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Effect of Heavy Lifting with a Head Strap on the Pelvic Floor across the Menstrual Cycle

Yvonne Biswokarma

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LOMA LINDA UNIVERSITY
School of Allied Health
in conjunction with the
Faculty of Graduate Studies

Effect of Heavy Lifting with a Head Strap on the Pelvic Floor across
the Menstrual Cycle

by

Yvonne Biswokarma

A Dissertation submitted in partial satisfaction of
the requirements for the degree
Doctor of Science in Physical Therapy

December 2016

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Each person whose signature appears below certifies that this dissertation in his/her opinion is adequate, in scope and quality, as a dissertation for the degree Doctor of Science.

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CONTENTS

Approval Page.....	iii
Acknowledgements.....	iv
List of Figures.....	x
List of Tables	xi
List of Abbreviations	xii
Abstract.....	xiii
Chapter	
1. Literature Review.....	1
Background for At-Risk Population	1
Isometric Simulation of Head Bearing Load (ISHBL).....	3
Hormonal Effects of the Menstrual Cycle on Connective Tissues.....	5
Effects of Core Temperature.....	8
Temperature	8
Other Factors.....	8
Transperineal Ultrasound (US).....	9
Measurement of Intra-abdominal Pressure (IAP).....	10
Rationale for the Study	11
Purpose.....	12
Hypothesis.....	12
References.....	15
2. Effect of Heavy Lifting with a Head Strap on the Pelvic Floor Across the Menstrual Cycle.....	20
Abstract.....	21
Background.....	21
Methods.....	21
Findings	22
Interpretation.....	22
Introduction:.....	23
Background and Objectives	23

Hormonal Effects of the Menstrual Cycle (MC)	25
Temperature Effects of the MC	26
Cultural Effects on the MC	26
Methods.....	27
Procedures.....	30
Participants.....	32
Data Analysis	33
Results.....	34
Discussion.....	38
Limitations	40
Conclusion	40
Contributors	42
Declaration of Interests.....	42
Acknowledgements.....	42
References.....	43
3. Background and Instrumentation Details.....	47
Background on Nepal	47
Research Venue	50
Instrumentation Rationale.....	52
Estimating Relative Estradiol Levels.....	56
Measuring Temperature.....	59
Measuring Pelvic Floor Mobility with Transperineal Ultrasound (US)	60
Measurement of Intra-abdominal Pressure (IAP).....	61
Explanation of Findings.....	63
Implications for Further Study.....	64
References.....	66

Appendices

A. Informed Consent Documents (English and Nepali)	70
B. Study Recruitment Poster (English and Nepali).....	88
C. Pelvic Floor Data Collection Sheet.....	90
D. OB/GYN Screening Form.....	91
E. Loma Linda University Institutional Review Board Approval.....	91
F. Nepal Health Research Council Approval	92

FIGURES

Figure	Page
1. Young Nepali women carrying loads with doko and namlo.....	4
2. Häggström, Mikael (2014) Reference Ranges for Estradiol.....	7
3. Pelvic Floor US image used in the study.....	10
4. Photo of the IVT sensor in hand for size reference.	11
5. Starting (a) and ending (b) positions for the doko lift.	31
6. Positioning of participants for ultrasound and pressure data collection for the six tasks.	32
7. IAP Graphs for Each Activity.....	39
8. Pelvic Floor US image used in the study.....	61
9. Photo of the IVT sensor in hand for size reference.	63

TABLES

Table	Page
1. Summary of the Risk Factors for POP, Comparing Nepal to the USA.....	13
2. Characteristics of the participants (N=22).....	29
3. Mean (standard error) of temperature (°C) by menstrual cycle (N=22).....	34
4. Mean (SE) displacement (mm) for each of 5 tasks by Menstrual phase (N=22)	35
5. Mean (SE) IAP (cm ² H ₂ O) for each of the 5 tasks in 2 different test phases during the menstrual cycle (N=22).....	36
6. Mean IAP for Doko lift as compared to mean of other tasks (N= 16).....	36
7. Pelvic Floor compliance mm/cmH ₂ O comparison for each task at ovulation and at menstruation.	37
8. Mean IAP for Doko lift as compared to mean of other tasks (N= 16).....	53
9. Showing average compliance for each task at ovulation and menstruation in mm/cmH ₂ O. N=22.....	56

ABBREVIATIONS

POP	Pelvic Organ Prolapse
SPOP	Symptomatic Pelvic Organ Prolapse
ISHBL	Isometric Head Bearing Load
IAP	Intra abdominal pressure
OBGYN	Obstetrics and Gynecology
NHRC	Nepal Health Research Council
IVT	Intra Vaginal Transducer
POP-Q	Pelvic Organ Prolapse Qualification Exam
US	Ultrasound
LH	Luteinizing Hormone
FDA	Food and Drug Administration
BAL	Ballistic isometric lift task used to simulate a doko lift
BALPFM	Ballistic lift with a pre-contraction of the pelvic floor
Cough	Unprovoked voluntary cough
PFM	Voluntary Pelvic floor contraction
Ramp	Gradual isometric lift against I head strap increasing pressure for 5-10 sec
VAL	Valsalva Maneuver
TAUS	Trans Abdominal Ultrasound

ABSTRACT

Effect of Heavy Lifting with a Head Strap on the Pelvic Floor Across the Menstrual Cycle

By Yvonne Biswokarma

Doctor of Science Graduate Program in Physical Therapy
Loma Linda University, December 2016
Dr. Everett Lohman III, Chairperson
Dr. Karen Brandon, Chairperson

Background: Pelvic organ prolapse (POP) occurs in 10% of women in Nepal, even 6% of nulliparous women have symptomatic POP.¹ This may be linked to the heavy lifting tasks performed by women using a head strap.² This study explored the impact of hormonal changes on the pelvic floor when performing these tasks during each phase of the menstrual cycle. Methods: The study included 22 female Nepali participants with a mean age of 27.4(3.6) years; all were from rural villages and frequently carried with a head strap. Using intravaginal pressure transducers (IVT), the mean change in intra-abdominal pressure (IAP) was found to be 37.1(4.3) cmH₂O when lifting a load with a mean weight of 19.8(3.2)kg using a head strap. Lifting tasks were simulated with isometric ballistic lifts against a head strap secured to the plith with the participant lying supine. The mean increase in IAP from rest was 31.6(2.1)cmH₂O. Displacement of the pelvic floor was measured by transperineal ultrasound. Mean displacement of the pelvic floor at ovulation was 5.1(0.4)mm and a mean of 5.9(0.4)mm during the early follicular phase (p 0.03). Conclusion: during the early follicular phase, when basal body temperature and beta estrogen are lowest, the compliance of the pelvic floor is greatest. Repetitive lifting during this time may predispose some woman to POP.

Key terms: prolapse, nulliparous, pelvic floor, lifting, menstrual cycle, laxity, compliance, elasticity, stiffness.

CHAPTER 1

LITERATURE REVIEW

Background for At-Risk Population

The population of interest in this study was women of reproductive age living in Nepal.

Pelvic organ prolapse (POP) has been noted to be a significant health problem in Nepal, with from 10 -25% of women affected³. The 2011 Nepal Health Demographic Report cites 10% of women have POP. Seven percent of women of reproductive ages 15-49 have POP, and 6% of nulliparous women have symptoms of POP.

In Nepal, 14% of women who developed POP did so as teenagers; the mean age of onset was 27 years, according to a 2006 study by the Institute of Medicine at Tribhuvan University, Kathmandu, Nepal.⁴ In contrast, the prevalence of symptomatic POP in western countries appears to be more common one to two decades later in life.⁵

In Nepal, there is only a one percent difference in rates of symptomatic POP in the general female population and nulliparous women ages 15-49.¹ Research by Dietz (2008) showed that vaginal delivery was the prime risk factor for POP, specifically levator ani tears or avulsion occurring during childbirth, particularly with forceps.⁵ If traumatic injury during vaginal delivery were the main risk factor for POP, it seems unlikely that parous and nulliparous women of the same age groups would experience the condition at such similar rates.

A review of the literature cited common risk factors of POP, including vaginal deliveries,⁶ poor pre- and post-natal care, position at delivery.⁷ Non-pregnancy or delivery related factors included menopause,⁷ genetics, aberrant connective tissue^{5,8} and

obesity.⁵ Factors related to child bearing do not account for the nearly identical rates of early onset POP among Nepali nulliparous women of the same age. Obesity is an unlikely cause, since only 2.9% of Nepali adults are obese.⁹ However, risk factors shared by both parous and nulliparous women in Nepal are a relationship between POP and the inherent weakness of supportive connective tissue.¹⁰ Though this may account for a genetic predisposition for the condition found in some ethnic groups, it is not known if identified changes in collagen are the cause or effect of prolapse.¹¹

Though the influence of hormones, including relaxin and estradiol, on tissue laxity has been explored,^{10,12,13,14} a literature review fails to identify a clear cause for loss of support by the pelvic floor in the absence of levator ani tears. Decreased estradiol at menopause is thought to cause a decline in the support provided by the pelvic floor.¹⁵ However, little is known about cyclic changes in elasticity and compliance of the pelvic floor during the menstrual cycle and how it may influence the dynamic demands required in daily tasks. If cyclic changes on the pelvic floor are found to be a common risk factor for women during their reproductive years, this may help to explain the development of POP in nulliparous women. Especially in Nepal where “Chhaupadi” is often practiced.^{2,16} This custom requires women to stay outside the house during menstruation and childbirth and forbids them from doing household chores such as cooking and religious duties. However, they are still required to do outdoor tasks that involve lifting and carrying loads while they are menstruating. This may lead to a disproportionate amount of heavy lifting during this part of their menstrual cycle.

Nepal demonstrates a unique situation with woman developing POP earlier than in western countries, and vaginal delivery is not consistently a factor. Menstrual cycles

have been shrouded with superstition in many cultures. Chhaupadi, practiced in Nepal with its accompanying heavy lifting maybe a clue as to why POP develops early for Nepali women and even in nulliparous women.²

Isometric Simulation of Head Bearing Load (ISHBL)

Studies in Nepal frequently identify carrying of heavy loads as a risk factor in POP and lifting 2.5 kg or more (especially when squatting) is known to increase intra-abdominal pressure (IAP) and create a downward force on the pelvic floor.¹⁷ In a study of 118 white women, normal mobility of the pelvic floor in nulligravid women, measured by descent of the bladder neck, was found to be 1.2-40.2 mm in a translabial ultrasound study of Valsalva maneuvers.¹⁸ However, this 2004 Dietz study did not control for menstrual phase, IAP, speed of movement, or the activation of pelvic floor muscles.

We must also consider the compliance properties of the tissues, the reciprocal of elastic properties. Elastance allows tissue to resist distension and recoil to its original shape, and compliance is the ability of a hollow organ to distend and resist recoiling to its original shape. Compliance equals the change in volume over the change in pressure.

$$C = \frac{\Delta V}{\Delta P}$$

Increased elasticity should help maintain pelvic organ positions and resist deformation of the pelvic floor under pressure. Increased compliance would allow the pelvic floor to deform more under pressure and leave the tissues stretched out and unable to support the pelvic organs in their positions. A more compliant pelvic floor would then be an inherent risk factor for pelvic floor dysfunction.¹⁹

Synergy motor patterns active in lifting and body position are other factors that could affect mobility of the pelvic floor. Gluteal muscles are involved in hip movement and stability during lifting, and have a synergistic effect on activity of the pelvic floor.²⁰ Activating the pelvic floor muscle creates a negative or inward displacement of the pelvic floor;²¹ therefore if the pelvic floor is not intentionally activated but are synergistically active with the gluteal muscles while lifting this may decrease downward displacement of the pelvic floor during increased IAP during functional lifting tasks. On the other hand, compared to a supine position, standing has been shown to weaken pelvic floor muscle contractions and increase intravaginal pressure.²² Thus positioning and motor patterns must be consistent during task performance for controlled repeated measures comparisons of pelvic floor mobility.



Figure 1. Young Nepali women carrying loads with doko and namlo.
Photo by Sudarshon Karki

Little is known about the impact of lifting on the descent of the pelvic floor among normal women performing functional lifting tasks unique to Nepal. Typically loads are carried using a head strap as shown in Figure 1. There is limited information on safe lifting when loads are carried in this manner. In accordance with Nepali governmental guidelines and Porter Progress recommendations, a 30kg load limit is placed on porters using these lifting techniques.²³ However, no guidance was found on preferable techniques or lifting methods specific to using a head strap. NIOSH lifting equation guidelines were all specific to carrying loads in the arms in front of the body.

There are no studies which show the normal changes in IAP when a woman lifts using a doko, and how these lifts might affect her pelvic floor mobility. Another factor not being explored is the effect of the menstrual cycle on pelvic floor mobility. Further research is needed to look at the complex interplay of hormone physiology, the biomechanics of the pelvic floor, and intra-abdominal pressure when women in this population perform certain load-bearing, functional tasks. Our study attempted to address these issues.

Hormonal Effects of the Menstrual Cycle on Connective Tissues

Levels of estradiol, the primary marker of the menstrual phase, increase around ovulation and stay elevated through the luteal phase and decline during the early follicular phase.²⁴

- Follicular phase: <20-145 pg/mL (184-532 pmol/L)
- Midcycle peak(ovulation): 112-443 pg/mL (411-1,626 pmol/L)
- Luteal phase: <20-241 pg/mL (184-885 pmol/L)

A woman's estradiol levels decrease after menopause. Research shows that decreased estradiol levels as low as 0-40 pg/mL have been linked to POP, since lower levels of estradiol weaken pelvic floor structures.¹⁵ However, there are no studies on changes in the pelvic floor across the menstrual cycle (<20-145 pg/mL), which at some points can be nearly as low as post-menopausal levels. Since hormonal fluctuations may be a factor affecting the tissue properties of the pelvic floor, mobility of the pelvic floor should be compared across all major phases of the menstrual cycle.

There is a lack of consensus in the literature as to which menstrual phase may have more inherent risk for tissue injury. Ovulation is thought to increase risk of ACL injury due to higher estradiol levels, and some studies found this may promote ligament laxity. Park found increased laxity and decreased stiffness in the knee joint at ovulation.²⁵ The supportive structures of the pelvic organs have receptors for estradiol and other gonadal hormones, and may be affected by the cyclic changes in these hormones.¹⁰ Lower estradiol levels have been shown to increase musculotendinous stiffness²⁶ and decreased elasticity²⁷ during menstruation.²⁸

Is increased stiffness a risk or a benefit? Dietz asserts that increased stiffness may be protective for POP among post-menopausal women, and that vaginal stenosis is the result rather than prolapse.²⁹ Dietz bases this on the observation that POP does not always progress with age and seems to even stabilize after menopause. To date, no studies were found that have evaluated the relationship between estradiol fluctuations in normal menstrual cycles and the stiffness or elasticity of pelvic floor tissues.

Testing blood hormone levels are the ideal way to monitor hormone levels.

Advanced Clearblue Ovulation tests (SPD Swiss Precision Diagnostics GmbH, Petit

Lancy, Switzerland) have been shown to be highly accurate in detecting levels of estrone-3-glucuronide (E3G; one of the urinary metabolites of estradiol) and luteinizing hormone (LH) around ovulation as compared to other home based methods.³⁰ These tests are less difficult for consumers to use without compromising accuracy.

The follicular phase of the menstrual cycle is typically from the first day of menses to the LH surge, which marks ovulation. The luteal phase of the menstrual cycle is from ovulation to the beginning of the next cycle. Three representative points from the distinct phases could be described as:

1. Within the first 4 days of menses (early follicular phase)
2. Within 24-48 hours of peak fertility indication
3. 6-10 days after LH surge

From Figure 2, it is clear that the greatest contrast in terms of estrogen levels are days 1 through 6 in the menstrual cycle, and ovulation days. We would expect to see the greatest differences in tissue properties between these two phases.

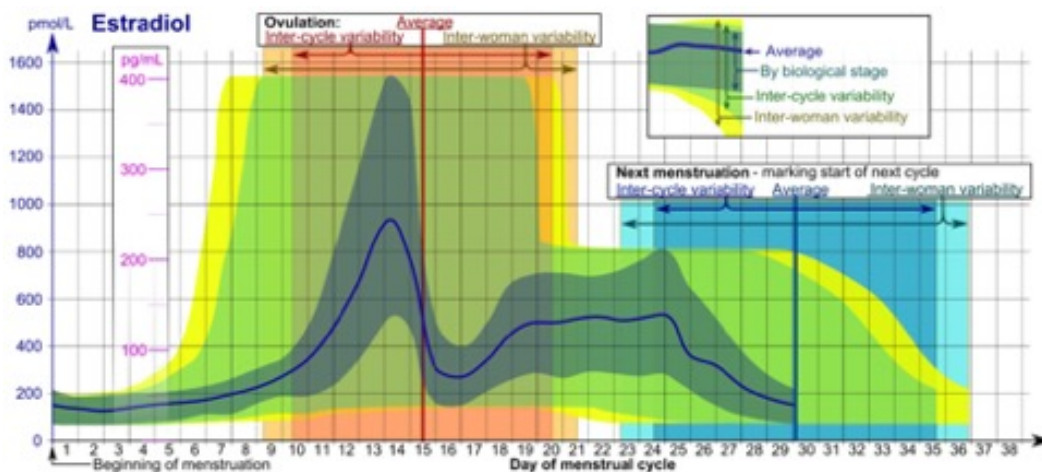


Figure 2. Häggström, Mikael (2014) Reference Ranges for Estradiol

Effects of Core Temperature

Temperature

Elastic properties of biological viscoelastic tissues are altered by temperature and loading rate. The temperature of tissue has been shown to affect its mechanical properties.^{31,32} Core body temperature is normally between 36-37.5°C.³³ Temperature also is affected by the menstrual cycle;³⁴ basal body temperature increases at the time of ovulation and remains elevated through the luteal phase. Therefore, vaginal temperature should be tested along with IAP to determine if temperature, along with other hormonal effects, impacts the displacement of the pelvic floor across the menstrual cycle. Basal body temperature is one half to one degree lower during the early follicular phase than after ovulation and throughout the luteal phase. Temperature changes have been shown to affect the performance of other ligaments in the body when tested across the menstrual cycle.³⁵

During menstruation, when estradiol and temperature are at their lowest points, the net effect is decreased elasticity and temperature, with increased stiffness, inflammation, and pain in the pelvic structures, versus at ovulation, when estradiol and temperature are at their peak.³⁶ In this study, we assessed temperature changes by taking continuous readings intra-vaginally with a fast response sensor (TSD202A, BIOPAC Systems, Inc. Goleta, CA , USA) attached to the IVT (Department of Bioengineering, University of Utah, Salt Lake City, Utah).

