THE LONG-TERM PELVIC FLOOR HEALTH OUTCOMES OF WOMEN AFTER CHILDBIRTH: THE INFLUENCE OF LABOUR IN THE FIRST PREGNANCY

by

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ABSTRACT

Introduction: Labour and/or vaginal delivery may have long-term pelvic floor health consequences. The purpose of this study was to estimate the influence of type of labour and pregnancy factors on these outcomes.

Methods: This population-based cohort study used linkage between the Nova Scotia Atlee Perinatal Database (NSAPD), the Medical Services Insurance (MSI) Database and the Canadian Institute for Health Information (CIHI) Discharge Abstract Database from 1988 to 2006. Urinary and anal incontinence, pelvic organ prolapse and fistula disorders were compared for women undergoing Caesarean section without labour to women undergoing labour and any method of delivery. Multivariate logistic analyses and time-to-event analyses were performed.

Results: Absolute risks for the selected pelvic floor health outcomes were small (regardless of type of labour in the first pregnancy). Women with one or more deliveries who had no labour in their first pregnancy had reduced risks for all pelvic floor health outcomes except fistula formation, although these finding were dependent on the outcome codes used in the analysis; they were also less likely to develop these outcomes during the study period.

Conclusion: Women undergoing obstetrically indicated caesarean section without labour in their first delivery had reduced risks of important pelvic floor health disorders, even after multiple deliveries. These findings contribute important information for health care providers when counseling women and their families who are weighing the risk of long-term pelvic floor disorders against the benefits of spontaneous vaginal delivery.

LIST OF ABBREVIATIONS USED

BMI	Body Mass Index
CIHI	Canadian Institute for Health Information
CI	Confidence Interval
DAD	Discharge Abstract Database
GEE	Generalized Estimating Equations
HDNS	Health Data Nova Scotia
HR	Hazard Ratio
MSI	Medical Services Insurances
MSID	Medical Services Insurances Database
NSAPD	Nova Scotia Atlee Perinatal Database
OR	Odds Ratio
PFD	Pelvic Floor Disorder(s)
MRI	Magnetic Resonance Imaging
SD	Standard Deviation

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CHAPTER 1 INTRODUCTION

In Obstetrics and Gynaecology, one of the most controversial topics involves the long-term maternal sequelae associated with mode of delivery or type of labour. While spontaneous vaginal delivery is considered the "natural" way to deliver, there is increasing evidence that labour and/or vaginal delivery may have long-term maternal health consequences, such as pelvic floor injuries, leading to urinary or fecal incontinence or pelvic organ prolapse. These conditions can be grouped together and commonly referred to as pelvic floor dysfunction (PFD). PFD symptoms may present in the immediate postpartum period and then gradually improve, but return and peak after the age of 50, usually after a woman has passed her reproductive age. Although urinary or fecal incontinence and pelvic organ prolapse are unlikely to be life threatening conditions, they impact negatively on a woman's sense of confidence, well-being, and ultimately her quality of life.

Urinary incontinence is defined as the involuntary loss of urine that is a social or hygienic issue for the individual afflicted [1], while anal incontinence (fecal or flatal) is defined as the involuntary or passive passage of stool or gas that occurs after an individual has already acquired the appropriate toileting skills. Pelvic organ prolapse is a condition whereby the female pelvic structures such as the uterus, bladder or rectum herniate into and at times, out of the vaginal canal. This in part is secondary to the loss of different levels of support structures within the pelvic floor, including muscles, ligaments and nerves. Urogenital fistulas are abnormal connections occurring between urogenital structures, creating a passage for the involuntary loss of urine, gas or stool through the vagina. A vesicovaginal fistula is a hole between the bladder and the vagina, and a rectovaginal or anovaginal fistula occurs between the rectum or anus with the vagina.

