Stress urinary incontinence in relation to pelvic floor muscle strength and associated factors in the third trimester of pregnancy: A cross-sectional study [version 1; peer review: 1 approved, 1 approved with reservations]

Astrid Yunita\textsuperscript{1}, Tyas Priyatini\textsuperscript{2}

\textsuperscript{1}Urogynecology and Reconstruction Surgery Division, Obstetrics and Gynecology Department, Harapan Kita Women and Children’s Hospital, Jakarta, Indonesia
\textsuperscript{2}Urogynecology and Reconstruction Surgery Division, Obstetrics and Gynecology Department, Faculty of Medicine, University of Indonesia, Jakarta, Indonesia

\textbf{Abstract}

\textbf{Background:} Many predictors of stress urinary incontinence (SUI) during pregnancy have been investigated. However, no studies have specifically identified a cutoff for pelvic floor muscle (PFM) strength and associated factors that could predict SUI during pregnancy. The aim of this study was to identify the cutoff between PFM strength and SUI, late in the third trimester of pregnancy and associated factors in Indonesian women.

\textbf{Methods:} A cross-sectional study was conducted involving 142 women with a pregnancy of 36–40 weeks of gestational age at the Obstetrics and Gynecology clinic of Tebet Subdistrict Hospital, Jakarta, Indonesia. The data were collected through a medical interview, Questionnaire for Urinary Incontinence Diagnosis, physical examination, perineometer, and cough test.

\textbf{Results:} SUI was identified in 54.2\% of the 142 women. PFM strength 25.5 cmH\textsubscript{2}O and estimated fetal weight (EFW) $\geq$3,100 g were the factors with the greatest influence on SUI (odds ratio (OR) = 2.52, \( p = 0.021 \), and OR = 3.34, \( p = 0.001 \), respectively). For women with PFM strength $\leq$25.5 cmH\textsubscript{2}O and EFW $\geq$3,100 g, the prediction for SUI was $\approx$75.39\%.

\textbf{Conclusion:} Weakening of the PFMs and EFW influence SUI. The cutoff values identified for both variables may be helpful for predicting SUI late in pregnancy.

\textbf{Keywords}

QUID, Stress urinary incontinence, pelvic floor muscle strength, perineometer
Corresponding author: Astrid Yunita (astrid11_yunita@yahoo.com)

Author roles: Yunita A: Conceptualization, Data Curation, Formal Analysis, Funding Acquisition, Investigation, Methodology, Project Administration, Resources, Supervision, Validation, Visualization, Writing – Original Draft Preparation, Writing – Review & Editing; Priyatini T: Conceptualization, Investigation, Methodology, Supervision, Writing – Review & Editing

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Introduction
Stress urinary incontinence (SUI) is defined by the International Continence Society as the involuntary loss or leakage of urine\(^1\), and is the most common type of urinary incontinence (UI) in pregnant women. The severity of SUI tends to become more pronounced as the pregnancy progresses because of the growth of the uterus, hormonal influences, and biomechanical alterations of the pelvis. As a result, both muscle tone and muscle strength in the pelvic region may decrease during pregnancy\(^2\). The prevalence of SUI among pregnant women is variable (range 18.6% to 75%), increases with gestational age, and is typically worst in the third trimester, followed by the second and first trimesters\(^3\). SUI represents a major health problem that affects about 54.3% of all pregnant women and has a negative impact on quality of life and health-care expenditures\(^4,5\).

Pregnancy may be associated with a reduction in the strength of the pelvic floor muscles (PFMs), which may lead to reduced strength and supportive sphincter function, and eventually, to SUI. However, the exact mechanism responsible for pregnancy-related SUI is not well understood. By actively supporting the pelvic organs and closing the urethral sphincter by contracting\(^6\), the PFMs play an integral role in the maintenance of the continence mechanism. Studies of pregnant women with SUI have found significantly decreased PFM strength in incontinent compared with continent pregnant women\(^1\). SUI during pregnancy can be prevented and PFM strength can be improved by pelvic floor muscle exercises (PFMEs). Oliveira et al.\(^4\) reported that performing PFMEs significantly increased PFM pressure and strength during pregnancy, and another study reported that this effect was maintained postpartum\(^7\).

