# Assessment of the prevalence of pelvic floor disorders in both vaginal and cesarean deliveries and their impact on the quality of life

**THESIS**

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# ***Protocol***

# Introduction:

Pelvic organ prolapse (POP) and stress urinary incontinence (SUI) are two common health-related conditions affecting women worldwide. POP may occur in 50% of parous women.[2, 3]

Pelvic organs are kept in place by the endopelvic fascia, and the levator ani muscles closing the pelvic floor. Relaxation or damage to the pelvic floor may result in uterine prolapse, rectocele, cystocele or enterocele. The etiology of POP is thought to be complex and multi-factorial.[6]

Risk factors include vaginal delivery(VD), pregnancy, ageing, connective tissue abnormalities, denervation/ weakness of the pelvic floor muscles, menopause, factors associated with chronically raised intra-abdominal pressure (e.g. heavy lifting), genetic factors, hypoestrogenism, trauma, musculoskeletal diseases, chronic diseases, smoking and prior surgery.[2,5,6]

Women with prolapse commonly have a variety of pelvic floor symptoms directly related to the prolapse including pelvic heaviness, dragging sensation in the vagina(discomfort in the vagina), bulge or protrusion coming down from the vagina and backache.[2]

Symptoms of bladder, bowel or sexual dysfunction are frequently present. These symptoms may be related to the prolapsed organ(e.g. poor urinary stream when a cystocele is present or constipation when a rectocele is present) or may be independent of theprolapse (e.g. symptoms of overactive bladder when a cystocele is present).[2]

Urinary incontinence (UI) is a storage symptom defined epidemiologically as the complaint of involuntary loss of urine, but when the prevalence of bothersome incontinence is sought, the previous definition of an ‘‘Involuntary loss of urine that is a social or hygienic problem’’ can be useful. Stress Urinary Incontinence is the complaint of involuntary leakage on effort, exertion, sneezing or coughing. It affects up to 50% of women worldwide as the most common treatable form of UI in females. [2,3]

Although it is not uncommon for POP and SUI to coexist in the same patient, the relationship is complex; each of the conditions and/or its surgical treatment may be a risk factor for the development of the other. [3]

Pelvic organ prolapse and SUI share many risk factors and both conditions are believed to result from pelvic floor damage in the form of fascial defects, muscular weakness or denervation injury.[4]

Urinary incontinence is a non-life threatening condition but remains an important cause of morbidity in women. It is estimated that UI disrupts the lives of about 20% of middle aged women but it affects different women differently. UI often leads to embarrassment and low self-esteem and in its severe forms may lead to social isolation. In working class women, UI has negative effects on their productivity and some will avoid employment because of fear of these embarrassing situations.[1]

Pregnancy and childbirth have long been considered as risk factors in the genesis of pelvic floor disorders. Mechanical and hormonal changes during pregnancy, as well as the mechanical strain during labor and delivery, may all cause partial denervation of the pelvic floor, and direct injury to pelvic muscles and connective tissue. These injuries may further lead to the development of SUI, anal incontinence, pelvic organ prolapse, and/or voiding dysfunction. Although many studies have shown some correlation between obstetric parameters and the development of these symptoms, there is no consensus regarding the impact and relative contribution of the different risk factors. Moreover, the etiology of pelvic floor disorders is multi-factorial. Additional risk factors other than pregnancy and childbirth include heredity, collagen abnormalities, obesity and aging. [5]

## Research Question:

Is there a correlation between the mode of delivery - as an independent factor- and the prevalence of pelvic floor disorders (both pelvic organs prolapse & stress urinary incontinence) in parous women?

## Research Hypothesis:

Null hypothesis: There is no correlation between the mode of delivery and the prevalence of pelvic floor disorders (pelvic organ prolapse &/or stress urinary incontinence) in parous women.

## Aim of work:

To estimate differences in prevalence of pelvic floor disorders (POP & SUI)by mode of delivery and their impact on patients' quality of life using assessment questionnaire.

## Participants and Methods:

**Study design:** Measuring the prevalence of pelvic floor disorders ( pelvic organ prolapse and stress urinary incontinence) regards the mode of delivery in women delivered since 5 years or more and its impact on the quality of their lives through history taking , clinical examination and questionnaire

**Type of the study:** Observational (non-interventional) cohort study

**Study setting:** Ain Shams Maternity Hospital

**Participants recruitment:** 464 parous women will be recruited from the gynecologic out-patient clinic of Ain Shams Maternity University Hospital. Data confidentiality and the right of patients in the approval or rejection

without affecting the service provide dis guaranteed. An Informed written consent to be obtained from each case.

