



## Symptomatic pelvic organ prolapse at midlife, quality of life, and risk factors.

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## 1 Title

2 Symptomatic pelvic organ prolapse at midlife, quality of life and risk factors in GAZEL cohort.

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27

28 **Précis**

29           In women in their 50s, symptoms of pelvic organ prolapse are associated with impaired quality of life,  
30   body mass index and number of vaginal deliveries.

31

## Abstract

**Objective:** To estimate quality of life (QoL), prevalence, and risk factors associated with symptomatic pelvic organ prolapse (POP) among middle-aged women.

**Methods:** A questionnaire was mailed to 3114 women aged 50-61 years in the GAZEL cohort; 2640 (85%) returned it. Symptomatic POP was defined by feeling a bulge from the vagina (sometimes, often, or all the time versus never or rarely). QoL was determined with the Nottingham Health Profile (NHP) questionnaire. Multiple linear regression was used to examine the association between frequency of POP symptoms and the QoL score. Logistic regression was used to estimate the impact of risk factors on past or present symptomatic POP (current symptoms or previous surgery for POP).

**Results:** The prevalence of symptomatic POP was 3.6% (96) and that of surgery for POP, 2.7% (70). POP symptoms were associated with difficulty defecating, lower abdominal pain, and difficulty voiding. The frequency of POP symptoms was associated with a poorer QoL score in each NHP domain (physical mobility, pain, emotional reaction, social isolation, energy and sleep). Even when we took general characteristics, medical history, and lifestyle associated with QoL into account, the global NHP score was significantly impaired by POP symptoms. Factors significantly associated with past or present symptomatic POP were high body mass index and the number of vaginal deliveries.

**Conclusion:** In our population of women in their 50s, POP symptoms are associated with impaired QoL, and the number of vaginal deliveries is a risk factor for past or present symptomatic POP.

**Key-words:** Pelvic organ prolapse, Quality of life, Delivery

## Introduction

The prevalence of pelvic organ prolapse (POP) increases with age and number of vaginal deliveries.<sup>1</sup> In the 18th century, Madame du Coudray attributed the onset of a "falling womb" to childbirth.<sup>2</sup> Despite this association, the mechanism of its onset remains obscure, and we do not know what organ is damaged, let alone how. While numerous surgical techniques have been developed for POP, epidemiologic surveys on this topic are rare. It is estimated that 15% of all hysterectomies are performed for POP and that the cumulative risk of surgery for POP is approximately 7% at the age of 80 years.<sup>3,4</sup> Mean age at this surgery is between 50 and 60 years of age.<sup>5</sup> Despite the frequency of recourse to surgery, the effect of POP on quality of life (QoL) is not well understood. A Medline search using the terms "quality of life" and "pelvic organ prolapse" showed no studies that examined the deterioration of general health-related QoL as a function of POP symptoms in a general population, that is, a population not selected because of POP symptoms.

Our main purpose was to estimate the impact of symptomatic POP on QoL and its prevalence among middle-aged women enrolled in a cohort study and to assess its obstetrical risk factors, while taking other characteristics into account. This cohort of French women (GAZEL cohort) completed questionnaires to estimate their general health-related QoL (NHP questionnaire) and the frequency of their POP symptoms.

## Methods

Our population belongs to the French GAZEL cohort ([www.gazel.inserm.fr](http://www.gazel.inserm.fr)), which began in 1989 with more than 20,000 men and women employed by the French national power company (EDF-GDF) who volunteered to participate in an epidemiological research program coordinated by INSERM (Institut National de la Santé et de la Recherche Médicale, that is, the French National Institute for Health and Medical Research).<sup>6</sup> Women of the GAZEL cohort aged 45-50 years between 1990 and 1996 ( $n = 3114$ ) were included in a separate prospective longitudinal survey, the “Women and their Health” study. Its principal objective is to study women's health as they reach menopause and afterwards.<sup>7</sup> These women receive a general health questionnaire each year as part of the overall GAZEL survey and a separate questionnaire specific to women's health issues every three years. In 2000, an additional questionnaire about incontinence and obstetrical history was mailed to all the women in this survey. Except as otherwise specified, data come from both 2000 questionnaires. Three other reports about incontinence based on the same questionnaires and database have previously been published.<sup>8-10</sup>

