0.0)	1	(0.6)	0.6245
(2) (2) yes, but just sometimes	3	(2.7)	3	(1.7)	
(3) (3) no	105	(97.2)	164	(97.6)	
11 – Did you plan your pregnancy?					

(1) (1) yes	68 (62.9)	107 (63.6)	0.9025
(2) (2) no	40 (37.0)	61 (36.3)	
12 – Do you use condoms?			
(1) (1) no	60 (55.5)	113 (67.2)	.0497
(2) (2) yes	48 (44.4)	55 (32.7)	

Chi-square and student's *t*-test. Statistically significant *p* value was less than 0.05.
Standart Derivation (SD)

The PSRI composite and specific scores by domains were compared between the case and control groups before and during pregnancy (Table 2). Among all pregnant women before pregnancy, the PSRI composite scores were similar between groups. Values were lower in the case group for only two specific scores by the domains frequency ($P<.0001$) and desire ($P<.0001$). During pregnancy, the specific PSRI scores were lower in the case group in many domains compared to the control group for frequency ($P<.0001$), desire ($P<.0001$), arousal ($P<.0001$), orgasm ($P<.0001$), satisfaction ($P<.0001$), intercourse start ($P<.0009$) and a higher score of perception of male sexual difficulties related to pregnancy ($P<.0001$). Therefore, the composite score in the case group was lower (41.3 ± 17.3) compared to the control group (54.5 ± 15.1).

Table 2. Comparisons of specific and composite PSRI scores between GDM and non-GDM groups before and during pregnancy.

Specific Scores	Before Pregnancy			During Pregnancy		
	GDM (n=108)	non-GDM (n=168)	<i>P</i> -value	GDM (n=108)	non-GDM (n=168)	<i>P</i> -value
Frequency Score	55.0 ± 22.6	55.9 ± 21.7	<.0001	31.9 ± 19.6	38.2 ± 18.4	<.0001
Desire Score	51.3 ± 49.5	82.4 ± 37.5	<.0001	46.3 ± 12.7	59.2 ± 22.3	<.0001
Arousal Score	50.0 ± 28.1	52.0 ± 24.0	0.5125	21.3 ± 27.5	46.1 ± 25.0	<.0001
Orgasm Score	60.6 ± 32.8	58.0 ± 31.1	0.5058	33.8 ± 29.6	51.4 ± 30.6	<.0001
Satisfaction Score	61.1 ± 23.2	65.9 ± 24.8	0.1086	27.0 ± 26.7	47.9 ± 23.1	<.0001
Dyspareunia Score	86.1 ± 34.7	84.5 ± 36.2	0.7186	49.0 ± 50.2	73.8 ± 44.1	0.4833
Intercourse start Score	58.3 ± 29.4	54.7 ± 29.0	0.3223	47.2 ± 23.5	49.4 ± 26.2	.0009
Female difficulties Score	84.2 ± 36.5	78.5 ± 41.1	0.2432	33.3 ± 47.3	53.5 ± 50.0	0.1863
Male sexual satisfaction Score	70.3 ± 29.8	66.3 ± 30.2	0.2815	32.8 ± 24.8	36.9 ± 24.6	0.7706
Male sexual difficulties Score	90.7 ± 29.1	89.8 ± 30.2	0.8153	89.8 ± 30.3	88.6 ± 31.7	<.0001
Composite score	66.8 ± 14.7	68.8 ± 15.7	0.2801	41.2 ± 17.3	54.5 ± 15.0	<.0001
Paired t-test						

The PSRI composite and specific scores by domains were compared between the case and control groups before and during pregnancy (Table 2). Among all pregnant women before pregnancy, the PSRI composite scores were similar between groups. Values were lower in the case group for only two specific scores by the domains frequency ($P<.0001$) and desire ($P<.0001$). During pregnancy, the specific PSRI scores were lower in the case group in many domains compared to the control group for frequency ($P<.0001$), desire ($P<.0001$), arousal ($P<.0001$), orgasm ($P<.0001$), satisfaction ($P<.0001$), intercourse start ($P<.0009$) and a higher score of perception of male sexual difficulties related to pregnancy ($P<.0001$). Therefore, the composite score in the case group was lower (41.3 ± 17.3) compared to the control group (54.5 ± 15.1).

The behavior patterns of the PSRI composite and specific scores are reported by domains, with 50 considered the “turning point” to separate rubbish and bad from good and excellent categorization for before and during pregnancy to show the influence of pregnancy on sexual function as well to classify sexual dysfunction as a whole (composite score) in pregnant women. The specific scores by domains are shown in Figure 2. Three different patterns were revealed. The first pattern was a decrease from pre-pregnancy to third trimester associated with a change from good to bad in the categorization in both groups: this model occurred for frequency ($P>.0001$ and $P>.0001$), arousal ($P>.0001$ and $P>.0001$), satisfaction ($P>.0001$ and $P>.0001$), intercourse start ($P>.0001$ and $P=.0139$) and male satisfaction ($P>.0001$ and $P>.0001$). The composite score of the case group decreased from pre-pregnancy to the third trimester, associated with changes over time from good to bad categorization confirming the strength of the deleterious impact of GDM diagnosis, treatment and the long-lasting maternal and offspring influence on maternal sexual

response.

The second pattern of PSRI scores showed a stable permanency in good categorization by specific domain only in the control group: this model occurred in desire ($P>.0001$), orgasm ($P>.0001$), dyspareunia ($P=.0006$) and female difficulties ($P>.0001$). This second pattern is shown by the composite scores that kept the same categorization revealing the influence of pregnancy on sexual function.

The third pattern was a stable permanency in good categorization in both groups during pregnancy. This model occurred only in the male difficulties score (case $P=0.3196$ versus control group $P=0.7327$) according to female perception.