Other Factors

Also, pro-inflammatory cytokines are elevated during menstruation and correlated with premenstrual syndrome (PMS).³⁶⁻³⁸ For this reason, testing for pelvic floor mobility

across the menstrual cycle may be inhibited by pain and muscle guarding. Dysmenorrhea also could be a confounding factor in studies of normal pelvic floor movement. In addition, chronic cough due to respiratory conditions, smoking or asthma, as well as constipation, have been known to influence POP and may alter normal pelvic mobility.³⁹

Transperineal Ultrasound (US)

Ultrasound (US) has been shown to be a valid tool for the measurement of pelvic floor and organ displacement or movement.⁴⁰⁻⁴⁴ Various methods of ultrasound imaging have been reviewed and addressed in the literature, such as transperineal US and suprapubic US and transabdominal ultrasound (TAUS); however, suprapubic TAUS was not chosen since the abdominal wall is not stationary during activity and breathing.⁴⁵ For this reason, transperineal US was chosen as a way to visualize the pelvic floor structures and measure transitional movements. Consistent imaging strategies were used, and scripted instructions for all test activities were undertaken to collect the most reliable data possible. Compared to other methods, US has been considered a reliable method of visualization of pelvic floor morphology.^{42,46} The movement of the urethralvesicular junction with changes in IAP has been used as a marker of pelvic floor mobility.¹⁸ Because positioning for the transperineal ultrasound imaging is difficult during squatting to standing movement, the US probe must be stabilized to produce accurate imaging. Also, displacements of the pelvic floor have been noted to be significantly different in supine versus upright positions;²² therefore simulating the positioning in functional tasks during testing of pelvic floor mobility is important for accuracy. Normal supine pelvic floor mobility while performing the Valsalva maneuver measured with translabial ultrasound was shown to vary widely from 1.2 – 40.2 mm.¹⁸ Perhaps much of this

variability was due to changes in the biomechanical properties of the tissue induced by fluctuations of estradiol across the menstrual phase.

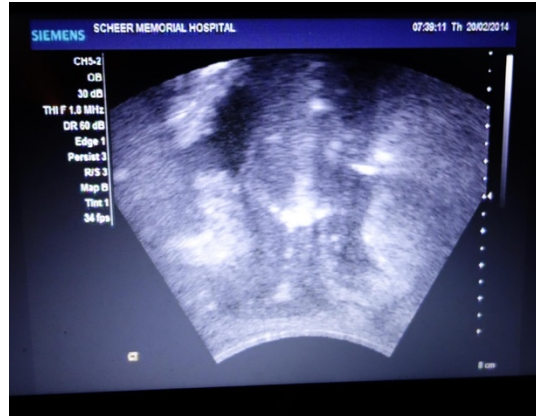


Figure 3. Pelvic Floor US image used in the study.

Measurement of Intra-abdominal Pressure (IAP)

Intra-abdominal pressure (IAP) rises during dynamic lifting activities.^{17,47}

Continuous monitoring of IAP would allow identification of peak IAP as it occurs with actual lifting of a typical load with head strap and the isometric simulation of head bearing lifting (ISHBL). The intravaginal pressure transducer (IVT) that was developed and validated at the University of Utah is ideal for measuring IAP in functional tasks.^{48,49}

This transducer was developed by the University of Utah and approved for use in research by the University of Utah Health Sciences Center Institutional Review Board.⁴⁸

The IVT is similar in size and shape to an O.B. brand tampon (see Figure 4). Women in initial trials have reported the IVT to be comfortable and that it did not impair movement.⁴⁹ Normal IAP for women performing functional tasks was found to be 40-80 cm H₂O.^{50,51} We found the peak-to-peak change in pressure with functional tasks to

typically range from 20 -100 cmH₂O. The IVT sensor, in conjunction with the use of BIOPAC modules and acquisition software, can allow for real-time IAP readings on the computer monitor. The IVT has been used in multiple positions for testing functional-task IAP, including supine and transitional movements.⁵⁰ The IVT calibration was done in Salt Lake City and the elevation is nearly identical to the testing location in Nepal. Sensors were not a cross contamination concern because they were placed in condoms while in use and treated with Cidex (ASP, Irvine, California) per manufactures instructions and rinsed in sterile saline prior to the next use. This is the protocol currently used in the operation theater at Scheer Memorial Hospital (the research venue) and also meets or exceeds the JHACO guidelines and manufactures recommendations for the sterilization of equipment that is reused with multiple patients.

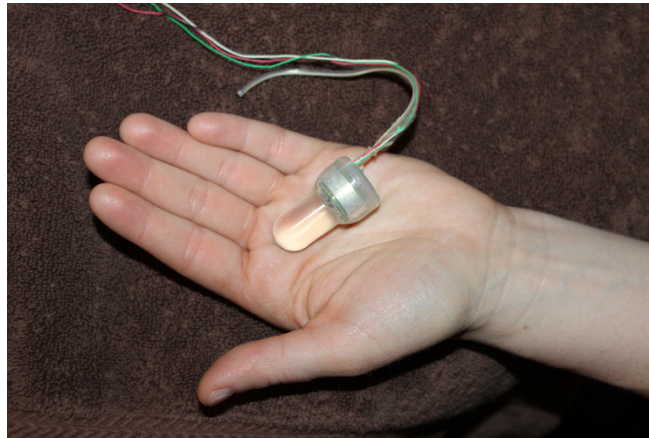


Figure 4. Photo of the IVT sensor in hand for size reference.

Rationale for the Study

Consistent excessive compliance or displacement at any one phase of the MC could indicate increased risk of tissue damage that could weaken support for pelvic

organs and predispose women to pelvic organ prolapse (POP). See Table 1 for list of common causes for POP and which are pertinent to the population in Nepal.

Purpose

To identify at least two phases of the menstrual cycle (MC) that are significantly different in the amount of displacement of the pelvic floor due to increased intra-abdominal pressure (IAP) with isometric simulation of head-bearing lifting (ISHBL) in Nepali women of reproductive age.

Specific aims of the study: This study will identify possible differences in the displacement of the bladder neck from rest while participants perform ISHBL at representative points in the menstrual cycle;

- 1) Early follicular phase (menses days 1-4)
- 2) Within 48 hours of ovulation
- 3) Mid-luteal phase (7-10 days after ovulation)

Hypothesis

- 1) There is a statistically significant difference in the mean displacement of the ventral urethralvesicular junction (VUVJ) from rest to maximum IAP with ISHBL between at least two of the phases of the menstrual cycle.
- 2) The higher the increase in IAP, the greater the descent in the VUVJ with ISHBL.
- 3) Compliance of the pelvic floor will be greatest in menstruation.
- 4) Engagement of the pelvic floor muscles (PFM) will be negatively correlated to pelvic floor displacement.

Table 1. Summary of the Risk Factors for POP, Comparing Nepal to the USA.

POP Risk Factor in the literature	Considered a Special risk factor Unique to Nepal	Rationale
Vaginal Delivery	No	6% of nulliparous women have POP. ¹
Vaginal delivery with forceps *	No	90% of women delivered at home with unskilled birth assistants. ⁴
Delivery with unskilled attendants	No	Overall, POP rates similar to Western countries when women delivered in hospitals. ^{4,52}
Multiple vaginal deliveries	No	30% of women developed symptomatic POP after the first delivery or even no delivery. ⁴
Genetic factors effecting collagen metabolism	No	As a country, Nepal has similar rates of POP as compared to other Western countries so genetics is not an obvious difference. ¹
Early age of marriage and child bearing	Yes	Nepali women may develop POP earlier than Western women because they typically have children six or more years earlier than in the US. ⁹
Gender discrimination / domestic violence	No	Domestic violence rates are the same in Nepal and the U.S. 22% of women experience domestic violence. ⁴
Heavy lifting	Yes	Our study participants self-report carrying 20-80kg regularly with a head strap.

Decreased estrogen	Yes	Heavy work is performed during menstruation when estrogen levels are low. ²
Early return to work after delivery	Yes	Average was 45 days before returning to work in Nepal; maternity leave is 10-42 days women may be less likely to do heavy manual work in the U.S. ⁴
Advanced age	No	POP develops at ages 20-30 in Nepal, 1-2 decades earlier than in the Western countries. ^{4,5}
Obesity	No	Only 2.9% of Nepali adults are obese. ⁹

* Considered the most significant risk factor for POP in the western countries.

References

1. Population Division Ministry of Health and Population NE, ICF International. Nepal Demographic and Health Survey 2011: Population Division Ministry of Health and Population Government of Nepal, 2012.
2. International A. Unnecessary Burden Gender Discrimination and Uterine Prolapse in Nepal. *Amnesty International February 2014* 2014; **Index:ASA31/001/2014**.
3. Radl CM, Rajwar R, Aro AR. Uterine prolapse prevention in Eastern Nepal: the perspectives of women and health care professionals. *Int J Womens Health* 2012; **4**: 373-82.
4. Institute of Medicine Tribhvan University Kathmandu N. A reproductive morbidity report on clinic based survey 2006; Status of Reproductive Morbidities in Nepal, 2006.
5. Dietz HP. The aetiology of prolapse. *Int Urogynecol J Pelvic Floor Dysfunct* 2008; **19**(10): 1323-9.
6. Elenskaia K, Thakar R, Sultan AH, Scheer I, Onwude J. Effect of childbirth on pelvic organ support and quality of life: a longitudinal cohort study. *Int Urogynecol J* 2013; **24**(6): 927-37.
7. Lien YS, Chen GD, Ng SC. Prevalence of and risk factors for pelvic organ prolapse and lower urinary tract symptoms among women in rural Nepal. *Int J Gynaecol Obstet* 2012; **119**(2): 185-8.
8. Couri BM, Lenis AT, Borazjani A, Paraiso MF, Damaser MS. Animal models of female pelvic organ prolapse: lessons learned. *Expert Rev Obstet Gynecol* 2012; **7**(3): 249-60.
9. Statistics CIACBo. The World Factbook. 2016. <https://www.cia.gov/library/publications/the-world-factbook/geos/np.html>.
10. Dietrich W, Elenskaia K, Obermayr E, et al. Relaxin and gonadal steroid receptors in uterosacral ligaments of women with and without pelvic organ prolapse. *Int Urogynecol J* 2012; **23**(4): 495-500.
11. Phillips CH, Anthony F, Benyon C, Monga AK. Collagen metabolism in the uterosacral ligaments and vaginal skin of women with uterine prolapse. *BJOG* 2006; **113**(1): 39-46.
12. Dragoo JL, Castillo TN, Braun HJ, Ridley BA, Kennedy AC, Golish SR. Prospective correlation between serum relaxin concentration and anterior cruciate ligament tears among elite collegiate female athletes. *Am J Sports Med* 2011; **39**(10): 2175-80.

13. Drews U, Renz M, Busch C, Reisenauer C. Ex vivo pharmacology of surgical samples of the uterosacral ligament. Part II: Effects of oxytocin and relaxin on arteries and vascular plexus. *Neurourol Urodyn* 2012; **31**(8): 1300-6.
14. Harvey MA, Johnston SL, Davies GA. Mid-trimester serum relaxin concentrations and post-partum pelvic floor dysfunction. *Acta Obstet Gynecol Scand* 2008; **87**(12): 1315-21.
15. Rizk DE, Fahim MA. Ageing of the female pelvic floor: towards treatment a la carte of the "geripause". *Int Urogynecol J Pelvic Floor Dysfunct* 2008; **19**(4): 455-8.
16. Haviland C. Nepal's 'confined women' want change. BBC News; 2009.
17. Gerten KA, Richter HE, Wheeler TL, 2nd, et al. Intraabdominal pressure changes associated with lifting: implications for postoperative activity restrictions. *Am J Obstet Gynecol* 2008; **198**(3): 306 e1-5.
18. Dietz HP, Eldridge A, Grace M, Clarke B. Pelvic organ descent in young nulligravid women. *Am J Obstet Gynecol* 2004; **191**(1): 95-9.
19. Ashton-Miller JA, DeLancey JO. Functional anatomy of the female pelvic floor. *Ann N Y Acad Sci* 2007; **1101**: 266-96.
20. Asavasopon S, Rana M, Kirages DJ, et al. Cortical activation associated with muscle synergies of the human male pelvic floor. *J Neurosci* 2014; **34**(41): 13811-8.
21. Stafford RE, Ashton-Miller JA, Constantinou CE, Hodges PW. Novel insight into the dynamics of male pelvic floor contractions through transperineal ultrasound imaging. *J Urol* 2012; **188**(4): 1224-30.
22. Frawley HC, Galea MP, Phillips BA, Sherburn M, Bo K. Effect of test position on pelvic floor muscle assessment. *Int Urogynecol J Pelvic Floor Dysfunct* 2006; **17**(4): 365-71.
23. UK PP. Trekking Guidelines 2016 2016. <http://www.portersprogressuk.org/advice-for-trekkers/trekking-guidelines/> (accessed 11/20/2016 2016).
24. Stricker R, Eberhart R, Chevailler MC, Quinn FA, Bischof P, Stricker R. Establishment of detailed reference values for luteinizing hormone, follicle stimulating hormone, estradiol, and progesterone during different phases of the menstrual cycle on the Abbott ARCHITECT analyzer. *Clin Chem Lab Med* 2006; **44**(7): 883-7.

25. Park SK, Stefanyshyn DJ, Loitz-Ramage B, Hart DA, Ronsky JL. Changing hormone levels during the menstrual cycle affect knee laxity and stiffness in healthy female subjects. *Am J Sports Med* 2009; **37**(3): 588-98.
26. Bell DR, Blackburn JT, Norcorss MF, et al. Estrogen and muscle stiffness have a negative relationship in females. *Knee Surg Sports Traumatol Arthrosc* 2012; **20**(2): 361-7.
27. Lee H, Petrofsky JS, Daher N, Berk L, Laymon M. Differences in anterior cruciate ligament elasticity and force for knee flexion in women: oral contraceptive users versus non-oral contraceptive users. *Eur J Appl Physiol* 2014; **114**(2): 285-94.
28. Eiling E, Bryant AL, Petersen W, Murphy A, Hohmann E. Effects of menstrual-cycle hormone fluctuations on musculotendinous stiffness and knee joint laxity. *Knee Surg Sports Traumatol Arthrosc* 2007; **15**(2): 126-32.
29. Dietz HP. Prolapse worsens with age, doesn't it? *Aust N Z J Obstet Gynaecol* 2008; **48**(6): 587-91.
30. Eichner SF, Timpe EM. Urinary-based ovulation and pregnancy: point-of-care testing. *Ann Pharmacother* 2004; **38**(2): 325-31.
31. Petrofsky JS, Laymon M, Lee H. Effect of heat and cold on tendon flexibility and force to flex the human knee. *Med Sci Monit* 2013; **19**: 661-7.
32. Petrofsky J, Al Maly A, Suh HJ. Isometric endurance, body and skin temperature and limb and skin blood flow during the menstrual cycle. *Med Sci Monit* 2007; **13**(3): CR111-7.
33. Petrofsky JS, Laymon M. Heat transfer to deep tissue: the effect of body fat and heating modality. *J Med Eng Technol* 2009; **33**(5): 337-48.
34. Baker FC, Waner JI, Vieira EF, Taylor SR, Driver HS, Mitchell D. Sleep and 24 hour body temperatures: a comparison in young men, naturally cycling women and women taking hormonal contraceptives. *J Physiol* 2001; **530**(Pt 3): 565-74.
35. Lee H, Petrofsky JS, Daher N, Berk L, Laymon M, Khowailed IA. Anterior cruciate ligament elasticity and force for flexion during the menstrual cycle. *Med Sci Monit* 2013; **19**: 1080-8.
36. Bertone-Johnson ER, Ronnenberg AG, Houghton SC, et al. Association of inflammation markers with menstrual symptom severity and premenstrual syndrome in young women. *Hum Reprod* 2014; **29**(9): 1987-94.
37. Chegini N, Ma C, Roberts M, Williams RS, Ripps BA. Differential expression of interleukins (IL) IL-13 and IL-15 throughout the menstrual cycle in endometrium

- of normal fertile women and women with recurrent spontaneous abortion. *J Reprod Immunol* 2002; **56**(1-2): 93-110.
38. Whitcomb BW, Mumford SL, Perkins NJ, et al. Urinary cytokine and chemokine profiles across the menstrual cycle in healthy reproductive-aged women. *Fertil Steril* 2014; **101**(5): 1383-91.
 39. Dietz HP. Pelvic organ prolapse - a review. *Aust Fam Physician* 2015; **44**(7): 446-52.
 40. Ferreira PH, Ferreira ML, Nascimento DP, Pinto RZ, Franco MR, Hodges PW. Discriminative and reliability analyses of ultrasound measurement of abdominal muscles recruitment. *Man Ther* 2011; **16**(5): 463-9.
 41. Junginger B, Baessler K, Sapsford R, Hodges PW. Effect of abdominal and pelvic floor tasks on muscle activity, abdominal pressure and bladder neck. *Int Urogynecol J* 2010; **21**(1): 69-77.
 42. Lone FW, Thakar R, Sultan AH, Stankiewicz A. Accuracy of assessing Pelvic Organ Prolapse Quantification points using dynamic 2D transperineal ultrasound in women with pelvic organ prolapse. *Int Urogynecol J* 2012; **23**(11): 1555-60.
 43. Stafford RE, Coughlin G, Lutton NJ, Hodges PW. Validity of Estimation of Pelvic Floor Muscle Activity from Transperineal Ultrasound Imaging in Men. *PLoS One* 2015; **10**(12): e0144342.
 44. Whittaker JL, Thompson JA, Teyhen DS, Hodges P. Rehabilitative ultrasound imaging of pelvic floor muscle function. *J Orthop Sports Phys Ther* 2007; **37**(8): 487-98.
 45. Hodges PW. Ultrasound imaging in rehabilitation: just a fad? *J Orthop Sports Phys Ther* 2005; **35**(6): 333-7.
 46. Dietz HP. Why pelvic floor surgeons should utilize ultrasound imaging. *Ultrasound Obstet Gynecol* 2006; **28**(5): 629-34.
 47. Iqbal A, Haider M, Stadlhuber RJ, Karu A, Corkill S, Filipi CJ. A study of intragastric and intravesicular pressure changes during rest, coughing, weight lifting, retching, and vomiting. *Surg Endosc* 2008; **22**(12): 2571-5.
 48. Coleman TJ, Thomsen JC, Maass SD, Hsu Y, Nygaard IE, Hitchcock RW. Development of a wireless intra-vaginal transducer for monitoring intra-abdominal pressure in women. *Biomed Microdevices* 2012; **14**(2): 347-55.
 49. Hsu Y, Coleman TJ, Hitchcock RW, Heintz K, Shaw JM, Nygaard IE. Clinical evaluation of a wireless intra-vaginal pressure transducer. *Int Urogynecol J* 2012; **23**(12): 1741-7.

50. Coleman TJ, Nygaard IE, Holder DN, Egger MJ, Hitchcock R. Intra-abdominal pressure during Pilates: unlikely to cause pelvic floor harm. *Int Urogynecol J* 2015; **26**(8): 1123-30.
51. Coleman TJ, Hamad NM, Shaw JM, et al. Effects of walking speeds and carrying techniques on intra-abdominal pressure in women. *Int Urogynecol J* 2015; **26**(7): 967-74.
52. Hendrix SL, Clark A, Nygaard I, Aragaki A, Barnabei V, McTiernan A. Pelvic organ prolapse in the Women's Health Initiative: gravity and gravidity. *Am J Obstet Gynecol* 2002; **186**(6): 1160-6.