At the time this study was initiated, there was no validated questionnaire for assessing pelvic floor symptoms in women without known pelvic floor disorders. The prevalence and severity of symptomatic POP was estimated from responses to the question: *In the past 4 weeks, have you experienced the sensation of a bulging from your vagina? Never, Rarely, Sometimes, Often, or All the time.* The question was constructed with the help of an expert and was modeled on the Bristol Female Low Urinary Tract Symptoms (BFLUTS) questionnaire and the Urogenital Distress Inventory.<sup>11, 12</sup> Understanding was not tested. Stress urinary incontinence was assessed by responses to a question from the BFLUTS questionnaire: *Does urine leak when you are physically active, cough or sneeze? Never, Rarely, Sometimes, Often, or All the time.* Women who answered *Sometimes, Often* or *All the time* were considered to have stress urinary incontinence. Other pelvic floor symptoms, i.e., urinary urge incontinence, voiding difficulties, constipation (fewer than 3 movements a week), defecation difficulties, lower abdominal pain or heaviness, and pain at intercourse, were assessed by the same method. Fecal incontinence was defined by involuntary loss of liquid or solid stool.

Other characteristics of the subjects considered in this analysis and recorded from the questionnaires are: general characteristics (age at questionnaire, educational level, body mass index, and menopausal status), medical history (diabetes mellitus, neurologic disease, cardiovascular disease, regular medical treatment, self-reported nervous breakdown, self-reported depressed mood, anxiety or stress, hysterectomy, previous urinary incontinence surgery, previous anal surgery, and previous POP surgery), lifestyle (household monthly income,

marital status, smoking habits, and regular physical exercise), and obstetrical history (parity, episiotomy, third-degree perineal tear, birth weight of heaviest child, age at first delivery and mode of delivery). Previous POP surgery was assessed by the questions: *Have you had a surgery? If yes, please specify the type of surgery* (a list was provided): *pelvic organ prolapse (falling organs) repair? Yes, No*. Self-reported nervous breakdown, and depressed mood, anxiety, or stress were defined by answers to a question presenting a list of health problems and asking the subjects to indicate those they had had during the past 12 months. The list included: Nervous breakdown as one answer, and depressed mood, anxiety or stress as another. We used logistic regression to examine the association between POP symptoms and other pelvic floor symptoms.

We used the Nottingham Health Profile (NHP), a generic instrument widely used to estimate general health-related QoL and validated in different populations, to determine whether symptomatic prolapse, like other chronic conditions, interferes with everyday life activities.<sup>13, 14</sup> The NHP questionnaire was included in the general health questionnaire administered in 2000. It is a generic QoL questionnaire, applicable to a broad range of populations and allowing comparisons between different clinical conditions. The NHP contains 38 items covering 6 dimensions: physical mobility (8 items), pain (8 items), emotional reactions (9 items), social isolation (5 items), energy (3 items), and sleep (5 items). The responses are dichotomous (yes/no) and concern the subject's condition at the time she is completing the questionnaire. A weight is assigned to each response so that a weighted score can be calculated for each of the six dimensions. The weighted scores for each dimension range from 0 (high QoL) to 100 (low QoL). Each subject's profile is described by 6 scores. It is also possible to construct a global score that is the mean of the 6 dimensions. We first used the Spearman rank test to analyze the correlation between the QoL scores in each NHP dimension and the severity of POP symptoms. We then examined the association between the global NHP score (mean of the scores for each dimension) and the severity of the POP (defined by symptom frequency), using a linear regression to take into account the possible confounding factors: general characteristics, medical history, lifestyle, and parity. We chose not to include in this model other pelvic floor symptoms significantly associated with POP in the preceding analysis.

Past or present symptomatic POP was defined by the report of symptomatic POP or a history of surgery for POP. Because this definition includes surgical history, we chose not to consider in the analysis other surgical history (hysterectomy, surgery for urinary incontinence and anal surgery), all of which were statistically associated with a history of surgery for prolapse. We compared the women with past or present POP to all the others and conducted a multivariable analysis with a backward stepwise logistic regression. Candidate variables for the multivariable model were those suspected to be risk factors for POP (age, BMI, occupation, menopausal

status, parity, and mode of delivery) or that could influence symptom reporting (educational level). A first model was constructed for all women. A second model (not shown) was restricted to parous women; it included obstetrical details (age at first delivery, birth weight of heaviest baby, episiotomy, and third-degree anal tears). Variables remained in the final multivariable model only if the odds ratio was significant after backward elimination; otherwise they were excluded.

Odds ratios and their 95% confidence intervals are reported for each association examined. All analyses were performed with Statview (SAS Institute Inc., Cary, NC).