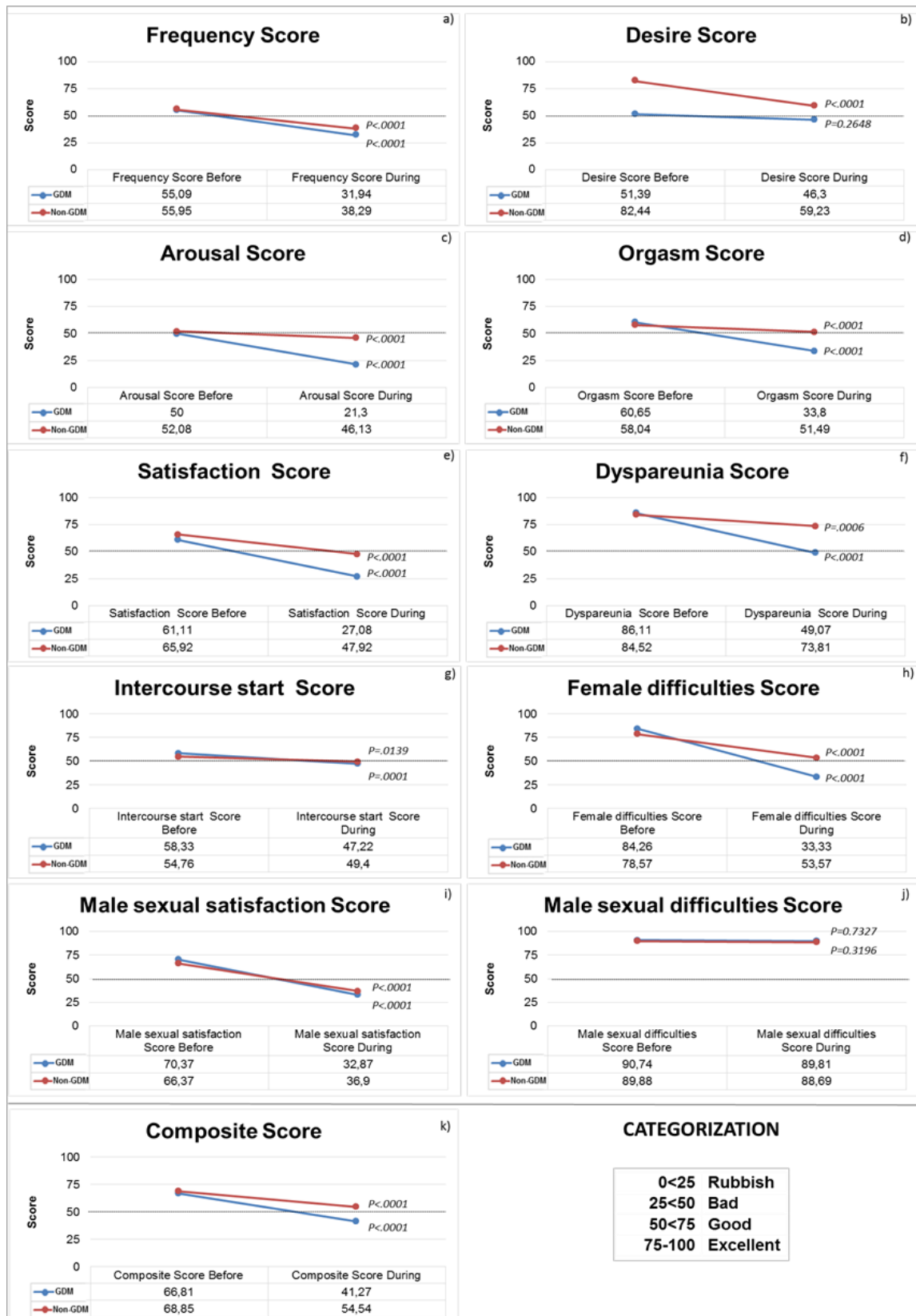


Figure 2. Comparison between before and during pregnancy of specific scores by domain and composite score in the PSRI categorization. Gestational Diabetes Mellitus (GDM) group, non-diabetic pregnant women (non-GDM) group. Paired t-test

Based on the PSRI composite score of 50 for sexual dysfunction, the overall prevalence of Pregnant Sexual Dysfunction (PSD) among sexually active pregnant women increased significantly from pre-pregnancy to the third trimester either in case or control groups (Table 3). This upward movement of PSD was higher in the case group (13.9% to 66.7%) compared to the control group (11.3% to 33.9%).

Table 3. Sexual dysfunction before and during pregnancy in GDM and non-GDM groups and comparison of sexual dysfunction between groups according to PSRI composite score.

	GDM	non-GDM	
Variable	(n=108)	(n=168)	<i>P</i> -value
Before Pregnancy	15 (13.9)	19 (11.3)	0.6538
During Pregnancy	72 (66.7)	57 (33.9)	<.0001
<i>P</i> -value	<.0001	<.0001	

Chi-square test.

Discussion

This study aimed to evaluate the conjoint impact of recent GDM diagnosis in a previously normal pregnancy associated with guidance, namely, that this maternal environmental disorder could lead to increased perinatal morbidity and mortality and that maternal glucose control was essential to maternal and fetal health and essential to decrease the severe short- and long-term effects on the mother's own health and that of her offspring and what effect this has on sexual function. These results are based on a well-characterized case-control clinical study sample of GDM pregnant women in which sexual function was evaluated using PSRI, a validated questionnaire for pregnancy.

The present study found that specific and composite PSRI scores identified that GDM diagnosis, treatment and long-lasting influence on mother and offspring in previous normal pregnant women had an impact on sexual function: a decrease in specific and composite scores associated with changes in the PSRI categorization from good to bad was detected, associated with an increase in sexual dysfunction. These big challenges occurred just after clarifications received by the mother about her GDM diagnosis and the guidance for her active participation in the glycemic control to avoid perinatal complications in the short and long term (30–33). These results are in accordance with previous studies in pregnancy showing not only that the pregnant physiological adaptations interfere with sexual function but also that maternal morbidity has long-term repercussions on women's sexual life.

Postpartum women often experience maternal morbidity, dyspareunia and less sexual activity; however, FSFI scores differed between groups in all studies. The female sex response cycle proposed by Basson (13) starts from a neutral phase, and the rewards of emotional closeness serve as the motivational factors that will activate

the cycle next time. To the best of our knowledge, this current study is the first to consider the burden of GDM diagnosis, treatment and the negative long-term consequences that may affect the emotional intimacy of both partners and, as a consequence, the sex lives of both partners (13,34).