CHAPTER 2
EFFECT OF HEAVY LIFTING WITH A HEAD STRAP ON THE PELVIC
FLOOR ACROSS THE MENSTRUAL CYCLE

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Abstract

Background

Pelvic floor trauma with vaginal delivery and heavy lifting, are thought to be risk factors for symptomatic pelvic organ prolapse (SPOP) in young Nepali women.¹ The 2011 Nepal Demographic and Health Survey found 6% of nulliparous women report SPOP, compared to 7% in the general population of Nepali women ages 15 – 49.^{2,3} The average age of SPOP onset in Nepal is 27.³ In western countries SPOP is usually reported between the 4th and 6th decade of life.^{4,5}

This study investigated the effect of increased intra-abdominal pressure (IAP) on pelvic organ descent during simulated lifting tasks in Nepali women across the menstrual cycle. The aims were to (i) calculate the descent of the pelvic floor organs during a simulated lifting task in a population of Nepali women, (ii) compare the descent between three stages of the menstrual cycle, and (iii) investigate the capacity of the pelvic floor muscles to resist pelvic organ descent by voluntarily contracting prior to performing the lifting task. We hypothesized that there was a relationship between heavy lifting during menstruation that could account for the unexpectedly high rates of young and nulliparous women with SPOP in Nepal possibly linked to their unique custom of Chhaupadi (ritual impurity during menstruation).⁶

Methods

22 asymptomatic Nepali women aged 18-30 years who regularly lift heavy loads were included in the study. Intra-abdominal pressure was measured intra-vaginally during both typical lifting tasks and simulated lifting tasks. Simulated tasks included: ballistic lifting, ramped lifting, ballistic lift with pre-contraction of the pelvic floor muscles,

cough, Valsalva, and pelvic floor contraction. Transperineal ultrasound (US) recorded displacement (mm) of the bladder base with simulated tasks during: menstruation, ovulation, and mid-luteal phase.

Findings

More pelvic floor displacement was found during menstruation than ovulation with simulated ballistic lifting (6.0 ± 1.6 vs 5.1 ± 1.5 , $p = .03$). However, there was no significant difference in pelvic floor displacement with lifting when the pelvic muscles were pre-contracted.

Interpretation

The pelvic floor supportive tissues may be at increased risk for stretching and injury when lifting a heavy load during menstruation versus ovulation. Pre-contracting the pelvic muscles when lifting may demonstrate a protective effect.

Key Words: prolapse, nulliparous, pelvic floor, lifting, menstrual cycle, laxity, compliance, elasticity, stiffness, chhaupadi.

Introduction:

Background and Objectives

Pelvic organ prolapse (POP) typically occurs when the passive and active pelvic support structures (e.g. connective tissue, ligaments and muscles) become weakened, stretched, or ruptured. Without support, the pelvic organs can descend under pressure into the vaginal canal and in advanced cases, protrude completely outside the introits.⁷ Symptomatic pelvic organ prolapse (SPOP) occurs when pelvic organs become so displaced that pelvic function is affected.⁸ Women report a feeling of something coming out of their vagina, or uncomfortable pressure that can be very painful and even make sitting and other daily tasks difficult.

Many women in Nepal who experience the devastating condition of SPOP do not seek help due to embarrassment, inability to pay for treatment, or lack of information regarding treatment options.⁹ Amnesty International deems SPOP a human rights issue in Nepal due to the serious impact SPOP has on the quality of life for these women.^{1, 10, 11} The 2011 Nepal Demographic and Health Survey reported that in the general population, 10% of Nepali women have POP. For women in their reproductive years, ages 15-49, 7% had POP, notably, 6% of nulliparous women in the same age category reported SPOP.² Furthermore, 14% of the women who developed SPOP did so in their teenage years. The mean age of onset is reported to be 27 years according to a study by the Institute of Medicine at Tribhuvan University Kathmandu.³ This is a sharp contrast to western women who typically develop SPOP after menopause.^{4, 12} Currently, the treatment options for SPOP in Nepal are vaginal hysterectomy, not an ideal outcome for young women of reproductive age, and pessary, which is less drastic but has poor patient compliance.¹³

Risk factors for SPOP include vaginal deliveries,¹⁴ poor pre- and post-natal care,¹⁰ position at delivery¹⁰ and menopause,¹⁰ genetics and aberrant connective tissue.^{4, 15} However, this does not account for the nearly identical rates of SPOP among nulliparous women of the same age. Previous studies have demonstrated a relationship between SPOP and weakness of supportive connective tissue and damaged pelvic floor muscles.¹⁶⁻¹⁸ The influence of estradiol concentration on tissue laxity has been explored on the ACL in the knee and the plantar fascia of the foot across the menstrual cycle (MC)¹⁹⁻²¹ However, there is little known about the effect of hormone concentrations on elasticity/compliance of the pelvic support mechanisms throughout the MC, and how it may influence the capacity of the pelvic floor to resist descent during demanding tasks which cause large increases in IAP.

Research in Context

Evidence before this study

We searched PubMed database with the terms ([pelvic organ prolapse], [Estradiol], [Menstrual Cycle], [intra-abdominal pressure] AND [pelvic floor dysfunction], and [Nepal]) with no date or language restrictions up to November 30, 2015 and searched the Nepal Health Ministry online reports and studies cited by them. No relevant studies making the connection between the menstrual cycle, increased intra abdominal pressure and pelvic floor dysfunction or prolapse were identified.

Added value of this study

To our knowledge this is the only study to address the issues of pelvic organ prolapse prospectively looking at the mechanical effects of the unique method of heavy lifting with a head strap and “doko” and its effect on the pelvic floor across the menstrual cycle.

Implications of all the available evidence

Results from this, and other studies looking at prevention of pelvic organ prolapse suggest that pre-contraction of the pelvic floor is an important technique when lifting heavy loads especially when menstruating. Globally 10% or more of woman will develop POP in their lifetime, and because Nepali women often develop symptoms early in their reproductive years prevention strategies are key to eliminating morbidity and the need for prohibitive surgical interventions.

Hormonal Effects of the Menstrual Cycle (MC)

Some support structures of the pelvic organs have receptors for estradiol (and other gonadal hormones), and therefore may be affected by the cyclic changes in their concentration.^{16, 22} Decreased estradiol concentration has been shown to increase musculotendinous stiffness²³ and decrease elasticity²⁰ during menstruation.²⁴ This has been extensively studied in the peripheral joints such as the knee and the ACL.²⁰ The pelvic floor may also have cyclic changes in the tissue properties due to fluctuations in the estradiol concentrations. At early follicular phases, estradiol ranges from <20-145 pg/mL and during ovulation it peaks at between 112-443 pg/mL.²⁵

Temperature Effects of the MC

Tissue temperature has been shown to affect the mechanical properties of the ligaments.²⁶ Basal body temperature changes across the MC; it is one half to one degree lower during the early follicular phase compared to the period after ovulation and throughout the luteal phase.²⁷ Temperature increases have been shown to create laxity in other ligaments in the body when tested across the MC.²⁰

During menstruation, when estradiol and temperature are at the lowest points, the net effect is decreased elasticity and temperature, with increased stiffness, in connective tissue and musculetendinous tissues compared to ovulation (when estradiol and temperature are at their peak).²⁰

Cultural Effects on the MC

The physiologic changes that occur throughout the MC may be particularly pertinent in Nepal. A typical work day for a woman living in rural Nepal would include many hours of preparing food, caring for children and livestock, as well as performing daily religious rituals. Her work load is considered to be 12-22% greater than that of the men.¹¹ Menstruation is associated with ritual impurity. For this reason, women are not allowed to cook or perform religious tasks while menstruating, or touch a man, the practice is called “Chhaupadi”. It has been illegal in Nepal since 2005 but it is still widely adhered to throughout the country.⁶ Due to these restrictions women are limited to outdoor work, which often involves carrying heavy loads. This means they do a disproportionate amount of their heavier tasks during the time they are menstruating.

Loads are carried with a cone-shaped basket on their back called a “doko” together with a head strap called a “namlo” which is worn over the forehead to support

the load. This method allows these women to carry very heavy loads long distances through steep and challenging terrain. Women with body weights between 40-60 kg reported they carried loads that were typically between 20-80 kg.

The aims of this study were to (i) calculate the descent of the pelvic floor organs during a simulated lifting task in a population of Nepali women, (ii) compare the descent between three stages of the menstrual cycle, (iii) investigate the capacity of the pelvic floor muscles to resist pelvic organ descent by voluntarily contracting prior to performing the lifting task.

Methods

This was a prospective repeated measures study conducted using a convenience sample of 22 Nepali women. The study protocol was approved by the Institutional Review Board of Loma Linda University Health and by the Nepal Health Research Council. All participants were recruited using a local open advertisement. Prior to enrolment, prospective participants were screened by the researchers, a gynecologist and orthopedic surgeon to ensure they met the inclusion criteria. Participants were non-pregnant women aged 18 to 30 years with regular menstrual cycles, who were asymptomatic for POP and engaged in activities that required regular use of a namol and doko for carrying loads. Exclusion criteria included history of pregnancy within the last 2 years, pre menarche, peri- and post- menopausal, SPOP (Stage 2 or greater on Pelvic Organ Prolapse-Quantification System or POP-Q), irregular periods, use of an intra-uterine device (IUD), and any spinal or orthopedic condition that would affect performance of the lifting tasks. Due to the use of Cidex (ASP, Irvine, California) as a

disinfecting agent for the Intravaginal Transducer (IVT) sensors, those with a history of bladder cancer were also excluded.

The informed consent was read aloud in Nepali to the women because 40% of adult Nepali women have no education.² A female nurse then conducted a standard questionnaire with each prospective participant to ensure that the participant fully understood the study prior to signing the informed consent. The general characteristics of the participants are in *Table 2*.

Table 2. Characteristics of the participants (N=22)

<i>Characteristic</i>	<i>Mean (SD)</i>	<i>No.</i>	<i>(%)</i>	<i>Median</i>	<i>Range</i>
<i>Age (year)</i>	27.4 (3.6)				
<i>Body mass index (kg/m²)</i>	19.8 (3.2)				
<i>Weight (kg) lifted</i>	19.8 (3.2)				
<i>Number of pregnancies</i>	1.7(1.0)				
<i>Number of vaginal deliveries</i>				2	(0-4)
<i>Number of days since carrying</i>				2	(1-210)
<u><i>Ethnicity</i></u>					
<i>Newar</i>		5	22.7		
<i>Chhetri</i>		4	18.2		
<i>Tamang</i>		5	22.7		
<i>Brahman</i>		8	36.4		
<u><i>Religion</i></u>					
<i>Hindu</i>		16	72.7		
<i>Buddhist</i>		6	27.3		
<i>Rural</i>		22	100		
<i>Non-smokers</i>		22	100		
<i>No chronic pain</i>		22	100		
<i>No bladder cancer</i>		22	100		
<i>No ortho or neuro pathology</i>		22	100		
<i>No pain impairing function</i>		22	100		
<u><i>Constipation</i></u>					
<i>No</i>		21	95.5		
<i>Yes</i>		1	4.5		
<u><i>Menstrual pain</i></u>					
<i>No</i>		16	72.7		
<i>Yes</i>		6	27.3		
<u><i>Irregular Periods</i></u>					
<i>No</i>		16	72.7		
<i>Yes</i>		6	27.3		
<u><i>Pelvic organ prolapse</i></u>					
<i>Stage 0</i>	20	90.9			
<i>Stage 1</i>	2	9.1			

Each participant attended three separate sessions coinciding with the different phases of the menstrual cycle: within the first 4 days of the onset of menses (early follicular phase), within 24-48 hours of ovulation, and 6-10 days later at mid-luteal phase.

Each participant was provided with a string of Cyclebeads® to assist with tracking their cycle days (CycleBeads® and Standard Days Method® Georgetown University) in addition to instructions and condoms to prevent becoming pregnant during the study. Furthermore, participants were provided with and educated on the use of the ClearBlue Advanced Ovulation tests (SPD Swiss Precision Diagnostics GmbH, Petit Lancy, Switzerland) to identify the time of ovulation.

Procedures

Intra-abdominal pressure was recorded using a validated intra-vaginal pressure transducer (IVT) (Department of Bioengineering, University of Utah, Salt Lake City, Utah)²⁸ and body temperature was recorded by a fast-response sensor (TSD202A, BIOPAC Systems, Inc. Goleta, CA , USA). IAP and temperature data were recorded at 1000 Hz using an analogue to digital converter (BioPac MP100, Goleta California) with 24 bits of resolution. Data was stored digitally and analyzed later with Biopac Acknowledge 3·9·1 software. The temperature sensor was attached to the IVT with tape at the base of the IVT, and covered with a latex-free condom. Ultrasound data measuring pelvic floor displacement were collected using an ACUSON X300™ ultrasound system (Siemens Healthcare Global, Erlangen, Germany) and associated transducer (10027930 4C1) which was placed on the perineum in the mid-sagittal plane.²⁹ US data were recorded in video format (frame rate: 30 Hz) using the analogue to digital converter system described above. The ultrasound (US) recording was optimized to include the

urethral-vesical junction, the anorectal angle and the body of the pubic bone as a landmark.³⁰

Participants were instructed how to insert the IVT. The positioning was confirmed with US imaging. Following IVT insertion, resting IAP was recorded. The participant then performed three trial lifts of a doko basket loaded with a weight based on the participant's subjective tolerance to the load. Loads were approximately 40% or less of the participant's body weight. Weights never exceeded 30 kg, the recommended guideline for commercial porters in Nepal.³¹ The mean load lifted by the participants was 19.8 kg. The load was lifted off the ground to a full standing position using a head strap.

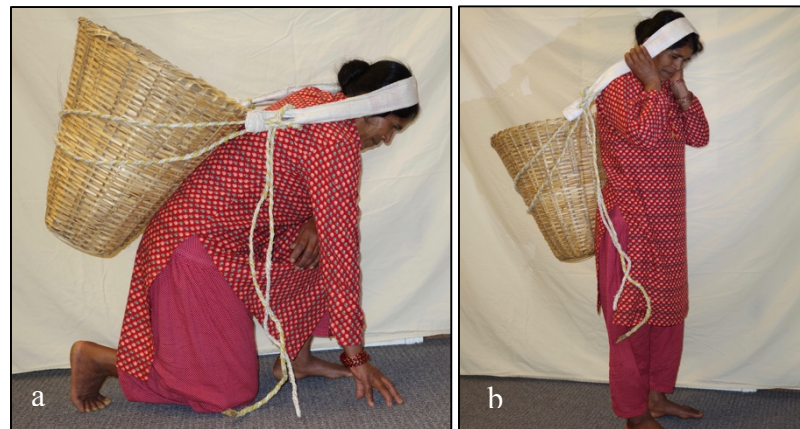


Figure 5. Starting (a) and ending (b) positions for the doko lift.

Peak IAP pressure was averaged over three doko lifts and used to calculate a target for the simulated lifting tasks. The standing lift test was conducted only at one data collection session for each participant, and is illustrated in. Isometric simulation of lifts with transperineal US was conducted with participants positioned on an exam table in supine, approximately 20 cm from a wall. This enabled placement of the dominant foot

on the wall with 90 degrees of knee flexion; the left leg rested over the end of the table, illustrated in figure 6.

Participants performed three repetitions of six different tasks in response to specific verbal instruction.³² Tasks included (i) a ballistic lift against a head strap, (ii) a slow ramped lift task performed over approximately 5-10 seconds toward the target IAP, (iii) an unprovoked cough, (iv) a Valsalva maneuver, (v) a Kegel or pelvic floor muscle contraction, and (vi) a ballistic head lift with Kegel pre- contraction.



Figure 6. Positioning of participants for ultrasound and pressure data collection for the six tasks.

Participants

Twenty-seven women completed the informed consent process and were enrolled into the study. However, only 22 were included in the final data analysis. Five were excluded for the following reasons: one had a death in the family and could not attend the data collection sessions; the second had a BMI over 30 and was chronically constipated, distorting her US images; the third started the study late and could only complete one session; the fourth had irregular cycles and did not ovulate or menstruate when expected;

the fifth was no longer living in a rural area and had been carrying water jars with her arms, not with a head strap.

Data Analysis

An experienced researcher measured the points on the US images at rest and at maximum displacement to determine the movement of the pelvic floor in millimeters. The reference points used were the ventral urethral vesicular junction³⁰, in each task as it moved in relation to the mid- point of the pubic symphysis for each trial. Matlab (MathWorks, Natick, Massachusetts, USA) was used to derive a vector for the displacement which occurred. The peak-to-peak IAP change in pressure was recorded for each trial using AcqKnowledge, (BIOPAC Systems, Inc. Goleta, CA, USA). To control for pressure differences due to variance in efforts, the trials with the most similar pressures in each phase were selected for analysis.

Data were analyzed using SPSS (IBM Corp. Released 2013. IBM SPSS Statistics for Windows, Version 22.0. Armonk, NY: IBM Corp). The general characteristics of the participants were summarized using means and standard deviations or median (min, max) for quantitative variables, and frequencies and relative frequencies for categorical variables. The normality of the variables was examined using the Kolmogorov-Smirnov and Shapiro-Wilk tests. A mixed 5 x 3 factorial analysis of variance (ANOVA) was used to assess changes in the displacement, temperature, and IAP of the various tasks (ballistic lift, ballistic lift with a pre contraction of the pelvic floor, unprovoked cough, Valsalva maneuver, and pelvic floor contraction) by menstrual phase (menstruation, ovulation and mid-luteal phase). Post hoc comparisons were conducted using a Bonferroni test. One-way repeated measures ANOVA was used to compare mean IAP using the doko lift with

the IAP of the various tasks across all phases. The changes in displacement and IAP between the early follicular and ovulation phases for the same tasks were further compared using a paired t-test. The level of significance was set at $p \leq 0.05$.

Results

The temperature for all tasks was lowest during menstruation and highest during ovulation and remained elevated through the luteal phase, but no significant difference was found among menstrual phases, mean temperatures are reported in **Table 3**.

Table 3. Mean (standard error) of temperature (°C) by menstrual cycle (N=22)

	<i>Menstruation</i>	<i>Ovulation</i>	<i>Luteal</i>	<i>P- value</i>
<i>Temperature</i>	36.8 (0.3)	37.3 (0.1)	37.2 (0.2)	0.16

When comparing the displacement, there was a trend toward greater differences between ovulation and menstruation as they represent the extremes in estradiol levels, but it did not reach statistical significance because the variance in the luteal phase was too similar to the other phases. Therefore, to highlight the effects of estradiol we have reported the results from paired t-testing comparing the ovulation and menstruation phases only.

Mean displacement of the pelvic floor varied from 3.4 mm (ballistic lift with pelvic floor pre-contraction) to 8.5 mm (Valsalva), and all means are reported in **Table 4**. Significantly less displacement was found during ovulation, except during Valsalva which was significantly more ($p = .005$). No significant difference was found between phases for the ballistic lift performed with pre-contraction (p value = 0.22). The PFM

demonstrated more displacement during menstruation than during ovulation ($p = .05$).

These measurements were within the normal range of pelvic floor mobility found in other studies using translabial ultrasound.³⁰

Table 4. Mean (SE) displacement (mm) for each of 5 tasks by Menstrual phase (N=22)

<i>Task</i>	<i>Ovulation</i>	<i>Menstruation</i>	<i>P values</i>
<i>Ballistic*</i>	5.1 (1.5)	6.0 (1.6)	.03
<i>Ballistic with PFM</i>	3.4 (1.5)	3.9 (2.0)	.22
<i>Cough*</i>	5.6 (1.5)	6.7 (2.3)	.02
<i>Valsalva*</i>	8.5 (3.2)	6.0 (2.5)	.005
<i>PFM*</i>	-3.6 (1.3)	-4.6 (1.6)	.05

*Abbreviations: SE, standard error; O, Ovulation; L, Luteal; M, Menstruation; BAL, Ballistic; BALPFM, Ballistic with pelvic floor contraction; PFM, Pelvic floor muscle contraction; a p values for the null hypothesis that there is no difference between the phases of the menstrual cycle. *significant change between ovulation and menstruation.*

Measurements of IAP changes are reported in **Table 5**. Mean IAP changes were not significantly different during ballistic lifts and ballistic lifts with PFM pre-contraction.