The GAZEL cohort scientific committee and the CNIL (Commission Nationale de l'Informatique et des Libertés, that is, the French Data Protection Authority) approved this study, which received no external funding.



## Results

Questionnaires were sent to 3114 women, 2640 (85%) of whom completed and returned them. Median age was 54 (range 50-61) years and median parity 2 (0-6); 79% were postmenopausal. Respondents and nonrespondents did not differ significantly for age (mean age 54.6 versus 54.9,  $p=0.14$ , t-test), while respondents had a higher educational level than nonrespondents (20% had a high school diploma versus 15%,  $p=0.012$ , Chi<sup>2</sup> test).

Data about POP symptoms were missing for 193 women (7.3%); 2296 (87.0%) reported no *sensation of a bulge from their vagina* in the past 4 weeks, 69 *rarely* (2.6%), 70 *sometimes* (2.7%), 18 *often* (0.7%) and 8 (0.3%) *all the time*. Additionally, 70 women (2.7%) had previously undergone surgery for POP. POP symptoms were associated with difficulty defecating, lower abdominal pain, and difficulty voiding (Table 2). Other pelvic floor symptoms (stress urinary incontinence, urge urinary incontinence, fecal incontinence, painful intercourse, urinary infection, and fewer than 3 bowel movements per week) were not significantly associated with POP symptoms, after adjustment for difficulty in defecation or voiding and lower abdominal pain.

The NHP QoL questionnaire was completed by 2285 women (87%). As Figure I shows, the frequency of POP symptoms was associated with increased (that is, poorer) QoL scores in all NHP dimensions: physical mobility ( $p<0.0001$ ), pain ( $p<0.0001$ ), emotional reaction ( $p=0.01$ ), social isolation ( $p=0.03$ ), energy ( $p=0.0002$ ), and sleep ( $p=0.008$ ). The correlation between the severity of POP symptoms and QoL impairment, measured by the global NHP score, persisted even after adjustments (linear multiple regression) for other factors with a significant effect on QoL: urinary incontinence, anal incontinence, diabetes, regular physical exercise, BMI (continuous variable), self-reported nervous breakdown, self-reported depressed mood, anxiety or stress, living with a partner, occupation, and household monthly income (Table 3).

Overall, 158 women (6.0%) were considered to have past or present symptomatic POP. Characteristics associated with it were BMI, and the number of vaginal deliveries (Table 4). The one-variable model that used mode of delivery to predict a history of symptomatic POP had an  $R^2=0.008$  (data not shown). The multivariable model for women with children, which also tested age at first delivery, episiotomy, a third-degree anal tear and birth weight of the largest child, found no other obstetrical variable to be significant (data not shown).

## Discussion

The principal limitation of our study was that POP was not clinically confirmed. Prolapse is a sign observed during clinical examinations, and epidemiologic surveys about this disease are difficult because of the indirectness of its study by questionnaires. Nonetheless what matters from a practical point of view is symptomatic prolapse that motivates the woman to seek care. That is, women see their doctors for a functional disease and not for an anatomical defect. Moreover, a study of QoL and the risk factors associated with POP symptoms requires the availability of a sample of women recruited outside of a medical practice. It thus seems useful from a public health perspective to look at the prevalence of prolapse symptoms in the general population.

A major advantage of our sample is that the women participating were not recruited because they had symptoms. Their status as volunteers probably explains the excellent response rate (85%). At the time we began this study, there were no questionnaires validated in a population at low risk for POP.<sup>15</sup> Unfortunately, the question we used (*have you experienced a sensation of bulging from your vagina?*) could not be combined with clinical examination. Seeing or feeling a vaginal bulge is considered a specific symptom of POP, but the sensitivity of this symptom is mediocre in low-risk populations.<sup>16</sup> Barber et al showed that the question *Do you usually have a bulge or something falling out that you can see or feel in your vaginal area?*<sup>17</sup> had a specificity of 99% but a sensitivity of 35% for prolapse at or beyond the hymen (grades II and III) in a population at low risk. The question used by Rortveit et al in their study (*has there been a visible bulging or protrusion from your vagina?*) had a sensitivity of only 16% for grade II or III prolapse.<sup>18</sup> Symptoms increased with the severity of prolapse; they were frequent for stages III and IV and usually absent at stages I or 0.<sup>19</sup> Tan et al examined 1912 women who answered the question: *Do you ever feel a bulge or that something is falling out of the vagina?*<sup>20</sup> The response was positive in 79-85% of women who had a stage III or IV prolapse compared with 6-11% of women with a stage I or 0. It is therefore probable that those who responded positively in our survey were those with the most serious prolapse. In our study, the bulging symptom was correlated with pelvic pain and difficulties in voiding and defecation (Table 2), which serves as evidence supporting the clinical relevance of the question. Ellerkmann et al showed that POP documented by a standardized clinical examination is often associated with these symptoms.<sup>21</sup> Finally, the more frequent the prolapse symptoms, according to this question, the greater the impairment of QoL in all NHP dimensions. This graded association between the frequency of prolapse symptoms and QoL is additional evidence of the question's clinical relevance.