Identification of predictors of SUI is important for the development of preventive strategies. Many predictors of SUI during pregnancy have been investigated. Some studies have focused on obstetric and neonatal factors, whereas others have noted the importance of clinical factors\(^8\). However, no studies have focused on identifying a cutoff for PFM and associated obstetric factors related to SUI in pregnancy. The aims of this study were: (1) to investigate the relationships between SUI and obstetric factors during pregnancy and patient characteristics in Indonesian women, (2) to identify the clinical predictors of SUI, particularly PFM strength, in the third trimester of pregnancy using a digital examination perineometer, and (3) to develop a predictive model of SUI with cutoff points for use in practice for the early detection, and possible prevention, of modifiable risk factors that contribute to the development of SUI during pregnancy.

Methods
Study design, setting and participants
This cross-sectional study was conducted in the Obstetrics and Gynaecology outpatient clinic of Tebet Sub District Hospital, Jakarta. The project was approved by the Medical Ethics Board of the Faculty of Medicine Universitas Indonesia (0317/UN2.F1/Ethics/2018).

The participants were enrolled between March and May 2018. They were recruited to the study during routine checkups where they were made aware of the study and asked to participate. Initially, 149 pregnant women in their third trimester (36–40 weeks) of pregnancy were enrolled in this study. Inclusion criteria included age between 20 and 45 years old and women in their third trimester of pregnancy (36–40 weeks gestational age). None of the women exhibited the exclusion criteria of urinary tract infection, previous surgery for pelvic dysfunction, previous UI, pregnancy complications (preeclampsia, eclampsia, lung edema, or sepsis), neurological dysfunction (mental retardation, dementia, Parkinson disease, multiple system atrophy, multiple sclerosis, myelodysplastic syndrome, spinal stenosis, disc diseases, previous trauma, or surgery of spinal cord). However, seven women were excluded because of the presence of diabetes, as shown in laboratory tests, resulting in a total of 142 participants. The goals of the study and the procedures indicated were explained to all participants, and those who agreed to participate signed a written informed consent form.

Data collection
Demographic characteristics such as age, gestational age, educational level, body mass index (BMI), weight, and height were recorded. Obstetric and neonatal characteristics and clinical factors were investigated as potential predictors of SUI. The obstetric and neonatal characteristics were parity, mode of delivery, and estimated fetal weight during pregnancy.

SUI was identified in a medical interview that included the symptom-based Questionnaire for Urinary Incontinence Diagnosis (QUID)\(^9\). In this study, QUID were modified and validated into the Indonesian language (Cronbach’s alpha values = 0.965 for SUI and 0.962 for urge UI). The diagnosis of SUI was based on the symptoms of involuntary loss of urine on effort or physical exertion, or on sneezing or coughing, in accordance with the definition of the International Continence Society.

For the physical examination, the participant’s leg was positioned in lithotomy position at the examination table with a full bladder. The patient was then asked to cough, if there was a fluid loss from the urethra together with the cough, it was considered as a positive cough test. Furthermore, if no leakage was observed, the cough stress test was repeated in standing position with full bladder\(^11,12\).

After taking these measurements, the obstetrician–gynecologist used a Peritron™ perineometer and digital palpation to measure the squeeze pressure as an indicator of the participant’s PFM strength during a maximum voluntary contraction. Pressure was measured in cmH\(_2\)O\(^{13-15}\). The sequence for muscle testing involved three repetitions of maximum voluntary contractions lasting 3s each, with a 10-s rest period between each. This sequence was followed by a 2-min rest break. The highest of three voluntary PFM contractions was recorded and used in the analysis. Before performing these contractions, the participants were taught the correct way to perform the PFM contractions by focusing on the PFM without excessive coactivation of the gluteal, hip adductor, and rectus abdominal muscles, as verified by visual inspection and digital palpation. All clinical measurements were taken by an obstetrics and gynecology doctor, and the questionnaire was administered by a trained interviewer.
Data analysis

The data were recorded in case registration forms and were analyzed using the Statistical Package for the Social Sciences (version 17.0; SPSS Inc., Chicago, IL). The participants’ demographic characteristics, outcome variable, and scores on the QUID and cough test are presented descriptively. The chi-squared test for categorical data and the Mann–Whitney U test for interval data were used to compare participants with and without SUI in the analysis to identify potential predictors. Predictors with p < 0.25 were entered into the classification and regression analysis, a multivariate nonparametric procedure. The accuracy of the classifications of the predictive model was determined according to the sensitivity, specificity, and area under the receiver-operating characteristic (AUC-ROC) curve. A level of significance of 0.05 was set to test whether the AUC-ROC curve in the predictive model differed from 0.5.