However, a significant difference was found for cough and Valsalva between menstruation and ovulation. For all other tasks IAP was significantly different across the phases even after selection of trials with the most similar IAP.

Table 5. Mean (SE) IAP (cm2H2O) for each of the 5 tasks in 2 different test phases during the menstrual cycle (N=22)

<i>Task</i>	<i>Ovulation</i>	<i>Menstruation</i>	<i>P values</i>
<i>Ballistic</i>	30.3 + 2.0	30.6 + 2.3	.86
<i>Ballistic with PFM</i>	29.9 + 3.3	33.6 + 4.3	.27
<i>Cough</i>	73.5 + 4.0	67.2 + 3.8	.02
<i>Valsalva*</i>	49.5 + 4.3	42.2 + 3.3	.02
<i>PFM*</i>	11.8 + 2.4	9.0 + 1.5	.047

*Abbreviations: SE, standard error; O, Ovulation; L, Luteal; M, Menstruation; BAL, Ballistic; BALPFM, Ballistic with pelvic floor contraction; PFM, Pelvic floor muscle contraction; a p values for the null hypothesis that there is no difference among the phases of the MC for each task. *significant change between ovulation and menstruation.*

Table 6. Mean IAP for Doko lift as compared to mean of other tasks (N= 16)

<i>Task</i>	<i>Mean (SE)</i>	<i>p –valuea</i>
<i>Bal</i>	31.6 (2.1)	1.00
<i>BalPFM</i>	33.3 (3.9)	1.00
<i>Cough</i>	77.6 (3.9)	<0.001
<i>Val</i>	47.3 (4.9)	1.00
<i>PFM</i>	9.0 (1.3)	0.001
<i>Doko lift</i>	37.1 (4.3)	

Abbreviation: IAP, intra abdominal Pressure; SE, Standard error; a p value from post hoc testing pairwise comparisons between doko lift and other tasks. BAL, Ballistic; BALPFM, Ballistic with pelvic floor contraction; PFM, Pelvic floor muscle contraction; a p values for the null hypothesis that there is no difference between the IAP change in a simulated task and the IAP change in an actual doko lift.

Table 6 shows the simulated lifting tasks mean changes in IAP as compared to an actual doko lifting task. The mean IAP changes seen during ballistic lifts, ballistic lift with a pre-contraction of the pelvic floor, and Valsava were not significantly different from IAP changes experienced during an actual doko lift ($p=1.0$). However, the mean IAP change during cough and PFM was significantly different from the mean IAP changes using the doko lift ($p < 0.001$ and $p = 0.001$, respectively, (see **Table 6**). These IAP levels were consistent with pressures found in women performing lifting tasks using IVT in other studies.^{33, 34}

Table 7. Pelvic Floor compliance mm/cmH₂O comparison for each task at ovulation and at menstruation.

<i>Task</i>	<i>Ovulation</i>	<i>Menstruation</i>
<i>Ballistic lift</i>	0.17	0.2*
<i>Lift with PFM</i>	0.11	0.12
<i>Cough</i>	0.08**	0.1
<i>Valsalva</i>	0.17	0.14
<i>PFM</i>	-0.3	-0.5

*Abbreviation: *Highest compliance, **lowest compliance in terms of downward displacement.*

Table 7 shows the complex interplay of tasks performed and tissue compliance in mm/cmH₂O (compliance = change in volume/change in pressure). The pelvic floor tissues displayed the highest compliance with ballistic lifting during menstruation 0.2 mm/cmH₂O and the least compliance with cough during ovulation 0.08 mm/cmH₂O.

These compliance levels were similar to those reported in studies looking at pelvic floor

displacement in cough and valsalva in healthy nulliparous and primiparous woman.^{35,36} Of interest is that the compliance varies with task and menstrual cycle phase, with the highest compliance or least stiffness occurs with ballistic lifting during menstruation 0.2mm/ cmH₂O.

Discussion

Our use of the IVT with transperineal ultrasound capturing simultaneous IAP and pelvic floor displacement with simulated functional tasks was a novel approach to measuring changes in the biomechanics of the pelvic floor across the menstrual cycle. This instrumentation was valid and effective in the measurement of the variables. The data we collected was within the expected values for lifting activities.³³ Other studies have not compared the dynamic reactions of the pelvic floor during functional lifting tasks across the menstrual phases. However, our study supports the hypothesis that there are significant changes in the mechanical properties of the musculotendinous tissues due to fluctuating estradiol. These findings were similar to studies of the Anterior Cruciate Ligament and plantar fascia where there was found to be an increased elasticity in ovulation as opposed to menstruation.^{20,21}

There is limited consensus on the role of decreased estradiol as a risk factor for POP. Dietz argues that increased stiffness of the tissues with post-menopausal decreases in estradiol might even be protective against injury from stretch.^{4,12} We found the opposite to be true. The pelvic floor moved consistently further in menstruation with lower pressures for ballistic activities than during ovulation. Thus, the pelvic floor displayed higher compliance during menstruation than during ovulation as is reported in *Table 7*. However, for the valsalva maneuver where the pressure changes were more

controlled and sustained (not ballistic) but IAP increases were higher the displacement was greater during ovulation than during menstruation. See **Figure 7** for illustrations of the IAP graphs for each activity showing more abrupt IAP changes in coughing and ballistic activities as compared to valsalva.

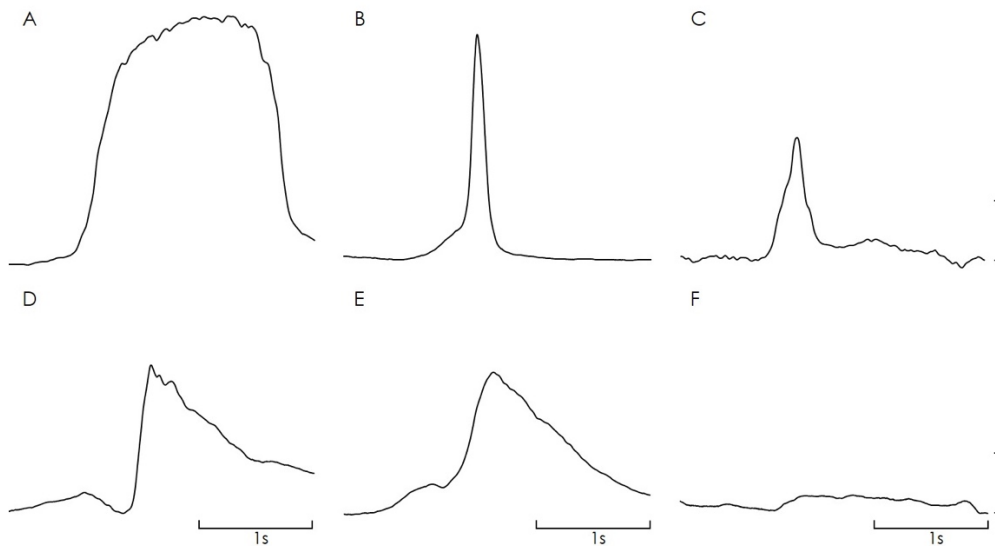


Figure 7. IAP Graphs for Each Activity.

Key: A valsalva, B cough, C doko lift, D ballistic simulation, E ballistic simulation with pelvic floor precontraction, F pelvic floor contraction. Scale equals 20cmH₂O.

Ballistic lifting during menstruation may cause an increased potential for the development of POP. Because, there is greater tissue compliance in menstruation. Repetitive stretching of passive support tissues could logically lead to POP³⁶.

Pre-contracting the pelvic floor before ballistic activities such as lifting may compensate for the ballistic stretch and displacement that occurs with increased intra-abdominal pressure.³⁷ In our study pre-contraction of the pelvic floor muscles decreased

displacement by approximately 30% across all MC phases. Therefore exerting a protective effect even during menstruation that made the displacement variance across phases non-significant.

Limitations

Positioning for the trans-perineal ultrasound imaging is difficult during transitional movement. However, displacements of the pelvic floor have been noted to be significantly different in supine versus upright positions.³⁸ This study attempted to match the mean peak IAP reached in an upright lift while the participant is lying in a modified hook position for the trans-perineal ultrasound imaging, with the lower extremities supported against a wall in a position similar to the squat used while lifting (modified hook/crook lying).

The IVT created some shadowing in the US images but typically did not obscure the landmarks being measured. While the IVT may have affected the natural movement of the pelvic tissues, the effect would have been the same across all testing situations.

Conclusion

Epidemiological studies have been done to assess the risk factors for POP in the at risk native population of rural Nepali women who regularly perform tasks carrying a heavy doko. Although these studies identify heavy lifting as a risk factor, none of them assessed the mechanical effects of the doko lifting on the pelvic floor. Also no studies examined the impact of the MC as a common risk factor to parous and nulliparous women. Vaginal deliveries are assumed to be traumatic to the pelvic floor structures and the main risk factor in POP development, however, there is some evidence that rates of

POP are actually similar in nulliparous woman in Nepal. Because Chhaupadi is practiced by all woman from the time of menarche it may to an additional risk factor for POP that has not been directly considered in the literature.

Musculotendinous structures are known to be affected by the cyclic changes in estradiol. Although this relationship is complex and not fully understood, the mechanical effects on the pelvic floor can be predicted. This study shows that when estradiol is low the pelvic floor is more compliant (menstruation) and more elastic when estradiol peaks (ovulation). Further research is needed to confirm increased pelvic floor compliance during menstruation.

Given the implications for the quality of life for millions of women in Nepal, development of a culturally sensitive, comprehensive prevention strategy for dealing with the issue of POP is imperative. Pelvic floor pre-contraction when lifting and avoiding heavy work during menstruation are promising preventative measures. Since both POP and surgical intervention have a major impact on cultural and socioeconomic factors, simple preventative measures maybe the key to a solution. Further studies are needed to confirm that education and preventive knowledge can in a practical way reduce the incidence of pelvic organ prolapse in rural Nepal.

Recommendations should include; i) training in pre-contraction of the pelvic floor muscles when lifting, and other ballistic activities throughout MC and ii) avoidance of heavy ballistic lifting during menstruation. These could be key in prevention of early POP pathology and symptomatology.

Contributors

YB did the literature review. PH, KB, RS, EL and YB designed the study. PH, RS, JP, with input from KB, EL and LB set up the methods and procedures. YB and UT did the data collection with guidance from RS, PH and JP. RS did the data reduction and preliminary analysis, YB assisted with data reduction. ND did the analysis and writing of the analysis section. All authors contributed to the data interpretation. YB wrote the first draft of the paper. All authors reviewed and provided input into the final version of the report and gave their approval for publication. Non-author contributors include Molly Dougherty, Ethan Allen and Evelyn Allen as technical editors and Sangram Biswokarma translated study materials into Nepali and assisted with data entry.

Declaration of Interests

We declare no completing interests.

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References

1. International A. Unnecessary Burden Gender Discrimination and Uterine Prolapse in Nepal. Amnesty International February 2014. 2014;Index:ASA31/001/2014.
2. Population Division Ministry of Health and Population NE, ICF International. Nepal Demographic and Health Survey 2011. Population Division Ministry of Health and Population Government of Nepal, Population; 2012.
3. Institute of Medicine Tribhvan University Kathmandu N. A reproductive morbidity report on clinic based survey 2006; Status of Reproductive Morbidities in Nepal. report Submitted to United Nations Population Fund (UNFPA) Pulchowk, Lalitpur, Nepal. 2006 2006.
4. Dietz HP. The aetiology of prolapse. *Int Urogynecol J Pelvic Floor Dysfunct.* 2008;19(10):1323-9.
5. Lowenstein E, Ottesen B, Gimbel H. Incidence and lifetime risk of pelvic organ prolapse surgery in Denmark from 1977 to 2009. *Int Urogynecol J.* 2015;26(1):49-55.
6. Haviland C. Nepal's 'confined women' want change. *BBC News*; 2009.
7. Dietz HP, Hyland G, Hay-Smith J. The assessment of levator trauma: a comparison between palpation and 4D pelvic floor ultrasound. *Neurourol Urodyn.* 2006;25(5):424-7.
8. Blain G, Dietz HP. Symptoms of female pelvic organ prolapse: correlation with organ descent in women with single compartment prolapse. *Aust N Z J Obstet Gynaecol.* 2008;48(3):317-21.
9. Shrestha B, Onta S, Choulagai B, Poudyal A, Pahari DP, Uprety A, et al. Women's experiences and health care-seeking practices in relation to uterine prolapse in a hill district of Nepal. *BMC Womens Health.* 2014;14:20.
10. Lien YS, Chen GD, Ng SC. Prevalence of and risk factors for pelvic organ prolapse and lower urinary tract symptoms among women in rural Nepal. *Int J Gynaecol Obstet.* 2012;119(2):185-8.
11. Radl CM, Rajwar R, Aro AR. Uterine prolapse prevention in Eastern Nepal: the perspectives of women and health care professionals. *Int J Womens Health.* 2012;4:373-82.
12. Dietz HP. Prolapse worsens with age, doesn't it? *Aust N Z J Obstet Gynaecol.* 2008;48(6):587-91.

13. Fitchett JR, Bhatta S, Sherpa TY, Malla BS, EJ AF, Samen A, et al. Non-surgical interventions for pelvic organ prolapse in rural Nepal: a prospective monitoring and evaluation study. *JRSM Open*. 2015;6(12):2054270415608117.
14. Elenskaia K, Thakar R, Sultan AH, Scheer I, Onwude J. Effect of childbirth on pelvic organ support and quality of life: a longitudinal cohort study. *Int Urogynecol J*. 2013;24(6):927-37.
15. Couri BM, Lenis AT, Borazjani A, Paraiso MF, Damaser MS. Animal models of female pelvic organ prolapse: lessons learned. *Expert Rev Obstet Gynecol*. 2012;7(3):249-60.
16. Dietrich W, Elenskaia K, Obermayr E, Horvat R, Mayerhofer K, Umek W, et al. Relaxin and gonadal steroid receptors in uterosacral ligaments of women with and without pelvic organ prolapse. *Int Urogynecol J*. 2012;23(4):495-500.
17. Dietz HP, Simpson JM. Levator trauma is associated with pelvic organ prolapse. *BJOG*. 2008;115(8):979-84.
18. Hansell NK, Dietz HP, Treloar SA, Clarke B, Martin NG. Genetic covariation of pelvic organ and elbow mobility in twins and their sisters. *Twin Res*. 2004;7(3):254-60.
19. Khowailed IA, Petrofsky J, Lohman E, Daher N, Mohamed O. 17beta-Estradiol Induced Effects on Anterior Cruciate Ligament Laxness and Neuromuscular Activation Patterns in Female Runners. *J Womens Health (Larchmt)*. 2015;24(8):670-80.
20. Lee H, Petrofsky JS, Daher N, Berk L, Laymon M, Khowailed IA. Anterior cruciate ligament elasticity and force for flexion during the menstrual cycle. *Med Sci Monit*. 2013;19:1080-8.
21. Petrofsky J, Lee H. Greater Reduction of Balance as a Result of Increased Plantar Fascia Elasticity at Ovulation during the Menstrual Cycle. *Tohoku J Exp Med*. 2015;237(3):219-26.
22. Hansen M, Kongsgaard M, Holm L, Skovgaard D, Magnusson SP, Qvortrup K, et al. Effect of estrogen on tendon collagen synthesis, tendon structural characteristics, and biomechanical properties in postmenopausal women. *J Appl Physiol (1985)*. 2009;106(4):1385-93.
23. Bell DR, Blackburn JT, Norcorss MF, Ondrak KS, Hudson JD, Hackney AC, et al. Estrogen and muscle stiffness have a negative relationship in females. *Knee Surg Sports Traumatol Arthrosc*. 2012;20(2):361-7.

24. Eiling E, Bryant AL, Petersen W, Murphy A, Hohmann E. Effects of menstrual-cycle hormone fluctuations on musculotendinous stiffness and knee joint laxity. *Knee Surg Sports Traumatol Arthrosc.* 2007;15(2):126-32.
25. Stricker R, Eberhart R, Chevailler MC, Quinn FA, Bischof P, Stricker R. Establishment of detailed reference values for luteinizing hormone, follicle stimulating hormone, estradiol, and progesterone during different phases of the menstrual cycle on the Abbott ARCHITECT analyzer. *Clin Chem Lab Med.* 2006;44(7):883-7.
26. Petrofsky JS, Laymon M, Lee H. Effect of heat and cold on tendon flexibility and force to flex the human knee. *Med Sci Monit.* 2013;19:661-7.
27. Devi SP, Reddy DV. Basal body temperature during the menstrual cycle in young women. *J Indian Med Assoc.* 1956;27(9):313-6.
28. Coleman TJ, Thomsen JC, Maass SD, Hsu Y, Nygaard IE, Hitchcock RW. Development of a wireless intra-vaginal transducer for monitoring intra-abdominal pressure in women. *Biomed Microdevices.* 2012;14(2):347-55.
29. Hodges PW. Ultrasound imaging in rehabilitation: just a fad? *J Orthop Sports Phys Ther.* 2005;35(6):333-7.
30. Dietz HP, Eldridge A, Grace M, Clarke B. Pelvic organ descent in young nulligravid women. *Am J Obstet Gynecol.* 2004;191(1):95-9.
31. UK PP. Trekking Guidelines UK Registered Charity No. 1112943; 2016 [updated 2016. Available from: <http://www.portersprogressuk.org/advice-for-trekkers/trekking-guidelines/>.
32. Stafford RE, Ashton-Miller JA, Constantinou C, Coughlin G, Lutton NJ, Hodges PW. Pattern of activation of pelvic floor muscles in men differs with verbal instructions. *Neurourol Urodyn.* 2015.
33. Coleman TJ, Hamad NM, Shaw JM, Egger MJ, Hsu Y, Hitchcock R, et al. Effects of walking speeds and carrying techniques on intra-abdominal pressure in women. *Int Urogynecol J.* 2015;26(7):967-74.
34. Coleman TJ, Nygaard IE, Holder DN, Egger MJ, Hitchcock R. Intra-abdominal pressure during Pilates: unlikely to cause pelvic floor harm. *Int Urogynecol J.* 2015;26(8):1123-30.
35. Howard D, Miller JM, Delancey JO, Ashton-Miller JA. Differential effects of cough, valsalva, and continence status on vesical neck movement. *Obstet Gynecol.* 2000;95(4):535-40.

36. Ashton-Miller JA, DeLancey JO. Functional anatomy of the female pelvic floor. *Ann N Y Acad Sci.* 2007;1101:266-96.
37. Bo K. Can pelvic floor muscle training prevent and treat pelvic organ prolapse? *Acta Obstet Gynecol Scand.* 2006;85(3):263-8.
38. Frawley HC, Galea MP, Phillips BA, Sherburn M, Bo K. Reliability of pelvic floor muscle strength assessment using different test positions and tools. *Neurourol Urodyn.* 2006;25(3):236-42.