The relatively rare character of this condition necessarily means that in a general population sample we find few symptomatic women, thus statistical power is limited and significant risk factors more difficult to show. Only 2.7% of our participants had a history of surgery for prolapse and 3.7% had symptoms suggestive of prolapse. These figures are close to those of studies based on clinical examination, which have found only a 0-2.1% prevalence of prolapse beyond the introitus (Stage III or IV) in women 50-59 years.<sup>22, 23</sup> The cumulative risk of surgery for POP or urinary incontinence is estimated at 4.7 to 5.1% for women in their 50s.<sup>3, 24</sup>

Another limitation is that our population sample is not exactly representative of middle-aged French women, because women enrolled in the GAZEL cohort were recruited from a work setting and volunteered to participate in medical research. We know, for example, that the women who agreed to participate in GAZEL had a higher education level and were in better health than nonparticipating employees.<sup>6-8</sup> From our point of view, that is not likely to affect the QoL impairment observed or the risk factors identified.

Few studies have examined the impact of POP on QoL with a generic QoL tool. We showed that the more frequent the prolapse symptoms, the greater the impairment of QoL in all of the NHP dimensions. Even in multivariable analysis taking numerous factors likely to be associated with QoL into account, the symptoms of POP remained associated with a significant impairment in overall QoL. In the case-control study by Jelovsek et al, the SF-12 (Short Form Health Survey) physical scale showed impairment in women with prolapse, while the mental scale was similar in both groups; this study did not include multivariable analysis. We have previously shown that impairment of QoL in the NHP dimensions of physical mobility and pain is proportional to the severity of urinary incontinence.<sup>9</sup> A similar result appears for POP symptoms (figure 1). This suggests that symptomatic POP can have an important impact on general health-related quality of life and interfere as a disability with physical mobility, pain, emotional reaction, social isolation, energy and sleep.

We still know very little about its causes. A congenital or acquired tissue factor is probable;<sup>25-27</sup> the position of the pelvis or the spine may play a role;<sup>28, 29</sup> and physical effort, constipation, a chronic cough, and obesity (BMI is a significant factor in our study) weighing on the pelvic floor may also be involved.<sup>30-33</sup> The most frequently suggested hypothesis is that of obstetrical trauma. Mant et al found a risk of hospitalization for POP proportional to parity.<sup>32</sup> Clinical examination shows that prolapse is more frequent in women with children.<sup>22, 23</sup> Several other cross-sectional surveys have shown that symptoms of POP are more frequent in women with vaginal deliveries.<sup>1, 34, 35, 36</sup> Nonetheless the role of vaginal delivery in the natural history of prolapse must be slight, for in our population it explains less than 1% of the symptomatic prolapses. Other mechanisms probably play a role in onset but we are limited by the cross-sectional nature of our study, which makes it

impossible to record the risk factor when it occurs. Only a longitudinal survey can identify traumatic events to the perineum as they occur. In the same GAZEL population, severe stress incontinence (15% prevalence) and fecal incontinence (9.5%) were not associated with mode of delivery.<sup>8, 10</sup> It is therefore probable that even though these pelvic floor disorders are often associated they do not share the same pathophysiologic mechanisms. This is consistent with the work by DeLancey, who showed that stress urinary incontinence is linked more to an aging sphincter than to the impairment of urethral support.<sup>37</sup>

In conclusion, although their prevalence is relatively slight, POP symptoms have a significant impact on the QoL of the women who have them. Even if it is probable that vaginal delivery plays a role in the genesis of POP, it is an incidental factor that explains only a very small part.