The physiopathological basis to explain some of the altered specific PSRI scores in GDM women may be offered based on our previous results in translational studies. GDM was associated with gestational-specific urinary incontinence that was a predictor of urinary incontinence and pelvic floor muscle dysfunction 2 years after C-section (2). Severe and moderate diabetes in pregnant rats showed morphological changes in the urethral muscle and rectus abdominis muscle characterized by thinning, atrophy, fibrosis, increased area of blood vessels, mitochondria accumulation, increased lipid droplets, glycogen granules associated with localization of fast and slow fibers, and a steady decrease in the proportion of fast to slow fibers (3,35–37). Severe diabetes in pregnant rats showed significantly increased stiffness in urethral tissue, decreased striated muscle and increased deposition of collagen fibers around the muscle fibers and a change in the organization of the collagen fibrils. An increase in the relative collagen type I/III ratio and a decrease in total glycosaminoglycans were also observed (35). The fast vs slow fiber type profiles, the different organization of the collagen fibrils, and the glycosaminoglycans profile found in urethral samples suggest that the pathology of the urethral fibromuscular system could be related to hyperglycemia-induced pelvic floor muscle dysfunction in GDM women. The analysis of PSRI-specific scores from GDM women including arousal, orgasm and satisfaction could be related to our clinical findings of pelvic floor muscle dysfunction associated with a failure to maintain healthy skeletal muscle. This may contribute to the development of pelvic floor dysfunctions via different pathways

observed in urethral and rectus abdominis muscles of diabetic pregnant rats. The confirmation of all these experimental findings in GDM women must be developed to account for different results found by different authors using FSFI as the instrument to evaluate sexual function in pregnancy (16,23).

The PSRI categorization above 50 as the “turning point” to separate the rubbish and bad from good to excellent allows us to classify PSD. The overall prevalence of PSD among sexually active pregnant women increases significantly from pre-pregnancy to the third trimester in both the case and control group. Although a decrease from pre-pregnancy to the third trimester with stable permanency in good categorization was observed only in the control group, these results enable us to confirm the negative impact of pregnancy on sexual function in the control group, as described in the literature (24). The main factors that may lead to sexual dysfunction within pregnancy are caused by perceived loss of attractiveness, low self-esteem due to body image and psychological factors. Physiological adaptations would be perceived as abnormal when compared to the non-pregnant state. During perinatal periods, low sex drive and dysfunctional problems are highly prevalent, but the data regarding the degree of normality within pregnancy are lacking. A systematic review has found a gradual decrease in vaginal intercourse from pre-pregnancy to the first and third trimesters (38) and a reduction in sexual function during pregnancy (39–42).

The downward movement of PSRI scores from pre-pregnancy to the third trimester was higher in the case group compared to the control group, confirming an additional impact of GDM, even though the FSFI questionnaire showed conflicting results in GDM women. Three studies did not detect differences between GDM and healthy women, one found lower FSFI scores in GDM women, and one found lower FSFI scores in GDM obese women (16,23,24,43,44). The Brazilian Cohort Study

showed no differences in the total FSFI scores between women with and without severe maternal morbidity (45). The reason for the conflicting results could be that FSFI was not specifically delineated for pregnant women, while PSRI is designed and validated for pregnant women.

Sexual function is a multidimensional phenomenon that is affected by many biological, psychological, and social factors (46,47) and maternal complications during pregnancy (45). The sexual function of pregnant women is unpredictable, and the literature is controversial, showing increasing or decreasing function or no changes (42). Pregnancy is a period with numerous physical, psychological and social changes that may affect sexual function, and GDM has an additional negative impact on sexual function.

Inevitably, the present study had some limitations including the maternal adherence to GDM treatment and control of glycemic levels. Nevertheless, this study is the first to perform an evaluation of the sexual function with a structured and validated questionnaire for pregnant women. Careful control of potential confounders has been proposed to minimize bias of reverse causality or unmeasured confusion. The cutoff points will need to be validated in prospective controlled studies to ensure a better-standardized collection of data to clarify the applicability of PSRI values to the obstetric population.

Further studies are needed to elucidate whether the mechanisms underlying the urethral and rectus abdominis muscles of diabetic pregnant rats are similar in GDM women. Considering that PSD can have an important negative effect on quality of life and partner relationships, the sexual function evaluated by PSRI should be considered as a tool to be used at prenatal care for sexual function evaluation either in research or in practice.

Conclusion

In conclusion, sexual function evaluated by the specific and composite Pregnancy Sexual Response Inventory (PSRI) scores might be useful to identify sexual dysfunction in GDM women. The downward movement of specific and composite PSRI scores associated with upward Pregnancy Sexual Dysfunction provide evidence of the additional impact of GDM that negatively switches sexual function in women with previously normal pregnancies.

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Supplemental Materials

QUESTIONÁRIO DA RESPOSTA SEXUAL NA GRAVIDEZ (PSRI) PREGNANCY SEXUAL RESPONSE INVENTORY

Paciente: _____ Data de nascimento: ____/____/____
QUESTIONÁRIO DA RESPOSTA SEXUAL NA GRAVIDEZ (PSRI - PREGNANCY SEXUAL RESPONSE INVENTORY)
I- IDENTIFICAÇÃO: _____