CHAPTER 3

BACKGROUND AND INSTRUMENTATION DETAILS

Background on Nepal

Nepal, an enchanting country nestled between China and India in South Asia, straddling the Himalayas. Home to approximately 30 million people, it is culturally and geographically diverse, with 125 registered population groups, who speak about 123 different languages and dialects.¹ Nepal's adult literacy rate 53% and life expectancy was 67 years.¹ The 2006 Status of Reproductive Health by the Institute of Medicine, Tribhuvan University, Kathmandu, Nepal found that 57% of Nepali women were employed in subsistence farming, selling what they can from their farm produce. The majority (over 70%) of women had delivered their first baby as teenagers. Ninety-one percent of births took place at home, either with traditional birth assistants or no assistance at all.² The population of interest in this study is women of reproductive age living in Nepal.

Pelvic organ prolapse (POP) is known to be a significant health problem in Nepal, with anywhere from 10 -25% of Nepali women affected.³ The Nepal Health Demographic Reports (2011) found that 10% of women have POP, 7% of women ages 15-49 had POP, and 6% of even nulliparous women had symptomatic POP.⁴ Many social and economic factors are cited as being related to POP, such as early marriage, gender discrimination, and heavy lifting during pregnancy and after delivery.⁵

POP can be debilitating for any woman, but perhaps even more so for women living in a developing country such as Nepal. This condition may lead to social rejection, and make her work activities difficult and painful. Some studies assert that women are

aware of risks, such as working too soon after giving birth, but feel that they are not empowered to change their circumstances to reduce their risk.³ Many women in Nepal who experience POP do not seek help because they are embarrassed, poor, and do not know that POP is treatable.⁶ POP has a major impact on the quality of life for these women.⁷

The issues of pelvic organ prolapse in Nepal have garnered international attention. Many NGOs as well as governmental organizations have been working to provide more accessible care and medical and surgical treatments to these women.⁸ Non-surgical options including pelvic muscle training and pessary fittings have also been studied.⁸ There are no long term studies showing conservative measures to be effective in reducing cases of POP.

Heavy lifting has been suspected as a risk factor for prolapse, though there is little known about the impact of functional lifting tasks on pelvic organ descent in women, some studies have measured increased IAP with lifting tasks.⁹ In Nepal, a unique method of lifting has long been used: a head strap known as a “namlo” is worn over the forehead extending back to the load, which is often carried in a cone shaped basket known as a “doko.” This method centers the load over the person’s center of gravity and allows very heavy loads to be carried long distances through topographically steep and challenging terrain. The women interviewed for this study reported carrying 20-80kg in their dokos, many of them on a daily basis. There is limited information on safe lifting loads when carrying a doko. A 30kg limit was established for commercial porters in accordance with Nepali governmental guidelines and Porter Progress recommendations for porters using these lifting techniques.¹⁰

When lifting very heavy loads, Nepali women are observed to squat down, balance the doko against their backs with the head strap around their foreheads and encircle the load (basket) behind them; then with a quick ballistic forward movement of their torso, the woman will pull the doko off the ground, shift the weight over their center of gravity (lower lumbar spine) and stand up. In preliminary investigation, peak muscle activation with EMG of abdominal muscles was observed at the moment of load acceptance and then decreased to nearly baseline once the load was in place and the woman was standing or walking. Intra-abdominal pressure, though measured separately, followed the same pattern. The ballistic force needed to shift the load into position was targeted as the point at which to measure pelvic floor displacement. There are no studies showing the normal IAP changes when a woman is lifting with a doko, and how this might affect her pelvic floor mobility.

Another factor that has not been addressed or investigated is the effect of the menstrual cycle on pelvic floor mobility. Due to cultural traditions regarding menstruation, Nepali women are not allowed to participate in religious rites or prepare food while menstruating.¹¹ Since both these activities take up a significant amount of a woman's time in rural Nepal, it is thought that during her menstruation a woman should spend more time performing manual outdoor tasks. This uneven distribution of heavy work across the menstrual cycle was verbally confirmed by women who attended the recruitment meetings for the study. Therefore, in this study we sought to determine if heavy lifting, during menstruation was causing increased mobility in the pelvic floor. If increased pelvic floor displacement was found to occur during menstruation, it might a factor in the higher-than-expected rates of POP seen among nulliparous women in Nepal.

Our study attempted to address these issues by measuring the increase in IAP with a typical doko lift, with a load determination algorithm starting with 40% or less of the body weight of the participant, loads were never to exceed 30kg and had to be easily tolerated by the participant.

Research Venue

The study venue was Scheer Memorial Hospital, in Banepa, Nepal. This is an Adventist mission hospital that has been in operation for over 50 years under the sanction of the former kings of Nepal. One of the oldest and most respected hospitals in eastern Nepal, it is located about 12 miles southeast of Kathmandu, the capital city. Scheer has 150 beds, offers 24 hour emergency care, as well as surgical, pediatric, internal medicine, orthopedic, and OB/GYN specialties. Diagnostic imaging, laboratory and pharmacy services are also available. There is a nursing school on campus that graduates 20 bachelor-level nurses each year.

The majority of the patients and staff live in small villages surrounding the hospital. Many of the villagers live a mostly subsistence farming lifestyle, which requires that every family member be involved, often in heavy manual labor. Women carry much of the load, usually caring for the garden and livestock. All these factors made Scheer Memorial Hospital an ideal location for recruiting participants and performing data collection.

Scheer Memorial Hospital has long been instrumental in community health education. This tradition is continued with regular community educational events produced by the School of Nursing, international teams of medical specialists, and the hospital staff on a regular basis. This study made a significant contribution by providing

an open invitation to community women to participate in an informational meeting conducted prior to recruitment activities. An open invitation was posted around the hospital and passed by word of mouth. The meeting involved providing cycle beads and condoms, with training in their use, to all attendees. Also provided were appropriate levels of training on POP prevention and basic reproductive health information related to the study. All supplies including condoms, cycle beads and ovulation tests, remaining after the study was completed were donated to the OB/GYN clinic to be provided to local women visiting the clinic. Plans are underway to disseminate the information within Nepal to healthcare providers, community focus groups, and local health aids.

Scheer Memorial was well situated with access to the medical equipment needed to conduct the study, licensed physicians to conduct the clinical screening, and easily accessible to the rural population of interest in the study. Scheer Memorial Hospital strongly supports excellence in service, education, and research. The researchers were able to brief the physicians in the hospital's strong orthopedics and OB/GYN programs, who screened the participants, on the study in detail with provide lists of criteria for the screening process. Prior to enrollment, each participant was required to submit a form showing they had been screened by both physicians and specialists.

Staff at the hospital are bilingual in Nepali and English and were well qualified and experienced in translating medical and clinical information. For our study, we used nurses who had been the researcher's anatomy students at the nursing school. All participating nurses were female, with an excellent grasp of the English language and fluent in Nepali. All the staff who assisted in the study were familiar with universal precautions when handling objects exposed to body fluids, and were further trained in the

disinfection process for the ultrasound probes, IVT, and wiring used in the study. Translators ensured that participants in the study were fully informed of the study procedures, risks, and objectives before they signed the informed consent forms.

Instrumentation Rationale

We sought to determine if functional lifting tasks would significantly displace the pelvic floor and how the various menstrual phases effect that mobility. In order to accomplish this, we needed to match the same IAP achieved in typical lifting tasks with the participant in a supine position to accommodate the transperineal US probe while simulating an isometric lift with a head strap. Positioning affects the strength of the pelvic floor and the IAP. In supine, the pelvic floor is stronger and typically IAP lower than when standing.¹² To measure pelvic floor mobility in standing would be logistically difficult with either transperineal or transabdominal US, as positioning the probe while the participant was moving through a natural lifting position would be very difficult. Probe orientation and stability are crucial to getting a clear image. To minimize the changes in pelvic floor mobility from standing to sitting, we were able to match the average peak IAP achieved in standing while performing the task in supine.

Table 8. Mean IAP for Doko lift as compared to mean of other tasks (N= 16)

Task	Mean (SE)	p –value ^a
Bal	31·6 (2·1)	1·00
BalPFM	33·3 (3·9)	1·00
Cough	77·6 (3·9)	<0·001
Val	47·3 (4·9)	1·00
PFM	9·0 (1·3)	0·001
Doko lift	37·1 (4·3)	

Abbreviation: IAP, intra-abdominal pressure; SE, Standard error; a p value from post hoc testing pairwise comparisons between doko lift and other tasks.

Table 8 shows there is no significant difference in the IAP changes between simulated lifting tasks and the actual doko lifts, $p = 1.00$.

Other factors which may affect the mobility of the pelvic floor are the biomechanics of the pelvic floor and synergy motor patterns active in lifting. Gluteal muscles, which are active during hip movement and provide stability during lifting, have a synergistic effect on the pelvic floor.¹³ With participants in supine while we measured pelvic floor mobility, the synergistic effects of the gluteal muscles on the pelvic floor may not have been as active in our simulated task as in the functional upright lift. As expected, an activated pelvic floor muscle was shown to decrease pelvic floor displacement in our study.¹⁴ However, since our aim was to measure the effect of the menstrual cycle on pelvic floor mobility, the positioning for US imaging and task performance were identical at each test session for each menstrual phase. Our study cannot address the effects the gluteal activation in an actual lift may differ from that in a simulated lift and how this may alter pelvic floor functional strength.¹³

The ultrasound used in the research project was the ACUSON X300™ ultrasound system (Siemens Healthcare Global, Erlangen, Germany) which was set up and connected to a laptop computer and video capture synched with the BIOPAC measurements. The probe used was the CH4-1 curved linear array, covered with a latex-free condom during transperineal US. After viewing the video, the trials with the most similar pressures were selected, then the still frames of the rest period before activity and peak displacement were saved for measurement in a custom Matlab (MathWorks, Natick, Massachusetts, USA) program. The ventral urethralvesicular junction was identified in each image and displacement was calculated by comparing the two images using a

relative coordinate system based on the center of the pubic bone. Trials selected for statistical analysis were those with the most closely matched IAP changes for each subject.

The intravaginal pressure transducer (IVT) used in our study was developed at the University of Utah for studies that allowed wireless recordings of IAP over extended periods of time while performing a variety of tasks. It has been validated and found to be more reliable and consistent in measurements compared with rectal sensors. The IVT was designed to be comfortable enough that women would not notice its presence when correctly inserted.^{15,16} We chose this sensor because it was more reliable than the rectal balloon type sensors, and much more comfortable and incurred less risk than a nasogastric sensor. The IVT seemingly did not alter pelvic floor compliance since we were able to demonstrate similar values compared to other studies. Our overall descent of the pelvic floor may have been limited, as the values we obtained were on the lower end of the normal range found by Deitz.¹⁷ However, since we were looking for differences across the menstrual cycle as long as IVT use was consistent across the cycle it should not have impeded our ability to detect changes across the cycle.

Each participant's baseline IAP, measured while standing and lifting in the lab, showed similar IAP levels to those found in studies of Western women for lifting and carrying tasks while walking. The maximum IAP for our study participants in all tasks typically ranged from 45-95cmH₂O, other studies showed ranges of 55-77 for Western-style carrying techniques.¹⁸ An average compliance for the pelvic floor of 0.083mm/cmH₂O² for cough in nulliparous women and 0.167mm/cmH₂O² for healthy primiparous women.^{14,19} By measuring both IAP and displacement of the pelvic floor we

could reliably calculate the compliance of the tissues across the menstrual cycle. Other studies did not control for the menstrual phase.

The ballistic nature of some tasks seems to have altered the compliance of the tissues across the menstrual cycle (see **Table 9**). Cough, which causes a quick spike in IAP, has a lower compliance than a task with a slightly more gradual change in IAP increase such as a Valsalva.¹⁹

Table 9. Showing average compliance for each task at ovulation and menstruation in mm/cmH₂O. N=22

Task	O	M
BAL	0.17	0.2*
BALPFM	0.11	0.12
Cough	0.08**	0.1
VAL	0.17	0.14
PFM	-0.3	-0.5

*Abbreviations: O, Ovulation; L, Luteal; M, Menstruation; BAL, Ballistic; BALPFM, Ballistic with pelvic floor contraction; VAL, Valsalva; PFM, Pelvic floor muscle contraction; *Highest compliance across tasks and menstrual phases. **This nearly the same as mean compliance in healthy nulliparous woman 0.083 mm/cmH₂O (14).*

Estimating Relative Estradiol Levels

Levels of the primary marker of the menstrual phase, estradiol, increased around ovulation and stayed elevated through the luteal phase and declined during the early follicular phase (see below).²⁰

- Estradiol levels in Follicular phase: <20-145 pg/mL (184-532 pmol/L)
- estradiol levels at Ovulation: 112-443 pg/mL (411-1,626 pmol/L)

- Estradiol levels in luteal phase: <20-241 pg/mL (184-885 pmol/L)

The literature shows that after menopause, decreased estradiol levels as low as 0-40 pg/mL have been linked to POP, because pelvic floor structures become weaker when estradiol levels are lower²¹. However, there are no studies on changes in the pelvic floor when estradiol levels fluctuate during the menstrual cycle, which at menstruation can decrease to post-menopausal levels <20-145 pg/mL.^{20,22} Because hormonal changes may be a factor affecting tissue properties of the pelvic floor, the study repeated testing measures in each of the major phases of the menstrual cycle. Though there is no consensus about which phases have an inherently higher risk of tissue injury, some studies have shown ovulation to increase risk due to higher estradiol levels, which may promote ligament laxity. Park found an increased laxity and decreased stiffness in the knee joint at ovulation.²² The supportive structures of the pelvic organs have receptors for estradiol (and other gonadal hormones), and may be affected by the cyclic changes in these hormones.²³ Lower estradiol levels has been shown to increase musculotendinous stiffness²⁴ and decreased elasticity²⁵ during menstruation.²⁶

Is increased stiffness a risk or a benefit? Dietz asserts that increased post-menopausal stiffness may be protective against POP, with resulting vaginal stenosis instead of prolapse.²⁷ The purpose of this study was to evaluate the relationship between estradiol fluctuations in normal menstrual cycles and the response of pelvic floor support tissues during functional tasks. This could have implications not only for Nepali women, but for all women who engage in heavy manual labor or athletic activities during potentially higher risk phases of their menstrual cycles.

Testing blood levels of hormones is outside the scope of this study. However, if significant differences in pelvic floor displacement with increased IAP are found between the various menstrual phases, it may lead to further investigation, including studies of blood levels of relaxin and estradiol.

This study marked the menstrual cycle from the first day of menses to the LH surge as the follicular phase. The LH surge marked ovulation as measured by the Clearblue Advanced Digital Ovulation Test. The luteal phase was marked from ovulation to the beginning of the next cycle. Data collection took place three times during this cycle:

1. Within the first 4 days of menses (early follicular phase)
2. Within 24-48 hours of the peak fertility indication
3. 6-10 days after the LH surge (Robinson & Ellis, 2007).

The at-risk population of Nepali woman is about 53% literate.¹ Thus we needed a home urinalysis test that would be easily interpreted by even illiterate women and non-English speakers. The Clearblue Advanced Digital Ovulation test (SPD Swiss Precision Diagnostics GmbH, Petit Lancy, Switzerland) was chosen because it is easy to see when ovulation has occurred within 4 days, based on the “smiley face” symbol rather than another symbol which might be hard to explain to women who may or may not be literate. Participants were taught how to use the advanced Clearblue ovulation tests using the teach-back method so they would be able to identify the day they should come in for testing at the time of ovulation. They were also given a string of cycle beads (CycleBeads® and Standard Days Method® Georgetown University) to track their cycles and provided with instructions for their use. Most participants knew exactly how many

days it had been since their last period and were able to identify the day in the cycle they were currently on, so we were able to immediately begin testing with women in the menstrual phase and luteal phases. In order to perform accurate testing and identify the actual time of ovulation all the participants were required to use the ovulation urinalysis tests from the 6th or 7th day in their cycle. The cycles of each participant were tracked by the researchers and the participants were reminded by phone to do their home urinalysis testing when appropriate. The cycle beads were chosen because they have been used in developing countries and illiterate populations to help women track their fertility and menstrual cycles effectively in other studies.²⁸ The women in our study were able to track their cycles effectively and we are fairly certain we tested at the correct times since the mean basal body temperature was elevated in ovulation, lower during the luteal phase, and lowest during the menstrual phase testing sessions.

Measuring Temperature

Elastic properties of tissues are altered by temperature and loading rate. The temperature of a tissue has been shown to effect its mechanical properties.^{29,30} Core body temperature is normally between 36-37.5°C.³¹ Temperature is also affected by the menstrual cycle,³² with the basal body temperature one-half to one degree lower during the early follicular phase than after ovulation and throughout the luteal phase. Temperature changes have been shown to affect the performance of other ligaments in the body when tested across the menstrual cycle.³³

To measure temperature we taped a fast-response sensor (TSD202A, BIOPAC Systems, Inc. Goleta, CA USA) to the base of the IVT. Both sensors then were inserted into a latex-free condom and after careful instruction, the participant was asked to insert

the instrument into her vagina, high enough that the device was resting above the pelvic floor muscles, was comfortable to the participant, and stayed in place.

During menstruation, when estradiol and temperature are at the lowest points, the net effect is decreased elasticity and temperature, with increased stiffness in the pelvic structures, versus at ovulation, when estradiol and temperature are at their peak.³⁴ In this study, we measured temperature changes by recording continuous readings intravaginally with a sensor attached to the IVT (Department of Bioengineering, University of Utah, Salt Lake City, Utah).

Measuring Pelvic Floor Mobility with Transperineal Ultrasound (US)

Ultrasound (US) has been shown to be a valid tool for measurement of the pelvic floor and organ displacement or movement.³⁵⁻³⁹ Various methods of US imagining have been reviewed and addressed in the literature. Transperineal US was chosen for this study as a way to visualize pelvic floor structures and measure transitional movements. Suprapubic US and transabdominal ultrasound (TAUS) measurement techniques were also explored; however, suprapubic TAUS would be difficult since the abdominal wall is not stationary during activity and breathing.³⁶ Consistent imaging strategies were used and scripted instructions for all test activities were followed to get the most reliable data possible. When compared to other methods, US has been considered a reliable method of visualization of pelvic floor morphology.^{40,41} The movement of the urethralvesicular junction with changes in IAP were measured with the subject in a modified crook lying position, since positioning for transperineal ultrasound imaging is difficult during squatting to standing movement. Because displacements of the pelvic floor have been

noted to be significantly different in supine versus upright positions.¹² This study attempted to match the mean peak IAP reached in an upright lift while the subject is lying in a modified crook position for the transperineal ultrasound imaging, with the lower extremities supported against a wall in a position relative to each other and similar to the squat used while lifting the actual doko. Normal mobility of the pelvic floor measured with translabial ultrasound (**Figure 8**) was shown to be widely varied from 1.2 – 40.2 mm.¹⁷ Perhaps much of this variability was due to changes in the biomechanical properties of the tissue changes induced by fluctuations of estradiol across the menstrual phase as Dietz study did not control for phase of the menstrual cycle.



Figure 8. Pelvic Floor US image used in the study.