Results

During the study period, a total of 149 gravidas were identified; all had attended the outpatient clinic, but seven were excluded because of the presence of diabetes as indicated by laboratory tests. The remaining 142 women were enrolled in the study; 66 were multiparous, 56 were primiparous, and 20 were nulliparous. The women were classified according to their prior deliveries as follows: vaginal delivery only (65.5% of participants), caesarean delivery only (11.3%), caesarean and vaginal deliveries (3.5%), vacuum extraction only (0.7%), vacuum extraction and vaginal deliveries (1.4%), and no prior delivery (16.2%). These modes of delivery showed that more than half of the participants (67.6%) had history of vaginal delivery (spontaneous and assisted vaginal delivery) and most of them was diagnosed with SUI 47.8%. Moreover, multiparous also play a pivotal role in SUI 60.6% compared to Primiparous and nulliparous (48.7%).

The prevalence of SUI was 54.2% based on QUID and positive cough test. QUID was designed to classify the type of urinary incontinence (SUI, urge urinary incontinence and mixed urinary incontinence), while the cough test strengthened the identification of women with SUI. Both measures ensured consistency and objectivity of approach in assessment, as explained before in data collection section. However, QUID without the presence of a positive cough test was still taken as SUI in this study (this research did not discuss the grade of severity of SUI).

The median age was 32 years (range 20–45 years), and the median gestational age was 38 weeks (range 36–40 weeks). Over half of women (46.5%) were included in the overweight criteria according to the Asia Pacific WHO classification and followed by 24.6% of women who were obese. The patients had a median PFM strength of 24.5 (14–90) cmH₂O. Multiparous women had a higher prevalence of SUI (60.6%), compared to primiparous and nulliparous women collectively (48.7%).

The results of the bivariate analysis of the two groups (SUI and non-SUI) are presented in Table 1. Age, gestational age, BMI, constipation, and parity did not differ between groups. The estimated fetal weight (EFW) (p < 0.05) and PFM strength (p < 0.05) differed significantly between the groups. Gestational age, EFW, and parity were higher in the SUI than in the non-SUI group, and significant data showed that PFM strength was significantly lower in the SUI group.

Estimated fetal weight, parity, and PFM were included in the multivariate analysis because they had p values < 0.25 in the first analysis. The results from adjusted multivariate logistic regression using the backward process are presented in Table 2. PFM strength and EFW were the most influential factors on SUI.

The AUC-ROC curve for PFM strength is shown in Figure 1A, and that for estimated fetal weight in Figure 1B. The best cutoffs for predicting the risk of SUI in pregnancy were a PFM strength

<table>
<thead>
<tr>
<th>Variable</th>
<th>SUI</th>
<th>Non-SUI</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td>32 (20–42)</td>
<td>33 (22–45)</td>
<td>0.37</td>
</tr>
<tr>
<td>Gestational age (years)</td>
<td>37 (36–40)</td>
<td>38 (36–40)</td>
<td>0.32</td>
</tr>
<tr>
<td>Body mass index (kg/m²)</td>
<td>28 (19.82–35.80)</td>
<td>26.56 (20.80–39.84)</td>
<td>0.29</td>
</tr>
<tr>
<td>Constipation, n (%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>19 (52.8%)</td>
<td>17 (47.2%)</td>
<td>0.84</td>
</tr>
<tr>
<td>No</td>
<td>58 (54.7%)</td>
<td>48 (45.3%)</td>
<td></td>
</tr>
<tr>
<td>Pelvic floor muscle strength (cmH₂O)</td>
<td>23 (14–90)</td>
<td>27 (16–90)</td>
<td>&lt;0.001*</td>
</tr>
<tr>
<td>Parity, n (%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Multiparous</td>
<td>40 (60.6%)</td>
<td>26 (39.4%)</td>
<td>0.15</td>
</tr>
<tr>
<td>Primiparous or nulliparous</td>
<td>37 (48.7%)</td>
<td>39 (51.3%)</td>
<td></td>
</tr>
<tr>
<td>Estimated fetal weight (g)</td>
<td>3,200 (2,570–3,600)</td>
<td>3,000 (2,565–3,452)</td>
<td>0.002</td>
</tr>
</tbody>
</table>

*Significant at 5% level. SUI, stress urinary incontinence.
Table 2. Results of the adjusted multivariate logistic regression.