- 1 - Qual a sua idade? _____
2 - Idade gestacional _____
3 - Seu estado civil é?
1 () casada/união estável
2 () solteira
3 () outros: _____
4 - Você estudou até que série?
1 () 1º grau completo/incompleto
2 () colegial incompleto/completo
3 () superior incompleto/completo
5 - Qual a sua religião?
1 () católica
2 () evangélica
3 () outras (budismo, judeu, umbanda, etc.)
6 - Você trabalha?
1 () do lar
2 () está empregada
3 () desempregada
7 - Quantos filhos você tem?
1 () nenhum
2 () um filho
3 () dois filhos ou mais
8 - Você fuma?
1 () sim, sempre
2 () sim, às vezes
3 () não
9 - Você bebe?
1 () sim, sempre
2 () sim, às vezes
3 () não
10 - Você usa drogas?
1 () sim, sempre
2 () sim, às vezes
3 () não
11 - Sua gravidez foi planejada?
1 () Não
2 () Sim
12 - Você usa camisinha?
1 () não
2 () parei com a gravidez
3 () sim, sempre ou quase sempre
II-Atividade Sexual - antes e durante a gravidez
13 - O número de relações sexuais com a gravidez
1 () diminuiu
2 () ficou igual
3 () aumentou
14a - Vocês tinham quantas relações por semana antes da gravidez?
1 () nenhuma
2 () uma ou duas
3 () mais que três
14b - Vocês tinham quantas relações por semana nos primeiros três meses de gravidez?
1 () nenhuma
2 () uma ou duas
3 () mais que três
14c - Vocês têm quantas relações por semana agora?
1 () nenhuma
2 () uma ou duas
3 () mais que três
15a - Qual nota você daria para sua vida sexual antes da gravidez?
1 () 0-3
2 () 4-7
3 () 8-10
15b - Qual nota você dá para sua vida sexual atualmente?
1 () 0-3
2 () 4-7
3 () 8-10
16a - Qual nota você acha que seu parceiro daria para a vida sexual de vocês, antes da gravidez?
1 () 0-3
2 () 4-7
3 () 8-10
16b - Qual nota você acha que seu parceiro daria para a vida sexual de vocês, atualmente?
1 () 0-3
2 () 4-7
3 () 8-10
17a - Você estava satisfeita com sua vida sexual antes da gravidez?
1 () não
2 () mais ou menos
3 () sim
17b - Você está satisfeita com sua vida sexual atual?
1 () não
2 () mais ou menos
3 () sim
18a - Você considerava seu desempenho sexual antes da gravidez?
1 () ruim/péssimo
2 () regular
3 () excelente/bom
18b - Você considera seu desempenho sexual durante a gravidez?
1 () ruim/péssimo
2 () regular
3 () excelente/bom
19a - Você tinha alguma dificuldade sexual antes da gravidez?
1 () sim
2 () não
19b - Você tem alguma dificuldade sexual durante esta gravidez?
1 () sim
2 () não
20 - Isso lhe incomoda?
1 () sim
2 () mais ou menos
3 () Não
21a - Com que frequência você tinha vontade de fazer sexo antes da gravidez?
1 () algumas vezes na semana
2 () uma vez ao dia
3 () outras (depende da ocasião, da disposição)
21b - Com que frequência você tem vontade de fazer sexo em média, hoje?
1 () algumas vezes na semana
2 () uma vez ao dia
3 () outras (depende da ocasião, da disposição)
22 - Sua vontade de fazer sexo com a gravidez
1 () diminuiu
2 () ficou igual
3 () aumentou
23a - Você tinha prazer nas relações antes da gravidez?
1 () não/raramente
2 () às vezes
3 () sempre/quase sempre
23b - Você tem prazer nas relações durante a gravidez?
1 () não/raramente
2 () às vezes
3 () sempre/quase sempre
24a - Você tinha dor na relação sexual antes da gravidez?
1 () sim
2 () não
24b - Você tem dor na relação sexual durante a gravidez?
1 () sim
2 () não
25 - Com quantos meses você passou a ter dor nas relações sexuais
1 () até 3 meses (1º trimestre)
2 () de 4 a 6 meses (2º trimestre)
3 () após 6 meses (3º trimestre)
26a - O início do ato sexual antes da gravidez geralmente era?
1 () forçado sem vontade
2 () iniciado pelo parceiro
3 () espontâneo/espontâneo com estímulo
26b - O início do ato sexual durante a gravidez geralmente é
1 () forçado sem vontade
2 () iniciado pelo parceiro
3 () espontâneo/espontâneo com estímulo
27a - Seu parceiro apresentava alguma dificuldade sexual antes da gravidez?
1 () sim
2 () não
27b - Seu parceiro apresenta alguma dificuldade sexual durante a gravidez?
1 () sim
2 () não



Anexos

Anexo 1

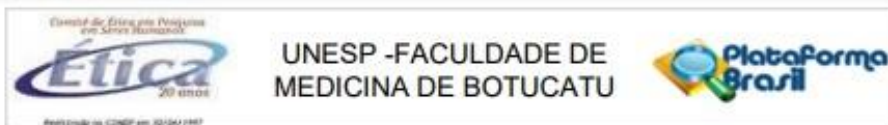
Pregnancy Sexual Response Inventory

I - Demographic characteristics	
1- Mother's age: Partners' age:	2- Gestational age:
3- Partnership status? (1) married/ living together (2) single (3) other _____	4- Education Level: (1) basic level (2) high school (3) college/university
5- Religion (1) Catholic (2) Evangelical (3) others _____	6- Do you work? (1) no (2) yes, and I have a job (3) yes, but now I am unemployed
7- Do you have children? () no () just one () two or more	8- Do you smoke? () yes, often or very often () yes, but just sometimes () no
9- Do you drink? () yes, often or very often () yes, but just sometimes () no	10- Do you use illicit drugs? () yes, often or very often () yes, but just sometimes () no
11- Did you plan your pregnancy? () yes () no	12- Do you use condoms? () no () yes, but I stopped before I became pregnant () yes, often or very often
II- Sexual Behavior/ Activity - before and during pregnancy	
13-In your opinion, did your frequency of sexual activity change after you became pregnant? (1) yes, it decreased (2) no, it's the same (3) yes, it increased	14a- Before your pregnancy, how many times per week were you having sexual intercourse? (1) none (2) 1-2 times (3) 3 or more times
14b- In the first trimester of pregnancy, how many times per week were you having sexual intercourse? (1) none (2) 1-2 times (3) 3 or more times	14c- At present, how many times per week are you having sexual intercourse? (1) none (2) 1-2 times (3) 3 or more times

15a- How would you rate your sex life before you became pregnant (0 = lowest, 10 = highest)? (1) 0-3 (2) 4-7 (3) 8-10	15b- How would you rate your sex life at present (0 = lowest, 10 = highest)? (1) 0-3 (2) 4-7 (3) 8-10
16a- How do you think your partner would rate his sex life before you became pregnant (0 = lowest, 10 = highest)? (1) 0-3 (2) 4-7 (3) 8-10	16b- How do you think your partner would rate his sex life at present (0 = lowest, 10 = highest)? (1) 0-3 (2) 4-7 (3) 8-10
17a- Were you getting any pleasure from your sex life before you became pregnant? (1) no (2) it was OK I suppose (3) yes	17b- Were you getting any pleasure from your sex life during pregnant? (1) no (2) it was OK I suppose (3) yes
18a- How would you rate your arousal before the pregnancy? (1) poor/ very poor (2) regular (3) excellent	18b- How would you rate your arousal during the pregnancy? (1) poor/ very poor (2) regular (3) excellent
19a- Were you having any sexual difficulties before the pregnancy? (1) yes (2) no	19b- Have you been having any sexual difficulties during the pregnancy? (1) yes (2) no
20- Do these difficulties distress you? (1) yes (2) a bit (3) no	21a- How often were you experiencing sexual desire (were you feeling sexual desire) before the pregnancy? (1) a few times a week (2) once a day (3) others (depending on the occasion)
21b- How often have you been experiencing sexual desire (have you been feeling sexual desire) during the pregnancy? (1) a few times a week (2) once a day (3) others (depending on the occasion)	22- What happened to your sexual desire after you became pregnant? (1) it decreased (2) it is the same (3) it increased
23a- How often were you achieving orgasm	23b- How often have you been achieving