Measurement of Intra-abdominal Pressure (IAP)

Intra-abdominal pressure (IAP) rises during dynamic lifting activities;^{42,43} therefore, the use of continuous monitoring of the IAP was important to this study. In order to identify when peak IAP occurs with isometric simulation of head-bearing lifting (ISHBL), an intravaginal pressure transducer IVT (**Figure 9**) was used.^{15,44} This

transducer was developed and approved for use in research done by the University of Utah Health Sciences Center Institutional Review Board.¹⁵ The IVT is similar in size and shape to an O.B. brand tampon. Placement was done by the subject and then confirmed with transperineal US. The sensor was reused, sterilized, and placed inside a condom for each trial. Subjects have reported it to be comfortable and that the IVT did not impair movement.¹⁵ Normal IAP for women performing functional tasks was found to be 40-80 cm H₂O.^{9,18} In our study, when we measured the peak-to-peak pressure changes and increase over resting baseline pressure with functional tasks, these pressure increases were typically between 20-100 cmH₂O. This sensor transmits the IAP as measured in the upper vagina to the BIOPAC to a computer monitor for real-time analysis. The sensor was used to track IAP during lifting tasks, ISHBL, and other tasks used for standardization in a modified crook lying position during transperineal US imaging. Calibrated and tested sensors were alternately used in the data collection. Sterilization was done by covering the sensors in latex-free condoms while in use; between uses the sensors and wires were soaked with Cidex (ASP, Irvine, California) per manufacturer instructions and rinsed in sterile saline prior to the next use. This is the protocol currently used in the operation theater at Scheer Memorial Hospital and also meets or exceeds the JHACO guidelines and manufactures recommendations for sterilization of equipment that is reused with multiple patients.

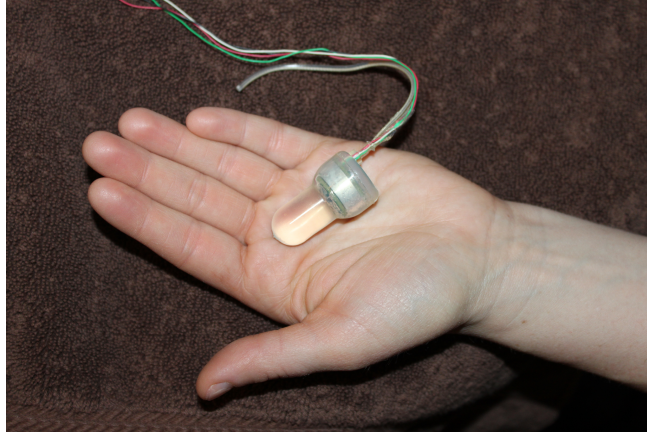


Figure 9. Photo of the IVT sensor in hand for size reference.

Explanation of Findings

The pelvic floor is at significant risk of damage in vaginal delivery, and rates of injury may be higher in deliveries using forceps.⁴⁵ However, in Nepal, where most births take place at home, the POP rates are very similar to those in Western countries, although reports of symptomatic POP occur about a decade or so earlier. Also nulliparous women in Nepal have relatively high rates of POP as well, since 10-20% of women have fascial defects even without vaginal deliveries.¹⁴ These defects in nulliparous women and the levator ani tears in vaginal deliveries for parous women impair the active support structures of the pelvic floor and put more pressure on the passive support structures. Perhaps the increased compliance that occurs in the early follicular phase and accompanies menstruation, superimposed on a lifestyle which requires heavy lifting during this time, plays a role in gradually stretching out the passive support structures and defects sooner for women in Nepal.

Strategies that may decrease the repetitive trauma to the pelvic floor and prevent the early onset of POP in at-risk women include; 1) pre-contracting the pelvic floor muscles when lifting, coughing, sneezing and laughing 2) avoiding heavy and ballistic lifting while menstruating 3) avoiding ballistic lifting strategies.

Implications for Further Study

Contributing factors we were not able to control for were muscle activation patterns and synergistic behaviors of muscles depending on the lifting strategies. Gluteal muscles have a synergistic effect on the pelvic floor muscles in men.¹³ In addition, pelvic tilting can increase or decrease stretch on the pelvic muscles; this was not controlled for and may have an effect on the strength of contraction of the muscles.

Some research shows relaxin levels increase during menstruation, but we were able to control for fluctuations in relaxin in our study.^{23,46} Further study needs to be done to determine if the changes in pelvic floor compliance are due to relaxin and estradiol and how or if they affect one another.

We were not able to control for parity and instead excluded women with stage 2 or more on a POP-Q testing. We were able to derive virtually the same compliance ratios in our mixed group of women with parity ranging from 0-4 as in other studies, looking at cough-induced displacement of the pelvic floor in nulliparous women.¹⁷ Further investigation needs to be done on the true effects of parity versus pelvic trauma that may be increasing the risks of developing POP in women.

To confirm and clarify our findings, further research is needed on the complex interplay of cyclic hormone physiology on tissue compliance and how this effects the biomechanics of the pelvic floor. Future studies should be done to fully verify normal

ranges for IAP and pelvic floor displacement incurred with head bearing lifting as it is done in at-risk populations. Head bearing lifting techniques may present a unique pattern of muscle synergy and firing patterns that merits detailed analysis. As more of this information is better understood we may be able identify the factors that are putting non-symptomatic women at risk of developing SPOP. Ideally we will be able to establish guidelines for lifting strategies which will allow women to avoid SPOP.

References

1. Statistics CIACBo. The World Factbook 2016 [11/21/2016]. Available from: <https://www.cia.gov/library/publications/the-world-factbook/geos/np.html>.
2. Institute of Medicine Tribhvan University Kathmandu N. A reproductive morbidity report on clinic based survey 2006; Status of Reproductive Morbidities in Nepal. report Submitted to United Nations Population Fund (UNFPA) Pulchowk, Lalitpur, Nepal. 2006 2006.
3. Radl CM, Rajwar R, Aro AR. Uterine prolapse prevention in Eastern Nepal: the perspectives of women and health care professionals. *Int J Womens Health*. 2012;4:373-82.
4. Population Division Ministry of Health and Population NE, ICF International. Nepal Demographic and Health Survey 2011. Population Division Ministry of Health and Population Government of Nepal, Population; 2012.
5. International A. Unnecessary Burden Gender Discrimination and Uterine Prolapse in Nepal. Amnesty International February 2014. 2014;Index:ASA31/001/2014.
6. Shrestha B, Onta S, Choulagai B, Poudyal A, Pahari DP, Uprety A, et al. Women's experiences and health care-seeking practices in relation to uterine prolapse in a hill district of Nepal. *BMC Womens Health*. 2014;14:20.
7. Lien YS, Chen GD, Ng SC. Prevalence of and risk factors for pelvic organ prolapse and lower urinary tract symptoms among women in rural Nepal. *Int J Gynaecol Obstet*. 2012;119(2):185-8.
8. Fitchett JR, Bhatta S, Sherpa TY, Malla BS, EJ AF, Samen A, et al. Non-surgical interventions for pelvic organ prolapse in rural Nepal: a prospective monitoring and evaluation study. *JRSM Open*. 2015;6(12):2054270415608117.
9. Coleman TJ, Hamad NM, Shaw JM, Egger MJ, Hsu Y, Hitchcock R, et al. Effects of walking speeds and carrying techniques on intra-abdominal pressure in women. *Int Urogynecol J*. 2015;26(7):967-74.
10. UK PP. Trekking Guidelines UK Registered Charity No. 1112943; 2016 [updated 2016]. Available from: <http://www.portersprogressuk.org/advice-for-trekkers/trekking-guidelines/>.
11. Haviland C. Nepal's 'confinedwomen' want change. *BBC News*; 2009/03/04 23:59:19 GMT.
12. Frawley HC, Galea MP, Phillips BA, Sherburn M, Bo K. Effect of test position on pelvic floor muscle assessment. *Int Urogynecol J Pelvic Floor Dysfunct*. 2006;17(4):365-71.

13. Asavasopon S, Rana M, Kirages DJ, Yani MS, Fisher BE, Hwang DH, et al. Cortical activation associated with muscle synergies of the human male pelvic floor. *J Neurosci*. 2014;34(41):13811-8.
14. Ashton-Miller JA, DeLancey JO. Functional anatomy of the female pelvic floor. *Ann N Y Acad Sci*. 2007;1101:266-96.
15. Coleman TJ, Thomsen JC, Maass SD, Hsu Y, Nygaard IE, Hitchcock RW. Development of a wireless intra-vaginal transducer for monitoring intra-abdominal pressure in women. *Biomed Microdevices*. 2012;14(2):347-55.
16. Egger MJ, Hamad NM, Hitchcock RW, Coleman TJ, Shaw JM, Hsu Y, et al. Reproducibility of intra-abdominal pressure measured during physical activities via a wireless vaginal transducer. *Female Pelvic Med Reconstr Surg*. 2015;21(3):164-9.
17. Dietz HP, Eldridge A, Grace M, Clarke B. Pelvic organ descent in young nulligravid women. *Am J Obstet Gynecol*. 2004;191(1):95-9.
18. Coleman TJ, Nygaard IE, Holder DN, Egger MJ, Hitchcock R. Intra-abdominal pressure during Pilates: unlikely to cause pelvic floor harm. *Int Urogynecol J*. 2015;26(8):1123-30.
19. Howard D, Miller JM, Delancey JO, Ashton-Miller JA. Differential effects of cough, valsalva, and continence status on vesical neck movement. *Obstet Gynecol*. 2000;95(4):535-40.
20. Stricker R, Eberhart R, Chevailler MC, Quinn FA, Bischof P, Stricker R. Establishment of detailed reference values for luteinizing hormone, follicle stimulating hormone, estradiol, and progesterone during different phases of the menstrual cycle on the Abbott ARCHITECT analyzer. *Clin Chem Lab Med*. 2006;44(7):883-7.
21. Rizk DE, Fahim MA. Ageing of the female pelvic floor: towards treatment a la carte of the "geripause". *Int Urogynecol J Pelvic Floor Dysfunct*. 2008;19(4):455-8.
22. Park SK, Stefanyshyn DJ, Loitz-Ramage B, Hart DA, Ronsky JL. Changing hormone levels during the menstrual cycle affect knee laxity and stiffness in healthy female subjects. *Am J Sports Med*. 2009;37(3):588-98.
23. Dietrich W, Elenskaia K, Obermayr E, Horvat R, Mayerhofer K, Umek W, et al. Relaxin and gonadal steroid receptors in uterosacral ligaments of women with and without pelvic organ prolapse. *Int Urogynecol J*. 2012;23(4):495-500.
24. Bell DR, Blackburn JT, Norcorss MF, Ondrak KS, Hudson JD, Hackney AC, et al. Estrogen and muscle stiffness have a negative relationship in females. *Knee Surg Sports Traumatol Arthrosc*. 2012;20(2):361-7.

25. Lee H, Petrofsky JS, Daher N, Berk L, Laymon M. Differences in anterior cruciate ligament elasticity and force for knee flexion in women: oral contraceptive users versus non-oral contraceptive users. *Eur J Appl Physiol.* 2014;114(2):285-94.
26. Eiling E, Bryant AL, Petersen W, Murphy A, Hohmann E. Effects of menstrual-cycle hormone fluctuations on musculotendinous stiffness and knee joint laxity. *Knee Surg Sports Traumatol Arthrosc.* 2007;15(2):126-32.
27. Dietz HP. The aetiology of prolapse. *Int Urogynecol J Pelvic Floor Dysfunct.* 2008;19(10):1323-9.
28. Lundgren R, Sinai I, Jha P, Mukabatsinda M, Sacieta L, Leon FR. Assessing the effect of introducing a new method into family planning programs in India, Peru, and Rwanda. *Reprod Health.* 2012;9:17.
29. Petrofsky JS, Laymon M, Lee H. Effect of heat and cold on tendon flexibility and force to flex the human knee. *Med Sci Monit.* 2013;19:661-7.
30. Petrofsky J, Al Maly A, Suh HJ. Isometric endurance, body and skin temperature and limb and skin blood flow during the menstrual cycle. *Med Sci Monit.* 2007;13(3):CR111-7.
31. Petrofsky JS, Laymon M. Heat transfer to deep tissue: the effect of body fat and heating modality. *J Med Eng Technol.* 2009;33(5):337-48.
32. Baker FC, Waner JJ, Vieira EF, Taylor SR, Driver HS, Mitchell D. Sleep and 24 hour body temperatures: a comparison in young men, naturally cycling women and women taking hormonal contraceptives. *J Physiol.* 2001;530(Pt 3):565-74.
33. Lee H, Petrofsky JS, Daher N, Berk L, Laymon M, Khowailed IA. Anterior cruciate ligament elasticity and force for flexion during the menstrual cycle. *Med Sci Monit.* 2013;19:1080-8.
34. Bertone-Johnson ER, Ronnenberg AG, Houghton SC, Nobles C, Zagarins SE, Takashima-Uebelhoer BB, et al. Association of inflammation markers with menstrual symptom severity and premenstrual syndrome in young women. *Hum Reprod.* 2014;29(9):1987-94.
35. Ferreira PH, Ferreira ML, Nascimento DP, Pinto RZ, Franco MR, Hodges PW. Discriminative and reliability analyses of ultrasound measurement of abdominal muscles recruitment. *Man Ther.* 2011;16(5):463-9.
36. Hodges PW. Ultrasound imaging in rehabilitation: just a fad? *J Orthop Sports Phys Ther.* 2005;35(6):333-7.

37. Junginger B, Baessler K, Sapsford R, Hodges PW. Effect of abdominal and pelvic floor tasks on muscle activity, abdominal pressure and bladder neck. *Int Urogynecol J.* 2010;21(1):69-77.
38. Stafford RE, Ashton-Miller JA, Constantinou CE, Hodges PW. Novel insight into the dynamics of male pelvic floor contractions through transperineal ultrasound imaging. *J Urol.* 2012;188(4):1224-30.
39. Whittaker JL, Thompson JA, Teyhen DS, Hodges P. Rehabilitative ultrasound imaging of pelvic floor muscle function. *J Orthop Sports Phys Ther.* 2007;37(8):487-98.
40. Dietz HP. Why pelvic floor surgeons should utilize ultrasound imaging. *Ultrasound Obstet Gynecol.* 2006;28(5):629-34.
41. Lone FW, Thakar R, Sultan AH, Stankiewicz A. Accuracy of assessing Pelvic Organ Prolapse Quantification points using dynamic 2D transperineal ultrasound in women with pelvic organ prolapse. *Int Urogynecol J.* 2012;23(11):1555-60.
42. Gerten KA, Richter HE, Wheeler TL, 2nd, Pair LS, Burgio KL, Redden DT, et al. Intraabdominal pressure changes associated with lifting: implications for postoperative activity restrictions. *Am J Obstet Gynecol.* 2008;198(3):306 e1-5.
43. Iqbal A, Haider M, Stadlhuber RJ, Karu A, Corkill S, Filipi CJ. A study of intragastric and intravesicular pressure changes during rest, coughing, weight lifting, retching, and vomiting. *Surg Endosc.* 2008;22(12):2571-5.
44. Hsu Y, Coleman TJ, Hitchcock RW, Heintz K, Shaw JM, Nygaard IE. Clinical evaluation of a wireless intra-vaginal pressure transducer. *Int Urogynecol J.* 2012;23(12):1741-7.
45. Dietz HP. Pelvic floor trauma following vaginal delivery. *Curr Opin Obstet Gynecol.* 2006;18(5):528-37.
46. Dragoo JL, Castillo TN, Korotkova TA, Kennedy AC, Kim HJ, Stewart DR. Trends in serum relaxin concentration among elite collegiate female athletes. *Int J Womens Health.* 2011;3:19-24.

APPENDIX A

INFORMED CONSENT DOCUMENTS (ENGLISH AND NEPALI)



LOMA LINDA UNIVERSITY
School of Allied Health Professions

Informed Consent

"Displacement of the Pelvic Floor with Isometric Simulation of Head Bearing Lifting at 3 crucial points in the Menstrual Cycle."

Reason for the study

Researchers are trying to find out why even young women can sometimes develop fallen uterus, and sometimes even without having a baby.

During each menstrual cycle there are changes that cause affects on the whole body. The changes can be grouped into 3 specific parts. The bleeding part, the time when pregnancy is most likely to occur if you have sex, and the time when the body is waiting and staying prepared if pregnancy happens. This study is going to try to answer the following questions. Is a woman more likely to develop a fallen uterus during one part of the month than during others? Is one part of the month a bad time to do heavy lifting because of the pressure it puts on the inside muscles and ligaments supporting the uterus? If we can learn the answers to these questions, we teach women when they need to protect themselves by carrying smaller loads.

You are invited to participate in helping the researchers find the answer to these questions.

Loma Linda University
Adventist Health Sciences Center
Institutional Review Board
Approved 1/16/14 Void after 1/7/2015
#5130382 Chair R. J. Ruggiano

Page 1 of 7

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“Displacement of the Pelvic Floor with Isometric Simulation of Head Bearing Lifting at 3 Crucial Points in the Menstrual Cycle”

Before you can be part of the project, we need to be sure it is safe for you to lift heavy loads and that you are healthy and not pregnant. To find out we will have you answer a list of questions about your health and how hard you work. You will be asked three questions by another person after the researcher has explained this paper to you. This is to see if you understood what you have been told about the study. If you understand and want to participate then you will get two free routine medical checkups. One at the woman's doctor clinic and one at the bone doctor's clinic. They will check you very carefully to be sure you are not at risk of getting hurt by lifting in the study and that your uterus is not falling a little bit already. They will also do a pregnancy test to be sure you are not pregnant before you can be in the study. If the doctors can find no problems you will be told when and where to come for the study. Below is a list of the things you will do if you participate in the study:

- First you will be taught how to do a special test that will tell you if your body is ready to get pregnant or not. It is very easy. First in the morning you urinate into a small cup. A small stick like a pen has one end that you will need to dip in your urine. Each time you test your urine you will look at the little window on the stick that will have either an empty circle, a flashing smiley face or a smiley face. You will draw a picture of what you see on a paper provided for each day. You will have to do this for 10 days, starting from 6th day after you start bleeding. You will need to come get tested on the day you get a smiley face that isn't flashing.
- You will come to the hospital 3 times once on the 1st or 2nd day of your period, once the day your urine test shows a smiley face that isn't flashing and once one week after that.
- When you come for your first testing session you will get weighted and measured. Then you will be given the small soft sensor you were shown at the information meeting. This is about the size of your finger and has a small wire coming out. The woman who helped make these sensors have tried them inside themselves and they say it is not uncomfortable. After it is inside you will hardly feel it at all. It will be inside a condom to keep it clean. You will go into the bathroom and go urinate then put it with the condom around it up inside your vagina exactly the way the researcher shows you. If you need help you can ask the woman researchers. It should not hurt and be easy to push inside. After you have it in you can put all your clothes on and just leave the wire coming out the top of your pants.
- You will be given a glass of water to drink. Try to drink all of the water.
- The wire coming out will connect to a machine that measures how much pressure you are putting on the muscles around your uterus and the

“Displacement of the Pelvic Floor with Isometric Simulation of Head Bearing Lifting at 3 Crucial Points in the Menstrual Cycle

temperature inside. The small sensor inside you measures this pressure and temperature.