Caesarean delivery without labour has been proposed as a way of preventing pelvic floor injury. There continues to be debate among health professionals who provide obstetrical care regarding the safest mode of delivery for both mother and infant. In 2005, Wu and colleagues reported the results of a web-based questionnaire administered to urogynaecologists and obstetrician/gynecologists in the United States to evaluate physician preference for Caesarean deliveries performed without labour in preventing pelvic floor disorders [2]. Of the physicians responding (response rate of 61%), 65.4% stated that they would perform a Caesarean section without labour in the absence of any obstetrical indication. Nearly 30% had already performed a Caesarean delivery without labour and 62% of urogynaecologists would support Caesarean delivery without labour to prevent long-term sequelae of urinary incontinence. Similar results were achieved by Kenton and colleagues the same year [3]. This questionnaire-based study demonstrated that 67% of recent graduates in Obstetrics and Gynaecology were willing to perform a Caesarean section without labour to prevent pelvic floor injury. A voluntary survey of Canadian health care professionals was undertaken and results published around the same time as the other surveys [4]. The authors reported that male health care providers were more apt to offer elective caesarean delivery without an obstetrical indication (35% vs. 16 %, OR 2.7, CI 1.2, 6.0). They were also more likely to emphasize the possible protective effect of caesarean delivery (55% vs. 38%; OR 1.9 CI 1.0, 4.0). This survey also determined that most health care professionals would opt for a caesarean delivery for themselves when faced with possible operative vaginal delivery (OR 1.98 CI 1.1, 3.5). With increasing media awareness and the burden of stigmas with such labels as “too posh to push”, there is an urgent need for well-designed evidence to guide appropriate management [5].

The purpose of this study was to determine the effect of type of labour and maternal, obstetrical and neonatal factors on long-term pelvic floor health sequelae. The Nova Scotia Atlee Perinatal Database is a unique resource that is able to provide detailed information about maternal, obstetrical and neonatal factors for deliveries to residents of Nova Scotia. Comprehensive provincial information dates back to 1988, providing more than twenty years of follow-up after an index delivery to assess the effect on a woman’s pelvic health status.

The Nova Scotia Atlee Perinatal Database was used in this study to categorize women based on type of labour (no labour and labour groups), and to capture relevant maternal and neonatal characteristics and obstetrical complications and interventions which may have influenced the type of labour on pelvic floor health outcomes of interest.

These data underwent linkage to the Medical Services Insurance (MSI) Database, which collects all information related to family physician and specialty physician, including inpatient and outpatient clinical billings, coded by disease diagnoses and procedures. This linkage allowed evaluation of patient utilization of physicians (such as urologists and gynaecologists) who provide care for incontinence and pelvic organ prolapse. It captured conservative as well as surgical interventions, from 1998 to 2006.

The Canadian Institute for Health Information (CIHI) Discharge Abstract Database contains information on medical diagnoses and procedures from hospital discharge data. This database was utilized to extract information regarding the primary pelvic floor health outcome variables using the International Classification of Diseases (ICD) codes (ICD-9 to 1998 and then ICD-10 after 1998). This database captures those women who had pelvic floor disorders that ultimately necessitated surgical intervention; this database allowed access to outcome data on the more severe cases of pelvic floor disorders requiring hospitalization between the years 1990 to 2006.

The results obtained from this database linkage study provide important information to health care providers and women who are weighing the risks of long-term incontinence complications and pelvic floor disorders with type of labour. This information has important implications in the translation of evidence-based knowledge into safe clinical practice. It provides information to guide effective preconception counseling, antenatal management, management during labour and delivery, and care in the postpartum period, to optimize future reproductive and gynaecologic health.

1.1 LITERATURE REVIEW METHODS

Periodic systematic reviews of the English literature, from 1966 to 2015 were undertaken for maternal gynaecologic outcomes following childbirth. Key words and Mesh headings included pelvic organ prolapse, urinary incontinence, urge incontinence, stress incontinence, anal incontinence, childbirth, mode of delivery, method of delivery, Caesarean delivery, Caesarean section, vaginal delivery, labour and maternal outcomes. The search was limited to studies on humans written in the English language. New and relevant updates to prior publications and abstracts presented at national and international scientific meetings were also reviewed and included based on their relevance.