before the pregnancy? (1) never/rarely (2) sometimes (3) often or very often	orgasm during the pregnancy? (1) never/rarely (2) sometimes (3) often or very often
24a- Were you experiencing pain during sexual intercourse before you became pregnant? (1) yes (2) no	24b- Have you been experiencing pain during sexual intercourse, during the pregnancy? (1) yes (2) no
25a-The intercourse start before pregnancy was: (1) forced, without any desire (2) partner usually made the first move (3) spontaneously or spontaneously with stimuli	25b- The intercourse start during pregnancy is? (1) forced, without any desire (2) partner usually makes the first move (3) spontaneously or spontaneously with stimuli
26a- In your opinion, do you think your partner was having any sexual difficulty before the pregnancy? (1) yes (2) no	26b- In your opinion, do you think your partner has been having any sexual difficulty during the pregnancy? (1) yes (2) no

Anexo 2 – Comitê de Ética em Pesquisa



PARECER CONSUBSTANCIADO DO CEP

DADOS DO PROJETO DE PESQUISA

Título da Pesquisa: COMPARAÇÃO DA RESPOSTA SEXUAL ENTRE GESTANTES HIPERGLICÊMICAS E NORMOGLICÊMICAS E REVISÃO SISTEMÁTICA DA GESTAÇÃO COMO FATOR DE RISCO PARA DISFUNÇÕES DE MÚSCULOS DO ASSOALHO PÉLVICO E DA SEXUALIDADE

Pesquisador: Sthefanie Kenickel Nunes

Área Temática:

Versão: 2

CAAE: 73305517.5.0000.5411

Instituição Proponente: Faculdade de Medicina de Botucatu/UNESP

Patrocinador Principal: Financiamento Próprio

DADOS DO PARECER

Número do Parecer: 2.283.776

Apresentação do Projeto:

Tratam os autos de atendimento às pendências apontadas no Parecer 2.258.800, as quais os pesquisadores atenderam de maneira satisfatória.

Objetivo da Pesquisa:

Constantes do Parecer 2.258.800

Avaliação dos Riscos e Benefícios:

Constantes do Parecer 2.258.800

Comentários e Considerações sobre a Pesquisa:

Constantes do Parecer 2.258.800

Considerações sobre os Termos de apresentação obrigatória:

Foi reapresentado o TCLE devidamente reformulado, atendendo aos termos da Resolução 466/2012.

Recomendações:

Não se aplica.

Endereço: Chácara Butignoli, s/n
Bairro: Rubião Junior
UF: SP Município: BOTUCATU
Telefone: (14)3880-1608 CEP: 18.618-970
E-mail: capellup@fmb.unesp.br

Continuação do Parecer: 2.283.776

Conclusões ou Pendências e Lista de Inadequações:

Sugiro aprovação, sem necessidade de envio à CONEP.

Considerações Finais a critério do CEP:

Projeto de Pesquisa APROVADO, deliberado em reunião EXTRAORDINÁRIA do CEP de 18/09/2017, sem necessidade de envio à CONEP.

O CEP solicita aos pesquisadores que após a execução do projeto em questão, seja enviado o Relatório Final de Atividades, o qual deverá ser enviado via Plataforma Brasil na forma de "NOTIFICAÇÃO".

LEMBRAMOS QUE A PRESENTE PESQUISA SOMENTE PODERÁ SER INICIADA APÓS DIA 18/09/2017 – DATA DA APROVAÇÃO DO CEP.

Este parecer foi elaborado baseado nos documentos abaixo relacionados:

Tipo Documento	Arquivo	Postagem	Autor	Situação
Informações Básicas do Projeto	PB_INFORMAÇÕES_BÁSICAS_DO_PROJETO_963483.pdf	12/09/2017 17:59:29		Aceito
TCLE / Termos de Assentimento / Justificativa de Ausência	TCLE.pdf	12/09/2017 16:02:47	Sthefanie Kenickel Nunes	Aceito
Projeto Detalhado / Brochura Investigador	Projeto.pdf	05/09/2017 10:20:13	Sthefanie Kenickel Nunes	Aceito
Folha de Rosto	folha_de_rosto.pdf	11/08/2017 13:58:33	Sthefanie Kenickel Nunes	Aceito
Declaração de Instituição e Infraestrutura	Declaracao.pdf	04/08/2017 11:27:54	Sthefanie Kenickel Nunes	Aceito

Situação do Parecer:

Aprovado

Necessita Apreciação da CONEP:

Não

Endereço: Chácara Butignoli, s/n
 Bairro: Rubião Junior
 UF: SP Município: BOTUCATU
 Telefone: (14)3880-1608
 CEP: 18.618-970
 E-mail: capellup@fmb.unesp.br



UNESP -FACULDADE DE
MEDICINA DE BOTUCATU



Continuação do Parecer: 2.283.776

BOTUCATU, 19 de Setembro de 2017

Assinado por:
SILVANA ANDREA MOLINA LIMA
(Coordenador)

Endereço: Chácara Butignoli, s/n

Bairro: Rubião Junior

UF: SP

Município: BOTUCATU

CEP: 18.518-970

Telefone: (14)3880-1608

E-mail: capellup@fmb.unesp.br

Página 03 de 03

Anexo 3 - Termo de Consentimento Livre e Esclarecido

TERMO DE CONSENTIMENTO LIVRE E ESCLARECIDO

(Terminologia obrigatória em atendimento à Resolução nº 466/12-CNS-MS)

Você está sendo convidada a participar de uma pesquisa chamada “COMPARAÇÃO DA RESPOSTA SEXUAL ENTRE GESTANTES HIPERGLICÊMICAS”, que pretende analisar a resposta sexual pela comparação do questionário PSRI em gestantes com *Diabetes Mellitus* Gestacional e gestantes normoglicêmicas.

Você foi selecionada a participar dessa pesquisa por apresentar características que se adequam a este estudo. A pesquisa consta de algumas perguntas sobre sua vida pessoal, histórico de doenças e hábitos. Você responderá a um questionário que apresenta dados de sexualidade. A entrevista durará em torno de 15 minutos. O presente estudo apresenta risco de constrangimento por conter perguntas relacionadas a sexualidade de fórum íntimo.