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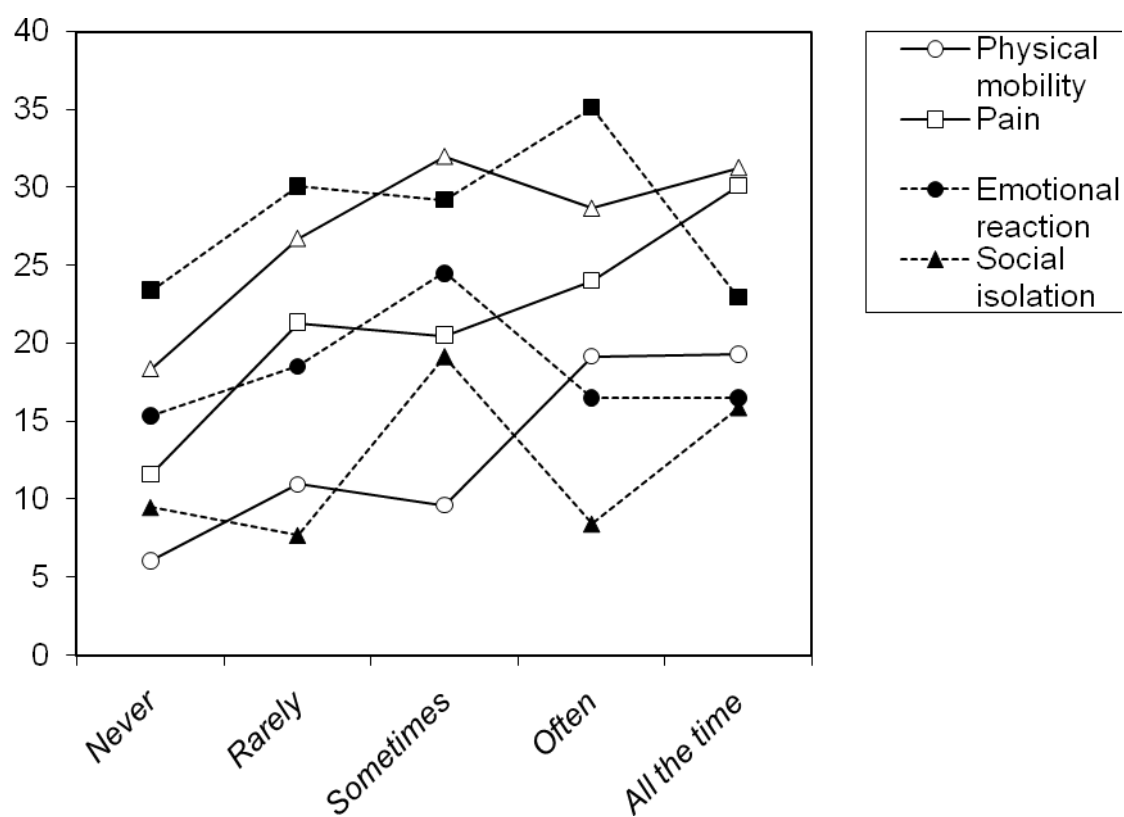
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**Figure I**

Mean quality of life score, in each NHP dimension, associated with POP symptoms frequency.

**Table 1**

Association between pelvic floor disorders and POP symptoms. Univariable and multivariable analysis using logistic regression.

Women's pelvic floor symptoms		N	POP symptoms % (n)	Univariable analysis crude OR (95%CI)	Multivariable analysis adjusted OR (95%CI) R <sup>2</sup> =0.54
Difficult defecation	No	1735	2.5 (44)	1	1
	Yes	730	7.0 (51)	2.98 (1.97-4.51)	1.62 (1.04-2.53)
Bowel movement <3/week	No	1998	3.4 (68)	1	<i>Excluded</i>
	Yes	454	5.9 (27)	1.85 (1.17-2.92)	
Fecal incontinence	No	2243	3.3 (74)	1	<i>Excluded</i>
	Yes	250	8.0 (20)	2.55 (1.53-4.36)	
Lower abdominal pain or heaviness	No	1960	1.8 (36)	1	1
	Yes	494	12.1 (60)	7.80 (5.09-11.95)	4.79 (2.98-7.71)
Painful intercourse	No	1566	3.1 (49)	1	<i>Excluded</i>
	Yes	350	7.7 (27)	2.66 (1.64-4.33)	
Stress urinary incontinence	No	1557	2.3 (36)	1	<i>Excluded</i>
	Yes	1072	5.6 (60)	2.43 (1.60-3.71)	
Urge urinary incontinence	No	2186	2.9 (63)	1	<i>Excluded</i>
	Yes	445	7.4 (33)	2.65 (1.72-4.10)	
Urinary infection during the past 12 months	No	2265	3.2 (72)	1	<i>Excluded</i>
	Yes	329	7.3 (24)	2.41 (1.50-3.90)	
Difficult voiding	No	2106	2.2 (46)	1	1
	Yes	433	10.9 (47)	5.5 (3.61-8.39)	2.70 (1.69-4.29)

Variables remained in the final multivariable model only if the OR was significant (p value < 0.05) after backward stepwise elimination.