The initial search retrieved 299 studies related to urinary incontinence, 220 studies on anal incontinence and 70 papers related to pelvic organ prolapse. Abstracts of all studies retrieved from this search were reviewed for relevance, 74 studies were included in this review based on applicability to the topic with priority given to studies that were original articles, clinical trials and recently published. A hand search of references identified by the electronic search was also performed.

There was significant overlap in outcomes that were studied, with many investigators having looked at pelvic floor disorders as a group. There were considerably more studies on incontinence than on pelvic organ prolapse. One study which reviewed the scientific literature concluded that pelvic organ prolapse is generally harder to study [6]; the authors explained that numerous etiological and pathophysiological factors and variations in definitions and diagnoses mitigate when and how pelvic organ prolapse is diagnosed and treated. This chapter presents a review of recently published literature in this area.

1.2 MATERNAL MORBIDITY AND ECONOMIC IMPLICATIONS ASSOCIATED WITH MODE OF DELIVERY

Significant considerations in the evaluation of outcomes associated with mode of delivery include maternal morbidity in the peri-partum period. The Term Breech Trial was a multi-centered, randomized controlled trial of 2088 women, undertaken to determine if planned Caesarean delivery compared to planned vaginal delivery reduced the risk of adverse perinatal outcomes in breech presentation at term by intention-to-treat analysis [7], and it is the only randomized trial to date to undertake this comparison. At three months follow-up postpartum, the authors reported a decrease in adverse perinatal outcomes without an increase in immediate maternal morbidity in the planned caesarean group; they reported an increase in maternal morbidity following Caesarean delivery during active labour and a reduction in maternal morbidity with a short active phase of the second stage of labour (pushing for less than thirty minutes) [8]. In addition to other assessments of maternal morbidity by mode of delivery, this question has been comprehensively studied in Nova Scotia and has demonstrated significant adverse maternal outcomes following Caesarean delivery performed in labour, including increased risks for infection, hemorrhage and intra-operative trauma [9-11].

A follow-up report from the Term Breech Trial evaluated the estimated cost of each of the two management strategies to determine whether planned Caesarean section in the context of breech presentation is more or less expensive than planned vaginal delivery [12]. The cost analysis was undertaken from the perspective of a third party payer, e.g. Ministry of Health. Health care resource utilization and associated unit costs were collected for all women and infants who participated in the trial. In order to increase the applicability to women in Canada, analysis was limited to women in nations with low perinatal mortality. The results were analyzed according to intention-to-treat and a sensitivity analysis was performed to explore the robustness of the results over alternative unit cost values. Planned Caesarean delivery was shown to be significantly less expensive than planned vaginal birth, with total costs of planned vaginal birth exceeding the cost of a Caesarean without labour when other interventions during labour were also undertaken, such as induction of labour with oxytocin and epidural anesthesia. This analysis was not the primary outcome measure and subgroup analysis was not planned as part of the original study protocol. Also, cost savings were restricted to the procedures and care during and immediately following the birth and did not take into account costs of care afterwards.

Studies from Nova Scotia considered the economic implications of type of labour and method of delivery in a low risk nulliparous population using a large provincial database [13, 14]. Cost assessment included maternal readmission, transfer to intensive care unit, obstetrician and anesthesia costs, nursing hours in labour and delivery, postpartum and neonatal care units, as well as costs of interventions such as epidural use, induction of labour and other consumables. Caesarean delivery during labour was the most costly method of delivery with nursing care in labour and delivery being the major contributor [13]. Long-term cumulative costs of hospital care in the first and subsequent pregnancies associated with differing modes of delivery in the initial pregnancy were also evaluated [14]. The cumulative cost of spontaneous vaginal delivery was significantly lower than the cumulative costs of assisted vaginal delivery or Caesarean delivery in labour for both one and two additional deliveries. The costs of initial spontaneous vaginal delivery were lower than the cost of Caesarean without labour for one additional delivery, but not for two additional deliveries [14].

