Impact of pelvic floor muscle training (PFMT) on quality of life among women suffering from stress urinary incontinence after first childbirth: a feasibility study

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Abstract

Objective: To determine the feasibility of performing a randomized controlled trial comparing Pelvic Floor Muscle Training (PFMT) and behavioral advice only for postpartum SUI.

Results: A feasibility study was performed with 207 women in 7-16 weeks postpartum at community postpartum clinics. Women reporting SUI were randomized to an intervention group (n=15), which followed an organized PFMT programme for six weeks and a control group (n=14). Control group was advised on routine postnatal care with behavioral advice. Both groups were assessed for QoL using a validated incontinence-quality of life (I-QOL) questionnaire at recruitment and in six weeks. There were 14% (29/207) of women suffering from SUI amongst the study sample. Before intervention there was no difference between I-QOL score in both groups. There was significant improvement (p<0.001) of I-QOL score in the interventional group (PFMT) compared to the control group (routine care with behavioral advice) after six weeks. Studying QOL improvement with this intervention is feasible for an interventional study. If directly inquired by the healthcare provider, women were willing to report, discuss and seek treatment for SUI.

Conclusion: SUI is a common postpartum problem in this urban cohort of Lankan women. These women can be effectively treated improving their QOL with PFMT intervention.

Key words: quality of life, postpartum, urinary incontinence, pelvic floor muscle training

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Introduction
SUI can be defined as involuntary urine leakage with coughing, sneezing and/or physical exertion. When urodynamic studies demonstrate involuntary loss of urine during increased intra-abdominal pressure, but the leakage is not accompanied by a contraction of the detrusor muscle, the condition is termed urodynamic SUI. The reported prevalence of SUI in pregnancy and postpartum is as high as 58.3%. Other risk factors that worsen the condition include parity, higher body mass index, UI before pregnancy vaginal birth, instrumental delivery and higher birth weight of the baby.

PFMT is recommended as a first-line therapy for UI with promising success amongst non-pregnant mid-life women with SUI. Information on PFMT from a health professional or from other sources (e.g. leaflets and websites) may not be effective unless proper professional supervision is being carried out. However, according to Cochrane review published in 2020, there is an uncertainty about the effectiveness of PFMT in women with postpartum SUI. For the patient, SUI has severe impact on life, such as poor QOL, negative effect on sexual and social life. This underlines the value of both preventive strategies and treatment interventions and the need for further research. Uncertainty exists whether PFMT gives a better cost-effectiveness compared to other treatment options. Aforementioned Cochrane review has also pointed out the deficiency of studies assessing incontinence-specific QOL among antenatal and postnatal women with UI.

Improvement of QOL by PFMT on women suffering SUI is therefore worthwhile to study in postpartum women. The full impact is masked by under-reporting due to social stigma. Pelvic floor muscle training has shown to be helpful in certain study settings. There is a paucity of studies done among Sri Lankan women and therefore assessment of the feasibility seems to be worthwhile prior to a large scale randomised controlled trial (RCT). The objectives were to determine the prevalence of SUI after childbirth and the feasibility to conduct a RCT to assess the effectiveness of PFMT for improving QOL among postpartum women with SUI in Sri Lanka.

Methods
Design and setting
A feasibility study was conducted in postnatal clinics at the De Soysa Hospital for Women (DSHW) and field postnatal clinic at Medical Officer of Health Office, Pitakotte, Sri Lanka. The methodology was supported by the recent work by Eldridge et al on ‘Defining Feasibility and Pilot Studies in Preparation for Randomised Controlled Trials: Development of a Conceptual Framework’.

Eligibility criteria
Eligibility criteria included: women who had their first childbirth, normal delivery at term [37-41 weeks], uncomplicated pregnancy followed by an uncomplicated postpartum period at the time of recruitment, no previously known lower urinary tract pathology, no active lower urinary tract infection as confirmed by the urine culture. This group of primigravida were the least likely group to report SUI postpartum and the most suitable cohort to study the feasibility in this regard.

Phase 1 – Initial survey
Consecutive women attending the health care facility were screened for eligibility. All eligible women were invited to participate. Recruited women were given a questionnaire to assess their symptoms related to the SUI. The questionnaire contained two sections; Section-1 explored the basic demographic details, Section-2 contained seven items regarding the nature of urinary leakage aiming to identify women with SUI. The I-QOL questionnaire is a commonly used and validated instrument specific to persons with stress and mixed types of urinary incontinence. It is a simple, self-administered questionnaire that takes on average five minutes to complete. In addition to a total score, three domains can be identified from the I-QOL: Activity and Limiting Behavior, Psychosocial Impact and Social Embarrassment. Higher scores indicate better a QOL.