O procedimento tem por finalidade avaliar a sexualidade de gestantes com e sem diagnóstico de *Diabetes mellitus* Gestacional e que fatores interferem em seu funcionamento. O conhecimento dessas características facilita o tratamento e a prevenção de desconfortos e morbidades posteriores.

Solicito também seu consentimento para consultar seu prontuário médico para coletar outras informações lá contidas referentes a consultas feitas anteriormente pela Senhora.

Caso você não queira participar da pesquisa, é seu direito, e isso não vai interferir em seu acompanhamento durante a gravidez. Você poderá retirar seu consentimento, em qualquer fase da pesquisa sem nenhum prejuízo. É garantido total sigilo do seu nome, resultado de exame ou doença, em relação aos dados relatados nesta pesquisa.

Você receberá uma via deste termo, e outra via será mantida em arquivo pelo pesquisador por cinco anos.

Qualquer dúvida adicional você poderá entrar em contato com o Comitê de Ética em Pesquisa através dos telefones (14) 3880-1608 ou 3880-1609 que funciona de 2ª a 6ª feira das 8.00 às 11.30 e das 14.00 às 17horas, na Chácara Butignolli s/nº em Rubião Júnior – Botucatu - São Paulo. Os dados de localização dos pesquisadores estão abaixo descrito:

Após terem sido sanadas todas minhas dúvidas a respeito deste estudo, CONCORDO EM PARTICIPAR de forma voluntária, estando ciente que todos os meus dados estarão resguardados através do sigilo que os pesquisadores se comprometeram. Estou ciente que os resultados desse estudo poderão ser publicados em revistas científicas, sem no entanto, que minha identidade seja revelada.

CONCORDO EM PARTICIPAR DA PESQUISA

Nome: _____

Assinatura: _____

Sthefanie Kenickel Nunes Data: ____/____/____ Assinatura: _____

Coorientadora: Profa. Dra. Angélica Mércia Pascon Barbosa, Rua Amador Bueno, 630, Assis-SP – Cel.: (14) 9613-7050 - E-mail: angelicapascon@gmail.com

Pesquisadora: Sthefanie Kenickel Nunes, Rua Lourenço Carmelo, 526 – ap 02 Botucatu-SP
Tel.: (14) 98168-3305 - E-mail: sthe.kenickel@hotmail.com

Anexo 4



DECLARAÇÃO DE APRESENTAÇÃO DE TRABALHO

Declaro, para devidos fins, que o trabalho “ULTRASSONOGRAFIA 3D DO ASSOALHO PÉLVICO DURANTE O 2º E 3º TRIMESTRE GESTACIONAL.”, foi apresentado no X Encontro Nordestino de Fisioterapia na Saúde da Mulher (Enfism), no III Encontro Nordestino de Fisioterapia na Saúde do Homem (Enfish) e no I Congresso Internacional de Fisioterapia em Pelviperineologia (Confisp), pelos autores: Fabiane Affonso Pinheiro, Angélica Mércia Pascon Barbosa, Carlos Izaías Sartorão Filho, Caroline Baldini Prudencio, Stephanie Kenickel, Tawana Pascon, Marilza Vieira Cunha Rudge.

OBS: Este trabalho ganhou em primeiro lugar na categoria de melhor pôster apresentado no evento.