These morbidity and cost studies provide a rationale for consideration of Caesarean delivery without labour for the patient subgroup at risk for higher rates of intra-partum intervention, such as older primiparous women. This information must be considered when evaluating long-term pelvic floor health outcomes associated with type of labour.

1.3 TYPE OF LABOUR AND ROUTE OF DELIVERY

In general, there are two basic routes of delivery, caesarean delivery or vaginal delivery. In another broad perspective, one can also consider two other ways of childbirth, one following labour and one without labour. Parturition is defined as the process of childbirth and encompasses all the stages that occur as mother is about to deliver her infant. With the onset of labour, there is often the rupture of amniotic membranes and rhythmic uterine contractions that progressively strengthen to bring down the baby through the birth canal. What naturally should follow are the progressive effacement (thinning) and dilation (opening) of the cervix that is the opening to the uterus that houses the baby and pregnancy tissues such as the placenta and amniotic membranes, fluid and cord. This is described as the first stage of parturition. Second stage follows after full dilation of the cervix, with maternal expulsive efforts or pushing that ultimately helps the baby pass through the birth canal. The third stage is the immediate period after mother has delivered her infant to the delivery of the placenta, and she is now postpartum. At any point in the first two stages of parturition, care providers may need to make a decision regarding intervention that may necessitate proceeding to a caesarean delivery, and during the second stage of assisting with instruments such as a vacuum or forceps to facilitate the vaginal delivery. Indications for such decisions often include both maternal and fetal factors, such as lack of progress with labour or signs of possible fetal distress.

A woman who has either chosen or been advised to proceed with a caesarean section without labour, usually presents late in the third trimester of pregnancy, often between 39 weeks to 40 weeks of gestation, to have surgery to deliver her baby. There may be early stages of labour at times, with rupture of membranes or onset of mild contractions, but she will often present for her Caesarean section prior to further progression.

1.4 EPIDEMIOLOGY OF PELVIC FLOOR DISORDERS

Pelvic floor disorders, such as urinary and anal incontinence and pelvic organ prolapse, are common in older women. It is estimated that 30-50% of women report having varying degrees of urinary incontinence, and typically up to 25% note leakage on a weekly to daily basis [15, 16]. The Epidemiology of Incontinence in the County of Nord-Trondelag (EPINCONT) study was a large community-based questionnaire study of the prevalence of any type of urinary incontinence in an unselected Norwegian female population over the age of twenty [17]. The overall response rate was 80% with a study population of about 28,000 women. This study demonstrated that 25% of women report involuntary loss of urine, with the prevalence of incontinence increasing with age (12% for women younger than 30 years of age and greater than 40% for women older than 90 years of age). One half of the women had stress urinary incontinence, 11% had urge incontinence, and 36% had a picture of mixed incontinence. This survey confirmed that involuntary loss of urine is highly prevalent among adult women.

Up to 10% of women living in the community report anal incontinence, of which about 50% report incontinence of feces [18, 19].

Pelvic organ prolapse has been observed in approximately 30% of middle-aged women enrolled in a large American trial evaluating hormone replacement therapy, the Women's Health Initiative [20]. Another survey study reported by Wu et al, in 2014 using the US National Health and Nutrition Examination Survey, demonstrated that one quarter of women report at least one of the pelvic floor disorders [21].

The actual burden of disease is likely significantly underestimated than what we capture in such studies. Many women with pelvic floor disorders may never present for medical therapy, or self-treat with over the counter remedies and management options. Some may be treated conservatively by their primary care physicians. One in nine women will eventually undergo surgery to correct these pelvic floor disorders during their lifetime [22].

1.5 PATHOPHYSIOLOGY OF PELVIC FLOOR DISORDERS

The pelvic floor consists of the levator ani muscles, the urethral and anal sphincters, and other structures, including the nervous supply to these muscles and connective tissue, which maintain normal function and strong support for the pelvic organs such as the bladder, uterus and rectum. Injury to the urethral sphincter and/or a change in its anatomic position leads to urinary incontinence. A damaged anal sphincter can lead to fecal or flatal incontinence, together commonly referred to as anal incontinence. Injury to the levator ani muscles and the nervous supply will lead to pelvic organ prolapse [23].