Phase 2 – Extraction of women with SUI
Eligible women with SUI were selected according to the survey (who scored more than 3) and recruited for the feasibility study with intervention and control arms. Validation into local, Sinhala and Tamil versions were performed using face validity. PFMT program was introduced to the intervention group. They had to follow the exercise program described below for six weeks. Control group had advice on routine postnatal care with behavioral advices only. After randomization,
intervention and control groups were subjected to interview and intervention in separate events to minimize leaking the information in between.

A computer generated list with randomly allocated list of blocks prepared and sequentially numbered. These blocks were allocated into two arms (PFMT versus behavioral advice) and included in sealed envelopes by a separate medical officer who is not involved in the study.

**Description of the intervention**

PFMT refers to the performance of repeated voluntary contractions of the muscles in the pelvic floor. There should be a protocol that outlines the frequency, intensity and progression of exercises, as well as the duration of the training period. Both initial training and maintenance of pelvic floor exercises are essential to ensure duration of PFMT in the longer term.

**Exercise program**

Women with SUI were given the necessary clear instructions on PFMT as outlined below. Initially they were supervised while at the hospital and/or clinic. However, maintenance of regular supervision could not be done. There were two types of exercises. Slow twitch exercise to improve muscle strength and fast twitch exercises to improve power. Patients were advised do slow twitch exercise first and then fast twitch exercises.

**Exercise 1 – Instructions**

Close and draw up muscles around back passage, as if you are trying to stop passing wind. Make sure that do not contract your buttock muscles while you do this.

Now close and draw up the muscles around your vagina and urethra, as though you are trying to stop the flow of urine.

Hold for a count five; do not hold your breath, breath normally. Then, slowly relax and let it go. Repeat five times in total.

**Exercise 2 – Instructions**

Squeeze and lift your pelvic floor muscles as strongly and as quick as possible
- Do not try to hold just squeeze and let go.
- Rest for few seconds between each squeeze.
- Repeat 5-10 times until your muscles feel tired.
- Do this exercises program three times per day.

I-QOL and this was filled by both control group and intervention group before intervention. I-QOL was administrated again six weeks after intervention.

**Control group**

This group received routine postnatal care advices with behavioral changes including limiting fluid intake; spread it though out the day and urinating more often to reduce the amount of urine leaks. Also avoiding jumping or running with a full bladder, which can cause urine to leak.

Patients were also advised to quit smoking/avoid passive exposure to reduce coughing and bladder irritation and avoid alcohol and caffeine/beverages which can stimulate the bladder. They were advised to lose weight if overweight, avoid constipation and avoid food and drinks that irritate the bladder such as spicy foods, carbonated drinks, and citrus fruits.

**Statistical analysis and ethical aspects**

Descriptive statistics was used to analyse nominal variables. Mann-Whitney U test was used to see any significant difference of I-QOL median scores before and after intervention in both groups. P value < 0.05 was considered as statistically significant. Prior informed written consent was obtained from the study participants. This study was conducted as part of an undergraduate research project (Author WJGSNTF) and prior ethical approval was obtained from the Ethical Review Committee, Faculty of Medicine, University of Colombo, Sri Lanka.

**Results**

A consecutively recruited sample of 207 postpartum women who had their first childbirth were interviewed at 7-16 weeks after delivery and 29 (14%) of them were suffering from SUI after childbirth.

The resultant 29 women were recruited for the feasibility study, 15 women for the intervention (PFMT)
Table 1. Basic demographic details of women with stress urinary incontinence after first childbirth

| Age (years) | Intervention group (n=15) | Control group (n=14) |
|-------------|--------------------------|---------------------|
|             | Frequency (%)            | Frequency (%)       |
| <25         | 5 (33.0)                 | 5 (35.7)            |
| 26-30       | 5 (33.3)                 | 5 (35.7)            |
| 31-35       | 4 (26.7)                 | 1 (7.1)             |
| >36         | 1 (6.7)                  | 3 (21.4)            |
| Number of weeks after childbirth |
| 16-15       | 3 (20.0)                 | 3 (21.4)            |
| 14-13       | 1 (6.7)                  | 1 (7.1)             |
| 12-11       | 1 (6.7)                  | 1 (7.1)             |
| 10-09       | 6 (40.0)                 | 5 (35.7)            |
| 08-07       | 4 (26.7)                 | 4 (28.6)            |