Atenciosamente,

Dra. Patricia Lordêlo
Presidente do Evento

Anexo 5



I CONGRESSO
INTERNACIONAL
DE FISIOTERAPIA EM
PELVIPERINEOLOGIA
X ENFISM - III ENFISH

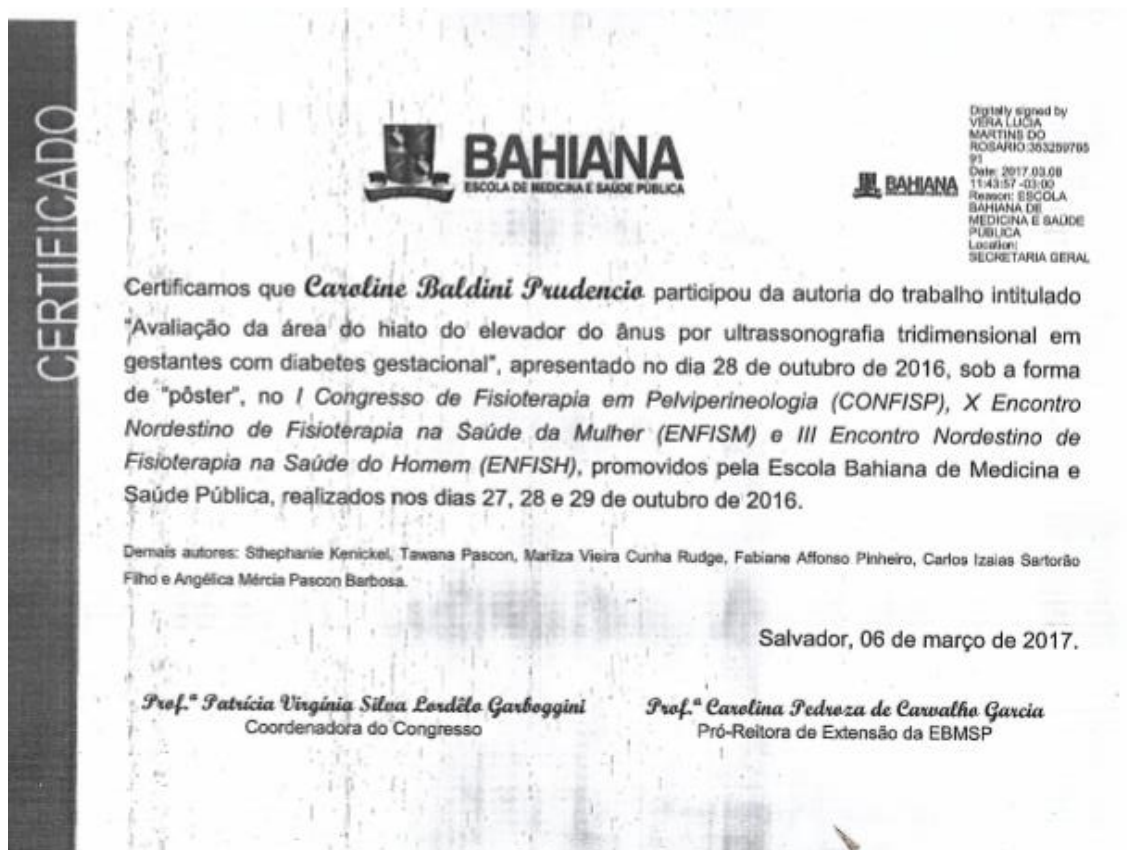
DECLARAÇÃO DE APRESENTAÇÃO DE TRABALHO

Declaro, para devidos fins, que o trabalho “AVALIAÇÃO DA ÁREA DO HIATO DO ELEVADOR DO ÂNUS POR ULTRASSONOGRAFIA TRIDIMENSIONAL EM GESTANTES COM DIABETES GESTACIONAL.”, foi apresentado no X Encontro Nordestino de Fisioterapia na Saúde da Mulher (Enfism), no III Encontro Nordestino de Fisioterapia na Saúde do Homem (Enfish) e no I Congresso Internacional de Fisioterapia em Pelvipérineologia (Confisp), pelos autores: Fabiane Affonso Pinheiro, Carlos Izaías Sartorão Filho, Angélica Mércia Pascon Barbosa, Caroline Baldini Prudencio, Sthefanie Kneickel, Tawana Pascon, Marilza Vieira Cunha Rudge.

Atenciosamente,

Dra. Patrícia Lordêlo
Presidente do Evento

Anexo 6



Anexo 7

CERTIFICADO

 **BAHIANA**
ESCOLA DE MEDICINA E SAÚDE PÚBLICA

 **BAHIANA**
ESCOLA DE MEDICINA E SAÚDE PÚBLICA

Digitally signed by
VIEIRA LUCIA
MARTINS DO
ROSARIO 353259766
91
Date: 2017.03.08
11:43:55 -03'00'
Reason: ESCOLA
BAHIANA DE
MEDICINA E SAÚDE
PÚBLICA
Location:
SECRETARIA GERAL

Certificamos que *Caroline Baldini Prudencio* participou da autoria do trabalho intitulado "Efetividade da eletroestimulação transcutânea do nervo tibial unilateral e bilateral como propostas de intervenção fisioterapêutica da incontinência urinária por urgência", apresentado no dia 28 de outubro de 2016, sob a forma de "tema livre", no *I Congresso de Fisioterapia em Pelvipérineologia (CONFISP)*, *X Encontro Nordestino de Fisioterapia na Saúde da Mulher (ENFISM)* e *III Encontro Nordestino de Fisioterapia na Saúde do Homem (ENFISH)*, promovidos pela Escola Bahiana de Medicina e Saúde Pública, realizados nos dias 27, 28 e 29 de outubro de 2016.

Demais autores: Stephanie Kenickel, Tawana Pascon, Mariza Vieira Cunha Rudge, Angélica Mécia Pascon Barbosa, Fabiane Affonso Pinheiro e Carlos Izaias Sartório Filho.

Salvador, 06 de março de 2017.

Prof.ª Patrícia Virginia Silva Lordêlo Garboggini
Coordenadora do Congresso

Prof.ª Carolina Pedrosa de Carvalho Garcia
Pró-Reitora de Extensão da EBMSP

Anexo 8

CERTIFICADO



Digitally signed by
VERA LÚCIA
MARTINS DO
ROSÁRIO.353259785
91
Date: 2017.03.08
11:43:36 -03:00
Reason: ESCOLA
BAHIANA DE
MEDICINA E SAÚDE
PÚBLICA
Location:
SECRETARIA GERAL

Certificamos que *Caroline Baldini Prudencio* participou da autoria do trabalho intitulado "Ultrassonografia 3D do assoalho pélvico durante o 2º e 3º trimestre gestacional", apresentado no dia 28 de outubro de 2016, sob a forma de "pôster", no *I Congresso de Fisioterapia em Pelvipérineologia (CONFISP)*, *X Encontro Nordestino de Fisioterapia na Saúde da Mulher (ENFISM)* e *III Encontro Nordestino de Fisioterapia na Saúde do Homem (ENFISH)*, promovidos pela Escola Bahiana de Medicina e Saúde Pública, realizados nos dias 27, 28 e 29 de outubro de 2016.

Demais autores: Stephanie Kenickel, Tawana Pascon, Marilza Vieira Cunha Rudge, Fabiane Affonso Pinheiro, Angélica Mércia Pascon Barbosa e Carlos Izaías Sartorão Filho.

Salvador, 06 de março de 2017.

Prof.ª Patrícia Virgínia Silva Lordêlo Garbeggini
Coordenadora do Congresso

Prof.ª Carolina Pedrosa de Carvalho Garcia
Pró-Reitora de Extensão da EBMSP

Anexo 9

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Barbosa A¹, Prudencio C¹, Pinheiro F¹, Sartorão Filho C¹, Pedroni C¹, Kenickel S¹, Vega S¹, Pascon T¹, Piculo F¹, Rudge M¹
1. UNESP

IMPACT OF GESTATIONAL DIABETES MELLITUS ON RECRUITMENT OF PELVIC FLOOR MUSCLES DURING HOLD CONTRACTION: COHORT STUDY

Hypothesis / aims of study

PFM function depends on the integrity and synergy of neuromuscular and metabolic system, connective structures altered by gestational diabetes mellitus (DMG). This is the first study to investigate disturbs in neuromuscular behaviour of PFM muscle and DMG. Therefore the aim of this study was to investigate and compare EMG activity in hold contraction of PFM in GDM women at 24–30 to 36–40 weeks of gestation.

Study design, materials and methods

Prospective cohort study conducted between 2015 and 2016 was approved by the Research Ethics Committee of the Institution (Protocol Number 972.104). After the knowledge of all procedures a written informed consent was obtained from all subjects. Helsinki Declaration on human experimentation guidelines was respected.

Inclusion Criteria: nulliparous or primiparous women who had undergone 1 previous elective Cesarean delivery between 24–30 weeks of gestation, singleton pregnancy and 18–40 years of age divided in two groups: GDM and normoglycemic according to ADA 2015. The exclusion criteria were clinical diabetes (type I or II or overt diabetes in previous pregnancy), urinary incontinence, >2 pregnancies, previous urinary incontinence, previous prolapse or incontinence surgery, no understanding of the command to contract PFM, neurological diseases, diagnosis of genital prolapse, cervical isthmus incompetence, smoking, dropouts, preterm birth and abortion.

Sample size was obtained by a pilot study. Determining a sample effect of 0.846, two-sided α of 0.05, and a power of 80%, 23 pregnant women in each group to detect differences were required.