It is believed that during childbirth, specifically vaginal delivery of a term infant, the pelvic floor is exposed to forces from the presenting part of the fetus as it passes through the vaginal canal, and also from maternal expulsive efforts to deliver her baby. The pelvic floor stretches and distends. This process is believed to disrupt the levator ani muscles and injure the pudendal nerve, resulting in functional as well as anatomical changes in the muscles, nerves and connective tissue of the pelvic floor [23]. It is not possible at the time of delivery to assess damage to the major muscles of the pelvic floor, nor their innervation. These injuries may not fully recover, and may lead to disorders of the pelvic floor.

Friedman et al. demonstrated in their prospective cohort study of over 600 women who were followed for up to 11 years that pelvic floor muscle strength is decreased after vaginal delivery as compared to women who had only Caesarean deliveries. The lowest pelvic floor strength was observed in women who had a forceps assisted delivery. The authors demonstrated a significant association between reduced pelvic floor muscle strength and anal incontinence and pelvic organ prolapse [24].

Pregnancy may in itself be a major risk factor. There is evidence that parity plays a significant role in the prevalence of pelvic floor disorders. One cross-sectional study, conducted as a national survey of women in the United States demonstrated that the prevalence of pelvic floor disorders nearly tripled from nulliparity (12.8%) to a parity of three or more (having delivered three or more babies) (32.4%). Specifically they looked at all incontinence and pelvic organ prolapse [25].

There are prospective studies utilizing magnetic resonance (MR) imaging and other diagnostic imaging tools, that suggests injury to the pelvic nerves and muscles leads to anatomic disruption of the pelvic floor after childbirth, leading to subsequent pelvic floor disorders, and that labour and vaginal delivery may be major risk factors for the development of these disorders [22, 26-31].

Indeed, there is a growing body of literature that indicates vaginal delivery may be an important risk factor for the development of future pelvic floor disorders. One nested case-control study involving linkage of the Swedish Hospital and Discharge Registry to the Swedish Birth Registry, with over 15,000 women with pelvic organ prolapse matched with controls, found that the risk of a subsequent hospital admission for undergoing surgery for pelvic organ prolapse was lower in women who had Caesarean delivery when compared with women who had a vaginal delivery, OR 0.18 (95% CI 0.16-0.20), with overall Hazard Ratio 0.20 (95% CI 0.18-0.22) [32]. In 2011, another study conducted from the Swedish national registry found that women with only vaginal deliveries had significantly higher rates of urinary incontinence (HR 2.9, 95% CI 2.4-3.6) and prolapse surgery (HR 9.2, 95% CI 7.0-12.1) as compared to women with Caesarean deliveries only. This study did not discriminate between caesarean deliveries with and without labour [33]

Handa et al, in a prospective cohort study of 1011 women, evaluating stress incontinence and prolapse, 5 to 10 years after a first delivery, demonstrated that women who had only vaginal births (excluding operative vaginal deliveries) when compared to women who had Caesarean delivery before active labour, had increased risk of stress incontinence (OR 2.9, 95% CI 1.5-5.5) and prolapse (OR 5.6; 95% CI 2.2-14.7) [34]. Similarly, Gyhagen et al, surveyed over 5200 women with one delivery 20 years previously and found that vaginal delivery was associated with a 67% increased risk of urinary incontinence and after 10 years this increased to 275% increased risk as compared to caesarean delivery. Vaginal delivery was associated with an increased risk of urinary incontinence (OR 1.7, 95% CI 1.5-1.9) and pelvic organ prolapse (OR 2.6, 95% CI 2.0-3.3) [35, 36].