*N.B.* Any detected patients will be guided to the specialized clinics

***The following inclusion criteria will be used:***

(1) Age group:35 years or older

(2) Parity: para 3 or more cases

(3) Last delivery since 5 years or longer

***The following exclusion criteria were used:***

(1) Age group: < 35 years

(2) Parity:<3 times

(3) Last delivery since less than 5 years

**Methods:** All patient recruited in the study will be subjected to:

(A) ***Complete medical & obstetric history***, with assessment of risk factors, parity, mode of deliveries, date of last delivery, etc.

(B) ***Physical examination,*** There are a number of components in the examination of patients with incontinence and/or pelvic organ prolapse.

- General Examination includes: Obesity (BMI).
- Abdominal/flank examination: for masses, bladder distention, relevant surgical scars
- Pelvic examination: examination of the perineum and external genitalia including tissue quality and sensation.
- Vaginal (half-speculum) examination for prolapse.
- Bimanual pelvic and ano-rectal examination for pelvic mass, pelvic muscle function, etc.
- Grading for prolapse (Traditional anatomical site prolapse classification).

- Stress test for urinary incontinence.
- Urodynamics.

***(C) The impact of POP and SUI on the patients' life style will be assessed using King's Health Questionnaire.***

## Sample size calculation:

Depending on (***Hafsa U Memon and Victoria L Handa, 2013***) who found pelvic floor dysfunction in 58% of women who had spontaneous vaginal delivery, compared with 43% of those who underwent cesarean section, and assuming the power= 0.90 and $\alpha$=0.05, and by using PASS 11$^{th}$ release the minimal sample size for an equal size comparative study groups to detect a significant statistical difference between spontaneous vaginal delivery and cesarean section is 232 in each group.

## Statistical methods :

The collected data will be coded, tabulated, and statistically analyzed using SPSS program (Statistical Package for Social Sciences) software version 18.0.

Descriptive statistics were done for quantitative parametric data as mean ±SD (standard deviation) and minimum& maximum of the range and for numerical non parametric data as median and 1st& 3rd inter-quartile range and minimum& maximum of the range, while they were done for qualitative data as number and percentage.

Inferential analyses were done for quantitative variables using independent t-test in cases of two independent groups with parametric data and Mann Whiteny U in cases of two independent groups with non parametric data.

In qualitative data, inferential analysis for independent variables were done using Chi square test for differences between proportions and Fisher's Exact test for variables with small expected numbers. While correlations were done using Pearson Correlation for numerical parametric data, and using spearman rho test for numerical non parametric and qualitative data.

The level of significance was taken at P value < 0.050 is significant, otherwise is non-significant. The p-value is a statistical measure for the probability that the results observed in a study could have occurred by chance.

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# List of Contents

# List of Abbreviations

| **Abbreviation** | **Meaning** |
|---|---|
| aOR | Adjusted odd ratio |
| BMI | Body mass index |
| CI | Confidence Interval |
| CS | Cesarean Section |
| ECM | Extracellular matrix |
| EDS | Ehlers–Danlos syndrome |
| EPINCONT | Epidemiology of Incontinence in the County of Nord-Trondelag study |
| FD | Forceps delivery |
| FDV | 1st desire to void |
| FI | Fecal incontinence |
| FSD | Female sexual dysfunction |
| HRQL | Health-related quality of life |
| ICS | International Continence Society |
| IUGA | International Urogynecological Association |
| JHS | Joint hypermobility syndrome |
| KHQ | King's Health Questionnaire |
| LAM | Levator ani muscle |

| **Abbreviation** | **Meaning** |
|---|---|
| LUTS | Low urinary tract symptoms |
| MCH | Maternity and Children's Hospital |
| MUCP | Maximum urethral closure pressure |
| MUI | Mixed urinary incontinence |
| OR | Odd ratio |
| PFDs | Pelvic floor disorders |
| PFM | Pelvic floor muscle |
| PFMT | Pelvic floor muscle trauma |
| PISQ | Pelvic Organ Prolapse/Urinary Incontinence Sexual Questionnaire |
| POP | Pelvic organ prolapse |
| QoL | Quality of Life |
| SD | Sexual dysfunction |
| SDV | Strong desire to void |
| SF-36 | Study Short Form-36 |
| SPSS | Statistical Package for Social Sciences |
| SUI | Stress urinary incontinence |
| UDI | Urinary distress inventory |
| UI | Urinary incontinence |
| UUI | Urge urinary incontinence |
| VD | Vaginal Delivery |

| **Abbreviation** | **Meaning** |
|---|---|
| WHO | World Health Organization |

# List of Tables

# List of Figures