- You will be asked to lift a basket that has a load in it less than half what you weight or less than 30 kg, off the floor with a head strap. You will do it 3 times.
- After that you will put on a long skirt that covers your legs and remove pants if you have them on, you should still feel very well covered. No one will need to look directly at your private areas. You will lay on a table on your back with your feet supported up on the wall. The researcher will sit next to you. She will gently put the ultrasound machine like you have seen in the pictures at the information meeting on your skin up between your legs. This is the same as the way we use the machine to see babies inside their mothers. In this study the ultrasound screen will show pictures of your bladder and uterus and how they are moving. The pictures will look like the ones shown you at the meeting.
- You will be asked to do six tasks:
 1. Hold your breath and push like you were trying to pass gas.
 2. Tighten the muscles around your vaginal opening like you are trying not to pee.
 3. Cough
 4. Try to lift up on a head strap while laying down, using your arms and head to pull, but not pushing with your feet, slowly pulling harder and harder for 10 seconds and then relax slowly for 3 seconds.
 5. Lift up against the head strap with your head and arms and you can push with your legs slowly pulling harder and harder for 10 seconds and then relax for 3 seconds.
 6. Lift up against the head strap with your head and arms, and you can push with your legs. This time you will pull up quickly and with strong force.

All these things will put gentle pressure on the muscles that hold your uterus up, just like the work you do at home does. The researcher will be able to see how they move and react to the pressure. You don't have to worry about remembering what to do. The lady researcher will tell you what you need to do. Just follow her instructions carefully. Each test will be repeated 3 times. It will take about an hour to do all the tests.

- There will be a camera taking pictures that do not show your private parts or face. It will only take pictures of the activity you are doing.
- You will have to come 3 times for the testing the second and third time you don't have to lift the basket. All you have to do is the tasks laying on the table.
- Each time you come for testing you will get 500 Nrs, for a total of 1500 Nrs and the last day you will be given the skirt you choose to wear for the testing.
- You will also get tea and bread or biscuits at the hospital canteen.

“Displacement of the Pelvic Floor with Isometric Simulation of Head Bearing Lifting at 3 Crucial Points in the Menstrual Cycle

- All the information we get about you will be kept very secret only the researcher will have a key to the place the records are kept. Only this form where you sign your name will have your name on it. You will be given a code number and all the rest of the records will only use the code not your name. This way people will not be able to read about the study later and know about your private information.
- The researchers will need to have your cell phone number to call you and remind you when to come for the testing. No one from the study will call you for any other reason or call you after the study is done unless you request a call.

Risks

Being in this study is no more risky than doing your daily work at home. The doctor visits are not more risky than normal doctor visits. You may get sore and tired muscle from some of the activities. The Ultrasound has no known risks of injury. The vaginal pressure sensor may cause some discomfort or irritation to the skin. The vaginal sensor will be in a latex free condom and may feel uncomfortable even with the use of hyper allergic lubricant to help with insertion as needed. Cross contamination is highly unlikely due to the standard universal precautions taken. You will be using condoms for sexual activity during the study so the chances of getting pregnant are low.

Benefits

You will get the benefit of 2 free doctor visits. You will learn a lot about yourself and how your body works, and how to prevent your uterus from falling down and out of your body. Because of your help with the study researchers will be able to learn and apply new knowledge in how to prevent and handle the problem of fallen uterus in Nepal and around the world. You will also get 1500 Nrs and a long simple skirt to keep.

Participants rights

No one will try to force you to be a part of the study if you do not want to be. Only if you really want to be involved and sign this paper will you be able to participate. If you change your mind you can stop any time and there will be no

“Displacement of the Pelvic Floor with Isometric Simulation of Head Bearing Lifting at 3 Crucial Points in the Menstrual Cycle

problem. However you only get the 500 Nrs when you come for each the testing and do all the tasks, and the skirt if you complete the study.

Confidentiality

All your names will be kept secret. No one will be given your personal information unless you write down for us that it is ok to give you name to someone else. If the results of the study are printed in a magazine or book your name will never be in the printed article.

Cost / Compensation

There is no cost for participating in this study. Each person will receive 500 Nrs for each of the 3 sessions for a total of 1500 Nrs possible for participating in the entire study. This is help pay for your travel to get to the study sessions, and for your time and energy used in the activities. You can also keep the skirt you use during the testing to cover your legs for privacy.

Impartial Third party

If you want to complain or have any questions about this study but you are not comfortable talking to the researchers you may contact the Administration Office of Scheer Memorial Hospital 977 11 66 1111 / 1112 you can speak to the Administrative secretary Junu Manandhar

“Displacement of the Pelvic Floor with Isometric Simulation of Head Bearing
Lifting at 3 Crucial Points in the Menstrual Cycle”

Informed consent statement

I have read this consent form or it has been read to me and explained by the researchers. My questions regarding the study have been answered so am able to understand. I want to participate as a subject in this study. Signing this consent document does not waive my rights nor does it release the investigators, institutions, or sponsors from their responsibilities. I may call Uma Thapa or Yvonne Biswokarma during regular office hours at 977 11 66 1111 / 1112 if I have additional questions or concerns. During non-office hours messages can be left at this number.

Must be done in the presence of the third party after they have interviewed the subject.

I have received a copy of this consent form and I understand it and wish to be included as a subject in this study.

Signature or thumb print of Subject

Date

Subjects Cell Phone number: _____

INVESTIGATOR’S STATEMENT

I have reviewed the consent form with the person signing above. I have explained potential risks and benefits of the study.

Signature of Investigator _____

Date _____

Signature of Translator _____

Date: _____

“Displacement of the Pelvic Floor with Isometric Simulation of Head Bearing Lifting at 3 Crucial Points in the Menstrual Cycle

Third Party check for full understanding of the potential subject

Instructions: This section to be completed by a different female assistant who was not in the room while the potential subject was being given the information from this consent form by the investigators. Choose at least 3 of the questions randomly from the list below and verbally ask the woman clearly in her native tongue to be sure they have understood the intent and content of this informed consent form. If their answers show appropriate understanding please mark with check mark ✓ if not with an X. The subject should know without prompting or reading their paper.

1. What do you think the study is about? _____
2. How many times will you need to come for testing? (correct answer is 3)

3. Why do you need to see a bone doctor and woman’s doctor before you can be in the study? _____
4. What are the risks of being in the study? _____
5. What are the benefits of being in the study? _____
6. Did the researcher answer all your questions? _____
7. What is an example of the tasks you will have to do in the study? _____
8. Can you be in the study if you are pregnant? _____
9. Can you be in the study if you have back pain that impairs your daily work? _____
10. Will there be men in the room while you get tested? _____
11. What will the Ultrasound pictures show? _____
12. Where will you put the sensor that tests the pressure inside you while you are lifting? _____

I witnessed _____ (subjects printed name) provide their signature of thumbprint on page 6 was done in my presence. The subject was able to correctly answer the questions asked of her without difficulty. I believe she understands the content of this consent form and is voluntarily agreeing to participate in this study.

Signature of third party: _____ Date: _____
Printed Name of Third party: _____

“Displacement of the Pelvic Floor with Isometric Simulation of Head Bearing Lifting at 3 crucial points in the Menstrual Cycle.”

Informed Consent: YES NO (Circle Correct Response)

Subject Number:

General demographic information:

1. Name: DOB:
2. Female yes no
3. Ethnicity:
4. Religion:
5. Weight:
6. Is you home Rural or Urban? Describe:

Exclusion:

1. Are you pregnant or any chance of being pregnant? Yes no
2. Are you using any form of birth control? Yes No Describe:
3. Have you ever been pregnant? Yes No Describe:
4. Abortions: Miscarriages: At what gestational age:
5. Deliveries: Vaginal: Caesarian sections:
6. Do you have any pelvic pain? Yes No Describe:
7. You have trouble holding your urine? Yes No Describe:

8. Do you have frequent constipation? Yes No Describe:
9. Have you ever been told your uterus is falling down into your vagina? Yes No
Describe:
10. Do you have pelvic or low back pain during your period that limits you function?
Yes No Describe:
11. Do you have irregular periods? Yes No
12. Have you had chronic or recurring respiratory infections of cough? Yes No
Describe:
13. Do you have any allergies? Yes No Describe:
14. Do you have any back problems that limit your ability to work? Yes No
Describe:
15. Do you have any neck problems that limit your ability to work? Yes No
Describe:
16. Do you have frequent head aches that limit your ability to work? Yes No
Describe:
17. Do you have any other physical pain or conditions that effect you ability to carry a
load? Yes No Describe:
18. Do you have any nerve problems or bones problems? Yes No Describe:

19. Have you had any history of bladder cancer? Yes No

Gynecological and Carrying history questions

1. How many days is your regular cycle? _____
2. When was your last period?
3. How long are your typical periods?
4. When was your last pelvic exam?
5. **Have you done frequent load bearing using a doko and namlo? Describe:
6. How much weight do you can you carry?
7. How often do you carry loads?
8. When was the last time you carried a load?
9. Do you smoke? Yes No

** Doko is a traditional cone shaped Basket used for carrying loads with a head strap. Namlo is the head strap used to carry loads in the traditional way in the hilly and mountainous regions of Nepal.

Decision: Include in the study Exclude from the study

सहमति पत्र

“रजस्वला चक्रको विभिन्न समयमा कृतिम हेड वियरिड राखेर गरिने परिक्षण र पेल्विक फ्लोर (आड) को विचलन”

उद्देश्य र प्रक्रिया

तपाईंको रजस्वला चक्र भरिमा कुनै बस्तु उचाल्दा तल्लो पेट (आड) मा पर्ने दवाव र यसको असर सम्बन्धमा विश्लेषण गरिने अनुसन्धानमा सहभागी हुन आग्रह गरिन्छ । यस अनुसन्धानमा सहभागी हुन स्विकार गर्नु अघि तपाईंले केहि पृष्ठहरूमा तपाईंले गह्रौ बस्तु उचाल्ने अभ्यास, स्वास्थ्य, रजश्वला चक्र र अन्य प्रजनन स्वास्थ्य तथा पारिवारिक र जनसांख्यिकियता सम्बन्धि सर्वेक्षण प्रश्नहरूको जवाफ दिनु पर्नेछ । अध्ययनमा सहभागी हुन तपाईं गर्भवती वा आगामी ३ देखी ४ हप्ता सम्म गर्भवती नहुने अवस्थाको हुनु पर्दछ । सहभागी हुदा तपाईंले नेपाली परम्पराको डोको नाम्लोको प्रयोग गरि केहि तौल उठाउनु पर्ने हुन्छ । जो तपाईंको शरिरको तौलको ४०% वा वा ३० के.जी भन्दा बढि हुदैन यसका अलवा तपाईंले ६ वटा सामान्य कामहरू जस्तै खोक्नु , धकेल्नु, आड खुम्चाउनु, टुकुक्क बस्सेर गोडा खसार्ने, लामो स्वास तानेर फान्नु) जसले तपाईंको आडमा भित्रि दवाब सिर्जना गर्न सक्दछन् त्यस्ता कामहरू उत्तानो परेर गर्नुपर्ने हुन्छ । तपाईंलाई आरामको समयमा अल्ट्रासाउण्ड गर्न लगाईनेछ । जसमा तपाईंको आड पेल्विक फ्लोरको रेकड गरिनेछ । तपाईंको आडमा परेको दवावको परिक्षण गर्न योनीको भित्रि एउटा सेन्सर राखी सो को जानकारी देखाउन तपाईंको कपडामा एउटा क्लिप झुण्डाएको हुनेछ । यस सेन्सरले आडमा परेको भित्रि दवावको निरन्तर जानकारी दिनेछ । यो सेन्सर धेरै महिलाहरूमा प्रयोग गरिसकेको छ र आरामदायि तथा अरुले सजिलै अनुमान गर्न सक्ने हुदैन । यो परिक्षणहरू तिन पटक सम्म दोहोराईनेछ । आगामी ३ देखी ४ हप्ता सम्म तपाईंले आफ्नो रजश्वला चक्रको ध्यान पूर्वक रेकर्ड राख्नुपर्छ र प्रत्येक विहान पिसाबको परिक्षण रजस्वलाको छैटौं दिन देखी ओभुलेसन दिन सम्म गर्नुपर्नेछ । स्त्री रोज परिक्षण र हाड जोर्नी परिक्षण गरिसकेपछि मात्र तपाईंलाई अध्ययनमा समावेस गरिनेछ जसमा महिला चिकित्सकले स्त्री रोग सम्बन्धि वा हाड जोर्नी सल्य चिकित्सकद्वारा घाँटी र ढाड तपाईंको पाखुराका मांशपेशीले तौल थाम्ने क्षमताको परिक्षण हुनेछ । यी परिक्षणहरूले तपाईं अध्ययनमा सहभागी हुन उपयुक्त हुनुहुन्छ वा तपाईंलाई अध्ययनमा सहभागी गराउन जोखिम छ वा छैन भन्ने कुरा निक्योले गर्नेछ । सहभागिताका लागि छनौट हुने सबै सर्त पूरा भएमा तपाईं बाँकी ३ परिक्षणहरू सहभागी गराउने मिति दिईनेछ ।

सहभागिको नाम:

मिति:

अध्ययनको पहिलो दिन तपाईंको उमेर, तौल र उचाईको अभिलेख राखिने छ। त्यसपछि तपाईंलाई पिसाब थैली खाली गराउन लगाउने छ र परिक्षण सुरुहुन भन्दा ३० मिनेट अघि १६०श पानी पिउने दिईने छ । रजस्वलाका समय रक्तश्राव रोक्न रोक्न प्रयोग गरिने प्याड जस्तै सानो Tampon Sensor लाई कण्डम भित्र राखेर तपाईंलाई सहज हुने सम्म योनी भित्र पठाउन लगाईने छ र यो काम तपाईंले गोप्य रूपमा बाथरुम भित्र गर्न पाउनु हुनेछ । त्यसपछि तपाईंको शरिरको तौलको ४० प्रतिशत वा ३० किलोग्राम भन्दा बढि नहुने तौल उठाउन लगाईने छ । त्यसपछि तपाईंले अन्य तिन पटक तौल उठाउने काम गर्नुपर्ने छ जसमा डोको भित्र तौल राखेर भुईभन्दा माथि तिन पटक उठाउन पर्ने छ । यस अवधिमा तौल उठाउदा पेलमिक प्लोरमा परेको दबावको औषत रेकर्ड गरिने छ । भित्तामा भुइयाएर राखेको दबाव मापक (Pressure Sensing) चट्टामा खुटा अड्याएर टेबल माथी उतानो परेर बस्न लगाइने छ । सो क्रममा तपाईंलाई तपाईंको शरिरमा कसिलो भएका कपडाहरु निकाल्न लगाएर शरिर पुरै ढाकिने गरि गाउन लगाउने दिईने छ र कृतिम US Head तपाईंको पेलमिक प्लोरमा राखिने छ। तपाईंको शारिरिक तापक्रम क्रियाकलाप अघि तथा पछि दुबै पटक लिईनेछ । यि सबै कुराहरु गर्ने तपाईंको गर्न तपाईंको मदतका लागि एक महिला अनुसन्धान कर्ता वा दोभासे तपाईंको कोठामा उपलब्ध हुनेछन । त्यसपछि तपाईंलाई स्वास रोक्ने र छोड्ने गराई पेलमिक प्लोरमा राखिएको US Head संगै उक्त प्लोर खुम्चाउन लगाईने छ र पहिले उभिएर तौल उठाउदाको जस्तै उतानो परेर पल्टिदा पनि दुईपटक तौल उठाउन लगाईने छ । जस्मा तपाईंले अघिल्लो क्रियाकलापमा जस्तै आन्तरिक दबाव मिलाउने प्रयास गर्नुहुनेछ । यो लामो प्रक्रियामा तपाईंले चिन्ता गर्नु पर्दैन किनभने अनुसन्धान कर्ताले तपाईंलाई बुझ्न कठिन भएको अवस्थामा प्रत्येक चरणहरु आफै प्रदर्शन गरेर देखाउने छन । सबै चरणहरु सकेर आरामका समयमा प्रत्येक क्रियाकलापहरुका साथै तपाईंको पिसाब थैलीको स्थान र पेलमिक प्लोरको संरचनालाई अल्ट्रासाउन्ड भिडियोमा रेकर्ड गरिने छ । प्रत्येक प्रयासको बिचमा एकमिनेट आराम गराउदै तिन पटक सम्म मापन गरिने छ । तपाईंले गर्नुभएको प्रत्येक क्रियाकलापको भिडियो खिचिने छ जसमा तपाईंको चिनारी आउने पहिचान खुल्ने तपाईंको मुखाकृति भिडियोमा रेकर्ड गरिने छैन । यो सम्पूर्ण प्रक्रिया पहिलो पटकका लागि ९० देखि १२० मिनेट सम्मको समय हुने र त्यसपछिका प्रत्येक परिक्षणहरु १ घण्टा बढिका हुने छैनन् ।

तपाईंलाई आवश्यक निर्देशनहरु सहित प्रत्येक बिहान आफ्नो पिसाब परिक्षण जसमा रजस्वलाको छैटौं दिन देखी लगातार १० दिन सम्म निरन्तर अवलोकन र रेकर्ड गर्नका लागि आवश्यक सामाग्रीहरु उपलब्ध गराइने छ । तपाईं रजस्वला भएको १ वा २ दिन भित्र १ पटक, पिसाबको LH परिक्षणबाट प्राप्त जानकारी अनुसार ओभुलेशन भएको

२४ देखी ४८ घण्टा भित्र दोस्रो पटक र ओभुलेशन पछिको ६ देखी ८ दिन भित्र तेस्रो पटक गरि परिक्षणका लागि ३ पटक उपस्थित हुनुपर्नेछ ।
माथि उल्लेखित सबै चरणहरूको परिक्षण तोकिएको परिक्षण कोठाभित्र र बनेपाको शिर मेमोरियल अस्पतालमा मात्र हुनेछ । परिक्षण समाप्त भएपछि परिक्षणको परिणामका सम्बन्धमा तपाईंलाई छोटकरी जानकारी दिईने छ । परिक्षणका लागि तपाईं उपस्थित हुनुभएको दिनहरूमा तपाईंलाई चिया, जुस र नास्ता दिईने छ र प्रत्येक परिक्षणमा सहभागि हुन आउदा यातायात, समय र तपाईंले उठाउनु परेको असहजता बापत रु ५०० दिईने छ ।

सहभागिको अधिल्लो नाम
मिति

“रजस्वला चक्रको विभिन्न समयमा कृतिम हेड वियरिड राखेर गरिने परिक्षण र पेल्लिक फ्लोर (आड) को विचलन”

जोखिमहरु

यस अध्ययन खोजमा सहभागी हुदाँ केहि जोखिमहरु छन तर दैनिक जिवनका जोखिम भन्दा छैनन् । घरमा केहि उठाउने वा बोक्ने काम गर्दा हुन सक्ने घाउ चोट जस्तै जोखिम हुन सक्छ । खुट्टाउने परिक्षणहरु (Screening Test) को जोखिम प्रसुती सेवा वा हाड जोरनी सेवाका लागी गरिने नियमित परिक्षण भन्दा बढि छैन । कृतिमता र तौल उठाउने क्रियाकलापहरुको कारण मांशपेशी दुख्ने वा उक्त क्रियाकलापको धेरै पछि अन्य मांसपेशी दुख्ने जोखिम भने हुनसक्दछ । अल्ट्रासाउन्डको कुनै खास जोखिम देखिदैन । योनि भित्र राखिने प्रेसर सेन्सरले भने केहि असहज वा चिडचिडाहट ल्याउन सक्छ यदि तपाईंको छालामा कण्डममा प्रयोग भएका रसायनहरुको असर पर्छ भने । यसो भएमा ल्याटेक्स फ्री कण्डम (latex Free Condom) को प्रयोग र एलर्जी कम गर्ने औषधीको प्रयोग गरिने छ ।

फाईदाहरु

निशुल्क परिक्षणका अलावा यस अध्ययनमा सहभागी हुँदा तपाईंलाई कुनै प्रत्यक्ष फाईदा छैन तथापी तपाईंको उत्सुकता सहितको सहभागिताले संसारभर समस्याको रुपमा देखिएको पेल्लिक फ्लोरको विचलनका मुख्य तत्वहरुको बारेमा हामीलाई विशिष्ट ज्ञान प्राप्त गर्न मदत हुनेछ । पेल्लिक फ्लोरको विचलन बाट महिलाहरुलाई जोगाउन अनुसन्धान कर्ता अझ थप जानकारीहरु संकलन गर्न चाहन्छन् ।

सहभागिका अधिकारहरु

सहभागिता पुर्णतया स्वेच्छिक हो । बिना सजाय अध्ययनमा सहभागिता ल्याउन सकिने छ ।

गोपनियता

सबै अभिलेख गोप्य राखिने छन् । तपाईंको लिखित अनुमति बिना यस अध्ययनमा रहेको तपाईंको संलग्नताको बारेमा अरुलाई भनिने छैन । अध्ययन पश्चात प्रकाशित हुने कुनै पनि कागजातमा तपाईंको परिचय खुल्ने कुनै पनि कुराहरु समावेश गरिने छैन ।

लागत/क्षतिपुर्ति

अध्ययनमा सहभागी शुल्क वा लगानी आवश्यक छैन । सहभागिले प्रत्येक ३ चरणको परिक्षणमा सहभागी भए बापत प्रत्येकको रु ५०० का दरले अध्ययन अवधिभरको एकमुष्ट रु १५००।- प्राप्त गर्ने छन् । परिक्षण स्थलमा उपस्थित भएका प्रत्येक दिन बिहान चिया नास्ता उपलब्ध गराईने छ ।

सहभागीको नाम:

मिति:

निशपक्ष तेस्रो ब्यक्ति/संस्था/ समूह

यस अध्ययनमा सहभागी हुने सन्दर्भमा यदि तपाईंले चाहनु भएमा कुनै पश्नहरु/जिज्ञासाहरु र सुझावहरु दिनका लागि निशपक्ष तेस्रो ब्यक्ति/संस्था संग सम्पर्क गर्न सक्नुहुनेछ । जसका लागि निम्न ठेगाना प्रयोग गर्न सक्नुहुनेछ ।

Office of Patient Relations at Loma Linda University. Loma Linda University Medical Center, Loma Linda California 92354. Phone 001-909-558-4647

सहभागिको नाम:

मिति:.....

