A CROSS-SECTIONAL SURVEY TO ASSESS THE PREVALENCE AND SYMPTOMS ASSOCIATED WITH LAXITY OF THE VAGINAL INTROITUS

Hypothesis / aims of study
Laxity of the vaginal introitus may occur following vaginal delivery. However, this condition is infrequently discussed between patients and physicians, likely due to a paucity of evidence-based treatment options. We hypothesized that introital laxity leads to loss of physical sensation and the development of sexual dissatisfaction during vaginal intercourse. Therefore, a survey was conducted with two primary aims: 1) to better quantify the prevalence of vaginal laxity among parous women ages 25-55 years of age and 2) to explore the association between vaginal laxity and changes in physical sensation or sexual dissatisfaction.

Study design, materials and methods
A cross-sectional survey was conducted utilizing focus groups and a national database of on-line registrants for women ages 25-55 who had experienced at least one vaginal delivery. This survey was conducted in two phases; a qualitative assessment survey utilizing focus groups from which directional information was collected followed by the second phase, a quantitative survey. For the qualitative phase, nine focus groups were conducted each comprised of six to eight women per group. Three groups per city were organized in Portland, Cleveland and Atlanta. Discussions were lead by a female moderator using a standardized script to explore perceptions and concerns of women presenting with vaginal laxity after vaginal childbirth and their attitudes toward resolution of this medical condition. Key areas for discussion included physical changes experienced since vaginal childbirth, confidence and relationship with partner, physical and psychological consequences specifically related to vaginal laxity, and barriers to discussion of vaginal laxity with health care providers, friends and family. Each focus group lasted approximately two hours; participants received $100 for attending. The second phase of the survey utilized a national database of on-line registrants of women aged 25-55 who had experienced at least one vaginal delivery. The survey consisted of five parts, namely (i) demographic data, e.g., age, ethnicity, education, employment status, household income, marital status and number of vaginal births, plans for future children, (ii) interaction with health care provider, friends and family. They candidly described body image changes following childbirth and the complexity of physical and emotional consequences due to vaginal laxity (e.g., reduced vaginal sensation, difficulty reaching orgasm). Vaginal changes were equated with loss of sexuality, burdensome sexual performance, and a yearning for intimacy and sexual confidence experienced before having children. The participants acknowledged the impediments to discussing sexual concerns with their physicians. In the second, quantitative phase of the survey, 421 (69.8%) of the 635 women who received on-line questionnaires completed the survey. Surveys were collected from women in every state in the continental US (14% of all responses were from CA, 5-6% from NY, MI, TX and FL). The respondents were predominately white (81%), college graduates (55%), employed full or part time (59%), suburban living (57%), income $70K or greater (71%), and married (90%), and a median of two childbirths. Some of the survey responses related to concerns about self-image, sexuality and sexual satisfaction are presented in Table 1.

Results
A total of 50 women participated in the focus groups. In the pre-selected age range of 25 to 45, slightly more than half were 25-35 years of age, predominantly college graduates, and evenly distributed amongst household incomes. Participants included a mix of women working outside the home or homemakers. They candidly described body image changes following childbirth and the complexity of physical and emotional consequences due to vaginal laxity (e.g., reduced vaginal sensation, difficulty reaching orgasm). Vaginal changes were equated with loss of sexuality, burdensome sexual performance, and a yearning for intimacy and sexual confidence experienced before having children. The participants acknowledged the impediments to discussing sexual concerns with their physicians. In the second, quantitative phase of the survey, 421 (69.8%) of the 635 women who received on-line questionnaires completed the survey. Surveys were collected from women in every state in the continental US (14% of all responses were from CA, 5-6% from NY, MI, TX and FL). The respondents were predominately white (81%), college graduates (55%), employed full or part time (59%), suburban living (57%), income $70K or greater (71%), and married (90%), and a median of two childbirths. Some of the survey responses related to concerns about self-image, sexuality and sexual satisfaction are presented in Table 1.