Personal, clinical, Obstetric and anthropometric data was collected. After, Vaginal palpation was performed by encouraging the women to perform a maximal voluntary contraction and hold it for 10 seconds, simulating the steps of the EMG test performed later. If the examiner felt an inward pressure and/or upward traction in palpation the electromyography protocol was performed.

For the EMG recordings, part of Glazer protocol was used to verify muscle activity during hold contractions. The sequence consisted of 60 second preliminary followed by five repetitions of 10 second contractions, each contraction preceded by a 10 second rest period, were defined as hold contraction.⁽¹⁾

The raw signal was processed by using MotecSuite software by an examiner blinded to the women's clinical data. The electrical data of the recruitment root mean square (RMS) from the period of five hold contractions were performed by using Hanning window processing, after calculation of each RMS arithmetic mean was performed to determine a mean single value for each contraction type. To normalize the EMG recruitment signal, we used the maximal voluntary contraction at 24–30 weeks of gestation because that was considered to be base data for analysis of changes in PFM activity.⁽²⁾

Results

Maternal age, gestational ages at two points, BMI, cesarean delivery were pared between groups. Concerning the glucose tolerance test as expected the values were different between groups.

Table 1. Analysis Intragroup of Normalized Root Mean Square (RMS) Values From Electromyography Activity of Pelvic Floor Muscles in Hold Contraction of the Normoglycemic (NG) and Gestational Diabetes Mellitus (GDM) at 24–30 and 36–40 weeks of gestation.

		24–30 Weeks of Gestation Median (Min,Max)	36–40 Weeks of Gestation Median (Min,Max)	P*
Hold Contraction	GDM (26)	0.57 (0.14,5.85)	0.41 (0.12,5.42)	.049
	Control (26)	0.70 (0.07,2.16)	0.70 (0.1,3.10)	.571

Data are the median (minimum, maximum) range.

* Analyses intragroup from 24–30 to 36–40 weeks of gestation based on Wilcoxon Test;

Interpretation of results

The normalized RMS values of PFM activity shown in Table 1 demonstrated the influence of GDM on pelvic floor activity. Intragroup differences are present only in GDM group. GDM group decreases hold contraction between two points. The results showed that GDM decreases PFM activity at hold contraction instead NG group maintain the PFM activity. These findings and the homogeneity of our data may suggest that GDM were responsible for changes on PFM activity detected by EMG

Concluding message

. Knowledge of the neuromotor behavior of PFM is of paramount importance for the training and reorganization of motor planning in pregnancy.⁽³⁾ This investigation contributes to the understanding of EMG activity in GDM women at two time points of gestation.

References

1. Hacadi CR, Glazer HI, Zamboni JPC, Burti JS, Almeida FG. Is There Any Change in Pelvic Floor Electromyography During the First 6 Months After Radical Retropubic Prostatectomy? Appl Psychophysiol Biofeedback. 2015;40(1):9–15.
2. Marshall P, Murphy B. The validity and reliability of surface EMG to assess the neuromuscular response of the abdominal muscles to rapid limb movement. J Electromyogr Kinesiol. 2003;13(5):477–89.

Anexo 10

411

Barbosa A¹, Sartório Filho C¹, Pinheiro F¹, Prudencio C¹, Vega S¹, Kenickel S¹, Piculo F¹, Pascon T¹, Junginger B², Rudge M¹

1. UNESP, 2. Charité Universitätsmedizin Berlin

ASSESSMENT OF THE LEVATOR HIATUS AREA BY THREE-DIMENSIONAL ULTRASOUND FROM PREGNANT WITH GESTATIONAL DIABETES.

Hypothesis / aims of study

Current evidences suggest that diabetes during pregnancy damages the striated muscle, a fact that may explain the high prevalence of urinary incontinence and pelvic floor dysfunction in women with gestational diabetes mellitus (GDM). (1-3)

The Hypothesis of this study is that women with GDM may have more changes in the pelvic floor muscle, in the area of levator hiatus, when compared with normoglycemic pregnant women.

The aim of study was evaluate and compare the Levator Hiatus area assessed at second trimester and later, at third trimester, by transperineal Three-dimensional Ultrasound from pregnant women with GDM.

Study design, materials and methods

A longitudinal study was conducted between March and December 2015, on 18 pregnant women, divided into 2 groups: 9 with GDM and 9 normoglycemic, according to 2015 American Diabetes Association criteria.

This study was approved by a Research Ethics Committee. The women who agreed to voluntarily participate in the study signed a consent form. The inclusion criteria were: singleton pregnancy and nulliparity. The exclusion criteria were: previous Diabetes or age less than 18. A standard translabial ultrasound scan was performed. A GE Voluson i 3D Ultrasound system (GE Medical Systems) with a RAB 2-6-RS 3D transducer was used for image acquisition. The transducer was placed on the perineum in the mid-sagittal plane with the women in lithotomy position. Three-dimensional ultrasound scans of the pelvic floor anatomy with a sweep angle of 85° were obtained at rest. The volume data sets were saved and standardized analysis was performed at a later date. Women from both groups (GDM and Normoglycemic group) were assessed at second trimester (between 24 and 28 weeks of gestation) and third trimester (between 34 and 38 weeks of gestation). Volumetric acquisitions were performed by the same examiner and analyzed off-line. The area (cm²) of levator hiatus in the minimal hiatal dimensions was measured in the axial rendered plane.

Results

Eighteen pregnant women were included, 9 normoglycemic with mean age of 28,2±4,2 (22-34) years old and 9 Pregnant women with Gestational Diabetes with mean age of 26,2±5 (20-35) years old.

	Normoglycemics	GDM	p*
24th to 28th	13,4±2,8 (9,94-18,52)	16,5±1,6 (13,45- 18,67)	0,01
34th to 38th	15,8±2,7 (10,6-18,4)	17,3±2,4 (12,95-20,67)	0,35
p**	0,036	0,281	

*inter groups ** intra groups p: <0,05

Interpretation of results

Both groups were similar when related to Age and Maternal weight gain. GDM group had Levator Hiatus area at second trimester significantly higher than that observed in the normoglycemic group. No significant differences were found between the groups at third trimester.¹

Concluding message

In conclusion, this study suggests that there are anatomical changes observed by 3D ultrasound of the pelvic floor during pregnancy complicated with Gestational Diabetes.

Further studies are needed to elucidate the potential role of GDM in the anatomical and functional changes of pelvic floor during pregnancy.

References

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Disclosures

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