<table>
<thead>
<tr>
<th>Variables</th>
<th>OR (95% CI)</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Estimated fetal weight (≥3,100 g)</td>
<td>3.34 (1.63–6.82)</td>
<td>0.001</td>
</tr>
<tr>
<td>PFM strength (≤25.5 cmH₂O)</td>
<td>2.52 (1.23–5.15)</td>
<td>0.021</td>
</tr>
</tbody>
</table>

OR, odds ratio; CI, confidence interval; PFM, pelvic floor muscle.

Discussion

Although much has been written about childbirth as a predisposing risk factor to pelvic floor damage and SUI, well-conducted studies have pointed to the impact of pregnancy itself. This study demonstrated a high prevalence of SUI symptoms (54.2%) in the late third trimester. This finding is similar to those of Whitford et al.\textsuperscript{17}, who reported a prevalence rate of SUI of 54.3%, and Martins et al.\textsuperscript{18}, who found an incidence range from 46.1% to 54%.

In the present study, the characteristic data explained that there were no difference between the age of the women in the SUI and non-SUI group; however, those aged >30 years was the median age in this study. Age is one of influencing factors for SUI; the study by Sangsawang\textsuperscript{5} found that pregnant women aged >30 years or who had their first pregnancy in their 30s were at high risk for SUI. Another study noted that women aged ≥30 years were susceptible to developing persistent and long-term SUI because of PFM defects\textsuperscript{19}. The nerve function and the total number of striated muscle fibers in the urethral sphincter decrease with age at a rate of 2% a year and these changes can lead to a decrease in urethral closure pressure\textsuperscript{20–22}. Despite the fact that the results of this study showed no age differences between the two groups, it could not conclude that age had no influence on SUI, and this needs to be further studied.

In the analysis of parity, nulliparous and primiparous women had the lowest prevalence of UI (51.3%), and the prevalence of SUI increased with parity to 60.6% in multiparous women. Spontaneous vaginal delivery was more strongly associated with SUI than delivery by other routes. These findings are similar to those of other authors, which have shown that age at childbirth, gestational age, parity\textsuperscript{2,23}, and mode of previous births\textsuperscript{24,25} influence the occurrence of SUI during pregnancy. However, the bivariate analysis of our data showed that age, gestational age, parity, BMI, and constipation had no significant
relationship with SUI (p > 0.05). Further studies are needed with a larger number of participants.

Pregnancy- and delivery-related factors are considered to be the main risk factors for SUI development during pregnancy because they can increase intra-abdominal pressure and lead to physiological changes that cause PFM weakness, resulting in bladder neck and urethral mobility, and eventually to urethral sphincter incompetence. The PFMs are involved in urethral sphincter contraction and relaxation. During relaxation, the PFMs help to withstand pressure from the pelvic organs. As the intra-abdominal pressure increases, the PFMs contract against the pelvic organs. Therefore, sufficient contractile ability of the PFMs is pivotal to prevent urinary or fecal incontinence during relaxation and allow both micturition and defecation.

This article adds important findings in terms of establishing cutoff points according to PFM strength and estimated fetal weight (EFW) to predict the risk of SUI during the late trimester in Indonesian women. PFM strength and EFW were the strongest predictors of SUI in the third trimester of pregnancy. A combined cutoff of PFM strength ≤25.5 cmH\(_2\)O and estimated fetal weight ≥3,100 g was associated with a 75.39% prevalence of SUI. To our knowledge, no previous study has objectively investigated the cutoffs for these two variables during the last term of pregnancy. For instance, Baracho et al. used the PFM strength and birth weight obtained after delivery and found a 17% prevalence of SUI. In Indonesia, Santoso reported a cutoff birth weight of ≥3,325 g, but this study obtained the data after delivery as opposed to during pregnancy. We were able to identify meaningful cutoff points during pregnancy that classified these participants according to the outcomes of SUI and non-SUI.

Taken together, these findings provide information that will help to guide services and health policies about the factors that predict SUI during pregnancy. This information may be useful for physicians trying to organize programs for the prevention and treatment of UI/SUI during and after pregnancy such as physiotherapy and PFMEs. PFM training is important for the prevention of SUI because it is effective in reducing urethral excursion and enhancing urethral sphincter function. Further longitudinal studies are needed for more complete testing of this data and to investigate whether these findings can be generalized to other settings.