**Table 2**

Multiple regression analysis of the association between overall quality of life, measured by the NHP global score, and the frequency of pelvic prolapse symptoms, self-reported nervous breakdown, self reported depressed mood anxiety or stress, back pain, urge urinary incontinence, fewer than 3 bowel movements a week, regular physical exercise, hysterectomy, neurologic disease, regular medical treatment, BMI, living with someone, occupation, monthly income. The other variables tested (age, high school diploma, smoking, menopausal status, parity, previous urinary incontinence surgery, previous POP surgery, previous anal surgery, stress urinary incontinence, fecal incontinence, urinary infection, diabetes, and cardiovascular disease) were not significant and were excluded from the final model.

NHP global score versus 16 independent variables, R <sup>2</sup> =0.32, F=48.0, p<0.0001		Coefficient (CI 95%)	p
POP symptoms (sometimes, often, or all the time)		4.15 (0.93-7.38)	0.012
Self-reported nervous breakdown		10.31 (7.03-13.58)	<0.0001
Self-reported depressed mood, anxiety, or stress		8.70 (7.29-10.11)	<0.0001
Back pain		5.42 (4.19-6.65)	<0.0001
Urge urinary incontinence		3.11 (1.52-4.70)	0.0001
Bowel movement < 3/week		3.95 (2.33-5.57)	<0.0001
Regular physical exercise (at least 1/week)		-3.03 (-4.25—1.80)	<0.0001
Hysterectomy		1.63 (0.07-3.19)	0.040
Neurologic disease		6.39 (3.93-8.86)	<0.0001
Regular medical treatment		2.14 (0.88-3.40)	0.0009
Body Mass Index (kg/m <sup>2</sup> )		0.20 (0.05-0.36)	0.011
Living as couple		-2.61 (-4.36—0.86)	0.0035
Occupation	Blue-collar, clerical staff	1.54 (0.12-2.96)	0.034
	Management or training	0.29 (-1.86-2.43)	0.80
Household monthly incomes,	< 1982 €	0.07 (-1.75-1.89)	0.94
	> 3810 €	-1.73 (-3.30—0.17)	0.030

**Table 3**

Association between women's characteristics and pelvic organ prolapse history (POP symptoms or previous POP surgery). Univariable and multivariable analysis with logistic regression.

Women's characteristics		POP history % (n)	Univariable analysis crude OR (95%CI)	Multivariable analysis adjusted OR (95%CI) R <sup>2</sup> =0.013
Age at questionnaire	< 55	5.6 (83)	1	<i>excluded</i>
	≥ 55	6.4 (75)	1.19 (0.80-1.77)	
Body mass index (kg/m <sup>2</sup> )	< 25	5.2 (87)	1	1
	≥ 25	7.2 (65)	1.41 (1.01-1.96)	1.41 (1.01-1.97)
Occupation	Blue-collar, clerical staff	6.9 (46)	1	<i>excluded</i>
	Supervisors, sales representatives	6.1 (103)	0.88 (0.61-1.26)	
	Management or training	2.8 (6)	0.38 (0.16-0.91)	
High school diploma	No	6.2 (128)	1	<i>excluded</i>
	Yes	4.3 (22)	0.68 (0.43-1.09)	
Menopausal status	Pre	5.1 (27)	1	<i>excluded</i>
	Post with HRT	6.1 (80)	1.20 (0.77-1.89)	
	Post without HRT	6.2 (49)	1.20 (0.74-1.95)	
Mode of delivery	None	2.9 (9)	1	1
	1 vaginal	5.2 (40)	1.89 (0.91-3.96)	1.91 (0.91-3.98)
	2 vaginal	6.8 (76)	2.49 (1.23-5.03)	2.49 (1.23-5.04)
	3 or more vaginal	9.6 (30)	3.61 (1.68-7.76)	3.55 (1.65-7.62)
	Cesarean only	2.2 (3)	0.75 (0.20-2.81)	0.73 (0.19-2.73)