Table 1: Comparison of Responses to Survey Questionnaire Items

<table>
<thead>
<tr>
<th>Survey Questionnaire Item</th>
<th>Agree</th>
<th>Disagree</th>
<th>Diff.</th>
<th>95% CI</th>
<th>Chi-Sqr</th>
<th>df</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>I no longer feel intimate with my husband/sexual partner since having children.</td>
<td>132 (31%)</td>
<td>222 (53%)</td>
<td>22.0%</td>
<td>15.2%, 28.2%</td>
<td>40.9</td>
<td>1</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>I am not as interested in sex since I had children.</td>
<td>168 (40%)</td>
<td>190 (45%)</td>
<td>5.0%</td>
<td>-1.2%, 1.3%</td>
<td>0.18</td>
<td>1</td>
<td>0.676</td>
</tr>
<tr>
<td>It is a priority to be fit and healthy.</td>
<td>319 (76%)</td>
<td>24 (6%)</td>
<td>70.0%</td>
<td>64.9%, 74.5%</td>
<td>423.5</td>
<td>1</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Sex is more of an effort than it was before children.</td>
<td>246 (58%)</td>
<td>122 (29%)</td>
<td>29.0%</td>
<td>22.3%, 35.4%</td>
<td>70.9</td>
<td>1</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Since I have had children I rarely or never initiate sex with my partner.</td>
<td>163 (39%)</td>
<td>192 (46%)</td>
<td>7.0%</td>
<td>0.2%, 13.8%</td>
<td>3.9</td>
<td>1</td>
<td>0.047</td>
</tr>
<tr>
<td>I’m just too tired to think about sex as often as I did before having children.</td>
<td>222 (53%)</td>
<td>122 (29%)</td>
<td>24.0%</td>
<td>17.3%, 30.5%</td>
<td>49.1</td>
<td>1</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>My husband/sexual partner says sex no longer feels the same since I had children.</td>
<td>60 (14%)</td>
<td>306 (73%)</td>
<td>59.0%</td>
<td>53.2%, 64.3%</td>
<td>295.7</td>
<td>1</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>I still feel sexy even after having children.</td>
<td>236 (56%)</td>
<td>112 (27%)</td>
<td>29.0%</td>
<td>22.4%, 35.4%</td>
<td>71.7</td>
<td>1</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>
My own sexual pleasure and satisfaction are important to me

| 325 (77%) | 42 (10%) | 67.0% | 61.6% | 71.8% | 381.7 | 1 | <0.0001 |

1=Strongly/Somewhat Agree, 2=Strongly/Somewhat Disagree, 3=Difference in Proportions

Interpretation of results

Approximately half of the women in all age groups expressed a diminished interest in sex after having children, initiated sex less frequently and felt like it was more of an effort. However, half of the respondents also indicated satisfaction with their sex life. Laxity of the vaginal introitus was expressed as a concern (“some” or “a little” or “a lot”) by 48% (201 of 421) of respondents. Eighty percent of respondents (335 of 421) had not discussed the topic with their OB/GYN. Eighty-five percent (357 of 421) of women knew how to perform the Kegel exercises, 76% (318) had done them, 48% (204) thought they were effective in tightening the vagina, 15% (65) indicated they were not effective and 36% (152) did not know if the Kegel exercises were effective in improving their vaginal tone. Approximately 50% or more of women felt that improving the tightness of their vaginal introitus would have a positive effect on the relationship with their partner, both their sexual confidence and overall confidence, the orgasmic experience of both them and their partner, and sexual satisfaction.

Concluding message

The results from this cross-sectional survey on sexual health after vaginal birth provide a new focus on laxity of the vaginal introitus as an important medical concern after vaginal childbirth, one that is infrequently discussed between patients and physicians, and under reported in the literature. The surveys are unique in assessing women’s attitudes about their body image, sexual health, and sexual relationships. Among the respondents who represented a 30-year age range from 25 to 55, approximately half expressed some degree of concern for “looseness” of the vaginal introitus. Potential treatment to tighten the vaginal introitus was considered to be positive for personal renewal, to improve orgasms and benefit the sexual relationship for both partners.

Specify source of funding or grant
Survey was sponsored by a grant from Viveve, Inc.

Is this a clinical trial?
No

What were the subjects in the study?
HUMAN

Was this study approved by an ethics committee?
No

This study did not require ethics committee approval because
The survey did not involve human subject research or experimentation. There were no ethics principles compromised with this survey. The confidentiality of all participants was protected and all participant identifying information was removed.

Was the Declaration of Helsinki followed?
No

This study did not follow the Declaration of Helsinki in the sense that
The survey did not involve human subject research or experimentation. There were no ethics principles compromised with this survey. The confidentiality of all participants was protected and all participant identifying information was removed.

Was informed consent obtained from the patients?
No