“रजस्वला चक्रको विभिन्न समयमा कृतिम हेड वियरिड राखेर गरिने परिक्षण र पेल्विक लोर (आड) को बिचलन”

मैले यस अनुसन्धान संग सम्बन्धित सबै विषय बस्तुहरु बढे र अनुसन्धान कर्ताको मौखिक ब्याख्या पनि सुने । अनुसन्धान संग सम्बन्धित मेरो जिज्ञाशाहरुको सन्तुष्ट हुने गरी जवाफ पनि पाँए । अनुसन्धानका सम्बन्धमा मैले बुझ्न सक्ने गरी ब्यख्या गरिएको हो र यसमा म सहभागिह हुन राजी छु । यस सहमति पत्रमा हस्ताक्षर गर्नुको अर्थ म र अनुसन्धान कर्ता, संस्था वा दाता आफ्नो अधिकार र कर्तव्यबाट छुटकारा पाउनेछन् भन्ने होइन् अनुसन्धान संग सम्बन्धित मेरो थप जिज्ञाका लागि मैले यस अनुसन्धानका मुख्य ब्यक्तिलाई Everett B. Lohman III, DSc,PT,OCS मा कार्यलय समय भित्र ००१-९०९-५५८-१००० थप (विस्तारलाईन) ८३१७१ मा सिधा सम्पर्क वा कार्यलय समय बाहेक सोहि नम्बरमा स्वर खबर (Voice mail) गर्ने छु । मैले यो सहमति पत्रको प्रतिलिपि बुझिलिएँ ।

.....
सहभागीको हस्ताक्षर

.....
मिति

अनुसन्धान कर्ताको भनाई
सहभागिको हस्ताक्षर सहितको सहमती पत्र मैले पुनर्विचार गर्ने । मैले अध्ययनका
सम्भावित जोखिमहरु र फाइदाहरुको बारेमा सहभागिलाई बताएको छु ।

.....
मिति:.....
अनुसन्धान कर्ताको हस्ताक्षर

“रजस्वला चक्रको विभिन्न समयमा कृतिम हेड वियरिड राखेर गरिने परिक्षण र पेल्लिभकृलोर (आड) को बिचलन”

सहमती छ छैन सही उत्तरमा घेरा लगाउनुहोस्

सहभागीको नम्बर

सामान्य जनसांख्यिकीय जानकारी

१. नाम जन्म मिति:
 २. महिला हो होइन
 ३. जनजातियता
 ४. धर्म
 ५. तौल
 ६. तपाईंको शहर सहरमा कि गाँउमा? वर्णन गर्नुहोस्

छनौट

१. के तपाईं गर्भवती हुनुहुन्छ वा गर्भवती अवस्थामा हुने अवस्थामा हुनु हुन्छ ?
 छु छैन
 २. गर्भ निरोधकका लागि केहि प्रयोग गर्नुभएको छ ? छ छैन वर्णन गर्नुहोस्
 ३. के तपाईं यस अघि गर्भवती हुनुहुन्थ्यो ? थिए थिइन वर्णन गर्नुहोस्
 ४. गर्भपतन बिचैमा खेर गएको कति महिनामा
 ५. सुत्केरी सामान्य मेशिन प्रयोग
 ६. के तपाईंको आड दुख्छ ? दुख्छ दुख्दैन वर्णन गर्नुहोस ।
 ७. पिसाब रोक्न समस्या छ ? छ छैन वर्णन गर्नुहोस्
 ८. के तपाईंलाई बारम्बार कब्जियत हुन्छ ? हुन्छ हुदैन वर्णन गर्नुहोस्

९. आडका अङ्ग सरेको पत्ता पाउनु भएको छ? छ छैन वर्णन गर्नुहोस्
१०. कहिल्यै आड वा कट्टी दुखेर काम गर्न नसक्नु भएको छ? छ छैन वर्णन गर्नुहोस्
११. के रजश्वला अनियमित हुन्छ? हुन्छ हुदैन
१२. के तपाईंलाई श्वास प्रश्वासमा खराबी भई खोकी लाग्ने गर्छ? गर्छ गर्दैन
१३. के तपाईंलाई कुनै एलर्जि छ? छ छैन उल्लेख गर्नुहोस्
१४. के तपाईंलाई ढाड दुख्ने गरेको छ? छ छैन उल्लेख गर्नुहोस्
१५. के तपाईंलाई घाँटीको समस्या छ? छ छैन उल्लेख गर्नुहोस्
१६. के तपाईंलाई बारम्बार टाउको दुख्ने गरेको छ? गर्छ गर्दैन उल्लेख गर्नुहोस्।

स्त्रीरोग र तौल उठाउने अभ्यास सम्बन्धी

१. नियमित रजश्वला चक्र कति दिनको छ?
२. अघिल्लो रजश्वला चक्रको अन्तिम दिन कहिले थियो?
३. विशेष अवस्था कति अवधिको छ?
४. अन्तिम पटक/पछिल्लो पटक कहिलो आड परिक्षण गर्नुभएको थियो?
५. के तपाईंलाई नाम्लो डोको सहित भारी बोक्नु हुन्छ? उल्लेख गर्नुहोस्।
६. कति तौल उचाल्न सक्नुहुन्छ?
७. कति पटक तौल उचाल्नु हुन्छ?
८. के धूम्रपान गर्नुहुन्छ? गर्छ गर्दैन।

APPENDIX B

STUDY RECRUITMENT POSTER (ENGLISH AND NEPALI)

**Loma Linda University
School of Allied health Professionals
Department of Physical Therapy
In conjunction with Scheer Memorial Hospital**

RESEARCH PROJECT

“Displacement of the pelvic floor with Isometric Simulation of Head Bearing Lifting at 3 Crucial Points in the Menstrual Cycle.”

Researchers need YOUR participation help us identify lifestyle risk factors that could be responsible for fallen uterus in young woman:

1. If you are a woman between the ages of 18-30.
2. You don't have any health problems that effect your ability to lift heavy weights.
3. You want to learn more about your body and how to protect yourself and others from developing a fallen uterus.
4. Participation in this study will involve 3, one hour sessions over 3-4 weeks.
5. Participants in this research study perform moderate traditional lifting tasks and that will allow the researchers to study the effects of lifting on the pelvic floor muscles during each phase of the menstrual cycle.
6. To find out more you can come to the Scheer Memorial Hospital Conference room on Friday, January 17 at 12 O'clock for a hour information and education program and get a free lunch.
7. If you do participate in the study you will be paid for you time.

Please contact Uma Thapa RN at 977 11 66 1111/1112 Scheer Memorial Hospital or email umathapa7@gmail.com or ygray@llu.edu if you are interested and would like more information.

Your participation is much appreciated.

लोमा लिण्डा विश्वविद्यालय
स्कूल अफ एलिड हेल्थ प्रोफेसनल्स
डिपार्टमेन्ट अफ फिजिकल थेरापी
तथा शीर मेमोरियल अस्पतालको संयुक्त प्रयासमा सञ्चालित

अनुसन्धान परियोजना

रजश्वला चक्रको तिनवटा महत्वपूर्ण समयमा कृतिम हेड वियरिड राख्दा पेल्विक फ्लोर (आड) मा पर्ने प्रभाव (सर्ने वा झर्ने)

वयस्क महिलाहरूमा आड खस्ने समस्याका जिम्मेवार जोखिम- तत्वहरू पत्ता लगाउन गरिने अनुसन्धानमा तपाईंको सहभागिताका लागि अवश्यक शर्तहरू:

१. तपाईं १८ देखि ३० वर्षको महिला हुनुपर्छ ।
२. गह्रौ बस्तु उचाल्न तपाईंको स्वास्थ्य समस्या हुनुहुदैन ।
३. तपाईं आफ्नो शरीरको बारेमा जान्न चाहनु हुन्छ र आड खस्ने/सर्ने समस्याबाट आफू र अरुलाई बचाउन चाहनुहुन्छ ।
४. अनुसन्धानमा सहभागि हुँदा ३ देखि ४ हप्ता भित्र प्रत्येक पटक १ घण्टा अवधिको तीन पटक परीक्षणमा सामेल हुनुहुनेछ ।
५. अनुसन्धानमा सहभागि हुँदा नेपालमा परम्परागत रूपमा महिलाले उठाउने गरेका (जस्तै डोको-नाम्लो) बस्तुहरू उठाउने काम गर्नुपर्ने हुन्छ । यसरी बस्तुहरू उठाउँदा रजश्वला चक्र भित्र आडको मांशपेशीमा पर्ने प्रभावका बारेमा अनुसन्धानकर्ताले अध्ययन गर्नेछन् ।
६. थप जानकारीका लागि तपाईं जनवरी १७ तारिख शुक्रवार १२ बजे शीर मेमोरियल अस्पतालको सम्मेलन कक्षमा उपस्थित हुन सक्नुहुनेछ । एक घण्टा लामो छलफलमा सहभागी हुँदा तपाईंलाई निःशुल्क खानाको व्यवस्था गरिएको छ ।
७. अध्ययनमा सहभागी हुन राजी हुनु भएमा तपाईंलाई सहभागी भत्ता दिइने छ । यदि तपाईं अध्ययनमा सहभागी हुन इच्छुक हुनुहुन्छ र थप जानकारी चाहनु हुन्छ भने कृपया निम्न ठेगानामा सम्पर्क गर्न सक्नुहुनेछ ।

शीर मेमोरियल अस्पताल

उमा थापा (RN) ९७७१६६११११/१११२

इमेल : umathapa7@gmail.com or ygray@llu.edu

तपाईंको सहभागिता सहानिय रहनेछ:

APPENDIX C

PELVIC FLOOR DATA COLLECTION SHEET

Nepal Pelvic Floor Study Data Collection Sheet

Participant identifier: _____

Date: _____

IAP Sensor number: _____

Height: _____

Weight: _____

Date of birth: _____

Session (Circle): Session 1/Session 2/Session 3

Circle phase below:

Early Follicular phase (menstruation), Ovulation phase, Luteal phase

Subfolder: my documents/Nepal data/<participant identifier>/Session#/

Trial	File name	Notes
Doka lift	P< >_Lift	Peak to peak voltage= 1- 2- 3- 4- 5- 6-
Valsalva/bear down (moderate 5/10)	P< >_Valsalva	
PFM contraction (moderate 5/10)	P< >_PFM	
Cough (voluntary) strong 8/10	P< >_Cough	
Supine lift – Ramp 5-10 sec up to target	P< >_Ramp	
Supine lift –Ballistic up to target	P< >_Ballistic	
Supine lift –Ballistic – Pre-activate PFM Up to target	P< >_PFMBallistic	

Notes

- Insert Participant identifier number between <>
- Name video file same as data file
- Target supine should be ~50% of peak during doka lift
- Pressure analysis – in Biopac software, only concerned about baseline to peak pressure change
- Nulliparous or not?

APPENDIX D

OB/GYN SCREENING FORM

OB/GYN Screening Form for Study Titled “Displacement of the Pelvic floor with Isometric Simulation of Head Bearing Lifting at 3 Crucial Points in the Menstrual Cycle”

To filled out by the OB/GYN

Pelvic Exam

1. Observation and the speculum exam

Date: _____

Patients Name:

POP-Q stage:

Age:

D.O.B: _____

Gender: Female

When was the last period

Medical History: Circle all that apply.

History of Rape
Heavy menstrual bleeding
Abdominal distortion
Pelvic pressure
Low back pain

dyspareunia

Infertility
Frequent urination
Constipation
Miscarriage or premature labor
Pain with defecation, urination
pelvic mass
STI
Anemic
Hormonal cycles
Parity Index: G₂ P₁ A₁
Cycles (3-4 /28-30)

Family Planning Method:

CI

Copper T

Depo

Norplant

Oral contraceptive

Condoms

Rhythm Method

Is there any abnormal vaginal conditions?

warts

discharge

tissue damage

scaring from episiotomy or other injury

Intact hymen

HPV, Herpes, Chlamydia

Vulvovaginitis

Patient unable to contract the pelvic floor muscles

2. Bimanual exam

Circle all that apply.

Vaginismus? level 1-5?

POP-Q level? (level of prolapse)

Endometriosis (causing pain during period that effects function?)

Uterine fibroids?

Uterine conditions

Ovarian condition

3. Recto-Vaginal Exam

Complete if indicated.

I certify that I have examined this woman and she has no conditions that could limit her ability to participate in this study.

Physician's

Signature: _____

Date: _____

APPENDIX E

LOMA LINDA UNIVERSITY INSTITUTIONAL REVIEW BOARD APPROVAL



LOMA LINDA UNIVERSITY
ADVENTIST HEALTH
SCIENCES CENTER

INSTITUTIONAL REVIEW BOARD

RESEARCH PROTECTION PROGRAMS
24887 Taylor Street • Suite 202 • Loma Linda, CA 92350
(909) 558-4531 (voice) • (909) 558-0131 (fax)

Initial Approval Notice - Full Board

IRB# 5130382

To: **Lohman III, Everett B**

Department: **Physical Therapy**

Protocol: **Isometric simulation of head bearing lifting and it's effects on the pelvic floor during the menstrual cycle**

The protocol and consent form for this study were reviewed and approved by the IRB at a regularly scheduled meeting on 08-Jan-2013. This decision included the following determinations:

Risk to research subjects: **Minimal**

Approval period begins: **08-Jan-2014** and ends **07-Jan-2015**

Stipulations of approval: 1) Waived HIPAA authorization.

2) Subsequent continuing review will be conducted using expedited procedures.

See attached list of items (if applicable).

See Appendix A for Conditions of Approval.

Adverse events and unanticipated problems must be reported in accord with the attached Adverse Event Reporting Matrix A.

All investigators are responsible for assuring that studies are conducted according to the approved protocol. Principal investigators are responsible for the actions of sub-investigators and staff with regard to this approval.

Please note the PI's name and the assigned IRB number, as indicated above, on any future communications with the IRB. Direct all communications to the IRB c/o the Office of Sponsored Research.

Thank you for your cooperation in LLU's shared responsibility for the ethical use of human subject in research.

Signature of IRB Chair/Designee: R L Rigsby

Date: 1/16/14

Loma Linda University Adventist Health Sciences Center holds Federalwide Assurance (FWA) No. 00006447 with the U.S. Office for Human Research Protections, and the IRB registration no. is IORG000226. This Assurance applies to the following institutions: Loma Linda University, Loma Linda University Medical Center (including Loma Linda University Children's Hospital, LLU Community Medical Center), Loma Linda University Behavioral Medicine, and affiliated medical practices groups.

IRB Chair:
Rhodes L. Rigsby, M.D.
Department of Medicine
(909) 558-2341, rrigsby@llu.edu

IRB Administrator:
Linda G. Halstead, M.A., Director
Research Protection Programs
Ext 43570, Fax 80131, lhalstead@llu.edu

IRB Specialist:
Anuradha Diekmann, MPH, CCRP
Research Protection Programs
Ext 86215, Fax 80131, adiekmann@llu.edu

APPENDIX F

NEPAL HEALTH RESEARCH COUNCIL APPROVAL



Nepal Health Research Council Estd. 1991

Ref. No. : 877

29 January 2014

Ms. Uma Thapa
Principal Investigator
Scheer Memorial Hospital
Banepa

Ref: **Approval of Research Proposal** entitled **Displacement of Pelvic floor with isometric simulation with head bearing lifting (ISHB) at 3 crucial points of menstrual cycle**

Dear Ms. Thapa,

It is my pleasure to inform you that the above-mentioned proposal submitted on 31 December 2013 (**Reg. no. 212/2013** please use this Reg. No. during further correspondence) has been approved by NHRC Ethical Review Board on 26 January 2014 (2070-10-12).

As per NHRC rules and regulations, the investigator has to strictly follow the protocol stipulated in the proposal. Any change in objective(s), problem statement, research question or hypothesis, methodology, implementation procedure, data management and budget that may be necessary in course of the implementation of the research proposal can only be made so and implemented after prior approval from this council. Thus, it is compulsory to submit the detail of such changes intended or desired with justification prior to actual change in the protocol.

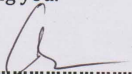
If the researcher requires transfer of the bio samples to other countries, the investigator should apply to the NHRC for the permission.

Further, the researchers are directed to strictly abide by the National Ethical Guidelines published by NHRC during the implementation of their research proposal and submit progress report and full or summary report upon completion.

As per your research proposal, the total research amount is US\$. 10,000.00 and accordingly the processing fee amounts to NRs. 9,955. 00. It is acknowledged that the above-mentioned processing fee has been received at NHRC.

If you have any questions, please contact the research section of NHRC.

Thanking you.


.....
Dr. Guna Raj Lohani
Executive Chief

Tel:+977-1-4254220, 4227460, Fax: +977-1-4262469, Ramshah Path, P.O. Box 7626, Kathmandu, Nepal.
Website: <http://www.nhrc.org.np>, Email : nhrc@nhrc.org.np