Table 2. Quality of life before and after six weeks of intervention in both groups

| At baseline       | Six weeks after PFMT |
|-------------------|----------------------|
| PFMT group (n=15) | Behavioral advice group, (n=14) | PFMT group (n=15) | Behavioral advice group, (n=14) |
| Median (IQR) QOL score | Median (IQR) QOL score | p value | Median (IQR) QOL score | Median (IQR) QOL score | p value |
| 78 (74.0-96.0)    | 79 (69.8-91.0)       | 0.72    | 108 (99-110)         | 86 (78.5-95.3)       | < 0.001 |

IQR- Interquartile range; QOL- Quality of life; PFMT- Pelvic floor muscle training.
Discussion

This study was done to determine the feasibility to conduct a RCT for the effectiveness of PFMT in improving QOL in women with postpartum SUI in Sri Lanka. Results show that it is feasible to conduct a RCT depending on the prevalence, case detection and the response rate. However, taking into account the 14% prevalence of postpartum SUI, and for improving external validity, it seems better to conduct the planned trial in several centers to get an adequate representative sample in a given time period. Since there are no previous studies in Sri Lanka, this short report gives potential parameters to calculate sample size of the future trial in the study setting.

The present study had a highly selective inclusion criterion and generally, the least likely group to suffer from SUI recruited. Multiparous women were excluded. Still they reported 14% prevalence. Prior to the direct questioning, none of the women voluntarily and actively sought advice or treatment for their condition despite multiple interactions with healthcare providers in Sri Lankan setting. When inquired directly by a trained female healthcare provider, women had no hesitation in reporting, discussing or seeking treatment for SUI. Therefore, midwives may be the ideal in initiating a help program for SUI postpartum. However, as they are already overburdened with multiple screening tasks, it is important to study the benefits, cost and feasibility before such an implementation. This justifies the necessity of a feasibility study in this regard. Hence, this study was not planned to assess treatment seeking behaviour or barriers to reporting.

Recent Cochrane review published in 2020 on ‘Pelvic floor muscle training for preventing and treating urinary and faecal incontinence in antenatal and postnatal women’, has concluded the lack of information regarding the impact of PFMT on QOL aspects and cost-effectiveness of PFMT among these incontinent women. Our study has reported a lower prevalence (14%) of SUI compared to other settings: Wesner et al, (30%) and Thom et al, (31%) among nulliparous women. However, these reports are more than 10 years old findings.

Cruz et al in 2014 found that those who received PFMT probably have better quality of life in late pregnancy. They have used the validated ‘Incontinence-specific Quality of Life Measure’ and the study has published only in its abstract form. The 30-item validated ‘Incontinence Impact Questionnaire’ (IIQ) has been used by the Woldringh et al in 2007 and categorised questionnaire scores making it is impossible to interpret these data. These are the only available two studies on this regard. Therefore, there is a clear need to design a study on this topic.

Conclusions

Studying QOL improvement with this PFMT intervention is feasible for an interventional study in our setting. SUI is a common postpartum problem in this urban cohort of Lankan women although the prevalence is low compared to other studies. These women can be effectively treated improving their QOL with simple PFMT interventions.

Limitations

Study was conducted in two study settings in an urban area. Therefore, results are not generalized in questioning its external validity and sample size might be inadequate to yield a significant power, hence, the conclusions. The questionnaire used in the study was translated into Sinhala and Tamil languages. However, only the face validity was done to assess translation and other psychometric properties have not been evaluated separately. Maintenance of regular supervision for PFMT could not be done, only supervision at the initial training was carried out.

List of abbreviations

| Acronym  | Description |
|----------|-------------|
| UI       | Urinary Incontinence |
| SUI      | Stress Urinary Incontinence |
| QOL      | Quality of Life |
| I-QOL    | Incontinence Quality of Life Questionnaire |
| PFMT     | Pelvic Floor Muscle Training |
| IQR      | Interquartile Range |

Declarations

Ethics approval and consent to participate: Prior informed written consent was obtained from the postpartum women. Ethical approval was obtained from the Ethical Review Committee, Faculty of Medicine, University of Colombo, Sri Lanka.

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Authors contributions
AJ contributed for conception, design, planning, analysis and writing/editing of the paper. WJGSNTF contributed for conception, design, planning, data collection and analysis. MP contributed for analysis and writing/editing of the paper. DMCSJ contributed for analysis and editing of the paper. All authors read and approved the final version.

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Availability of data and materials
Datasets generated from this study will be available from the corresponding author (AJ) upon a reasonable request.

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