As a cross-sectional study, this research is limited by the lack of assessment of the mechanisms underlying the relationship between risk factors and SUI. In addition, we did not check baseline PFM strength before pregnancy or analyze data according to ethnicity. Differences in ethnicity may explain some of the differences between the findings of our study and those of others. The causal relationships between EFW, PFM, and SUI should be assessed further in future studies.

In conclusion, the two predictors of SUI identified here are modifiable by preventive approaches, mainly with physical therapy and education. Increasing PFM strength should help to prevent SUI during pregnancy. Indonesian women with PFM strength ≤25.5 cmH\(_2\)O and an estimated fetal weight ≥3,100 g should be encouraged to increase their PFM strength to avoid SUI late in pregnancy. We found that in women with an EFW ≥3,100 g, the risk of SUI decreased from 75.39% to 54.9% when the PFM strength increased from ≤25.5 cmH\(_2\)O to >25.5 cmH\(_2\)O.

Data availability


File ‘SUI in pregnancy Data 2’ contains all underlying data analyzed in this study.

Data are available under the terms of the Creative Commons Zero “No rights reserved” data waiver (CC0 1.0 Public domain dedication).

Acknowledgments

The authors thank to Faculty of Medicine Universitas Indonesia, all doctors and research assistants who participated in this study, and all urogynecology consultants who helped with this project.

References

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Version 1

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Angie Rantell
Department of Urogynaecology, King's College Hospital, London, UK

I think that this is a sound idea but I have several questions about the quality of the study and paper. In the introduction the definition of SUI is not correct, they have provided the definition of UI. They comment about prevalence in pregnancy but not about how many it resolves in post partum.

Methods

- There is no standardization of the cough test - how was a full bladder defined.
- Why was PFMT taught by Dr's - is this normal practice, were physios involved.
- Mode of delivery - what about forceps - do you not do this?

Discussion

- There is no mention about what is normal PFM strength on perineometry in women without SUI who are not pregnant.
- How will this going to change practice?
- You report that you found modifiable factors but how is EFW modifiable.
- There is no comment about what is normal antenatal care regarding PFMT and advice.

Is the work clearly and accurately presented and does it cite the current literature?
Yes

Is the study design appropriate and is the work technically sound?
Partly

Are sufficient details of methods and analysis provided to allow replication by others?
Partly
If applicable, is the statistical analysis and its interpretation appropriate?
I cannot comment. A qualified statistician is required.

Are all the source data underlying the results available to ensure full reproducibility?
Partly

Are the conclusions drawn adequately supported by the results?
Partly

**Competing Interests:** No competing interests were disclosed.

**Reviewer Expertise:** Urogynaecology, pelvic floor dysfunction / sexual dysfuntion

I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard, however I have significant reservations, as outlined above.

Reviewer Report 21 October 2019

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The present article is an interesting study. From the background of the study, showed that stress urinary incontinence (SUI) is a common in pregnancy caused by several things including uterine growth, hormonal influences, and biomechanical disorders in the pelvis. These factors make the muscle tone and muscle strength in the pelvic region decrease during pregnancy.

The authors describe that the background of the research concisely and is easy to understand the reasons for doing this research. Previously, a lot of studies have been done to investigate the effect of pregnancy on SUI, but little evidence has shown about PFM cut off value for SUI. The authors investigate the relationships between SUI and obstetric factors during pregnancy and patient characteristics in Indonesian women, to identify the clinical predictors of SUI, particularly PFM strength, in the third trimester of pregnancy using a digital examination perineometer, and to develop a predictive model of SUI with cutoff points for use in practice for the early detection, and possible prevention, of modifiable risk factors that contribute to the development of SUI during pregnancy. From the present study, we can see the the cut off PFM strength and fetal weight to correlated with SUI in pregnancy.

I think that the present study does not have big problem and is well-organized.

**Is the work clearly and accurately presented and does it cite the current literature?**
Yes
Is the study design appropriate and is the work technically sound?  
Yes

Are sufficient details of methods and analysis provided to allow replication by others?  
Yes

If applicable, is the statistical analysis and its interpretation appropriate?  
Yes

Are all the source data underlying the results available to ensure full reproducibility?  
Yes

Are the conclusions drawn adequately supported by the results?  
Yes

**Competing Interests:** No competing interests were disclosed.

**Reviewer Expertise:** Urogynecology, voiding dysfunction in women

I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard.

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