On average, women may not present with symptoms of pelvic floor disorders until after their childbearing years, typically as they enter menopause, 20 to 30 years later [37, 38]. It is also believed that the deficiency in local hormonal support that is induced after menopause compounds the process of pelvic floor disorders. There are estrogenic receptors in all of the tissues of the female pelvis. During the reproductive age (12 to 49 years old), the integrity of muscles, ligaments, fascia, and nervous supply as well as function of the pelvic organs are maintained by estrogen. After menopause and with the decline of estrogen production by the ovaries, there is a peak in occurrence of these disorders of the pelvic floor, and therefore it may be difficult to separate the confounding issue of aging from the incidence of pelvic floor disorders after menopause [37, 39-41].

1.6 THE INFLUENCE OF TYPE OF LABOUR AND ROUTE OF DELIVERY ON URINARY INCONTINENCE

The association between route of delivery (including Caesarean and vaginal delivery) and urinary incontinence has been evaluated using a variety of methodological techniques, including questionnaire, cross-sectional, and prospective cohort studies and randomized controlled trials. A follow-up to the EPINCONT study evaluated the risks of incontinence associated with Caesarean section and vaginal delivery [42]. Data on incontinence on about 15,000 women younger than 65 years of age was linked to the medical birth registry of Norway. These women were either nulliparous or had undergone only Caesarean delivery or only vaginal delivery. Information such as frequency, amount of urine loss, the circumstances, urgency, and to what extent she considered leakage of urine a problem was collected if there was reported involuntary loss of urine. The prevalence of any incontinence was 20.7%. The prevalence of moderate or severe incontinence was 8.7%. The prevalence of stress, urge and mixed incontinence were 12.2%, 1.8%, and 5.9%, respectively. The prevalence of any incontinence increased with increasing age, BMI, years since last delivery and on the vaginal delivery group with parity. Any incontinence was greater in the Caesarean section and vaginal delivery groups when compared with the nulliparous group (OR 1.5, 95% CI 1.2-1.9 and OR 2.3, 95% CI 2.0-2.6, respectively). There was no difference in the prevalence of incontinence by type of Caesarean group (with or without labour). Body mass index was not found to be a confounding variable. The proportion of any incontinence among women who delivered vaginally that would be preventable by Caesarean delivery was estimated to be 35%. The population-attributable risk of incontinence with vaginal delivery was 33%. Women delivering by Caesarean section had higher risk for any incontinence over nulliparous women, but vaginal deliveries increased this risk, particularly for moderate to severe incontinence.

Buchsbaum and colleagues investigated the role of familial factors and vaginal delivery in their study on the development of urinary incontinence in nulliparous postmenopausal women and corresponding rates in their biological sisters who had at least one vaginal delivery [43]. Pairs of postmenopausal sisters were recruited through advertisements, and eligible sister pairs were asked to complete questionnaires regarding episodes of urinary incontinence. They were also invited to undergo examination. Demographics between the sister pairs were similar. Investigators found a high concordance but no statistically significant difference in the rate of urinary incontinence between nulliparous women and their parous sisters (P=.08). The authors hypothesized an underlying familial or genetic predisposition for the development of urinary incontinence.

In contrast to the Buchsbaum study, the Evanston-Northwestern Twin Sisters questionnaire study demonstrated that delivery mode is a major environmental determinant of stress urinary incontinence [44]. The investigators used a large cohort of identical twin sisters in an attempt to differentiate between environmental and genetic determinants. Two hundred and seventy-one sisters were enrolled and completed validated questionnaires on pelvic organ prolapse and urinary incontinence. Increasing age, parity, and body mass index all conferred increased risk of stress urinary incontinence. Vaginal birth was also a strong predictive factor for stress urinary incontinence (OR 2.28, 95% CI 1.14-4.55). Episiotomy and forceps deliveries were not independently predictive of stress urinary incontinence.

Cross-sectional studies have reported that more than a third of women report symptoms of stress urinary incontinence during pregnancy, suggesting that damage to the pelvic floor leading to stress urinary incontinence may occur prior to delivery [45, 46]. Numerous prospective studies evaluating women at varying times post-partum, however, have shown an increased incidence of urinary incontinence in the vaginally delivered groups (up to 32%) when compared to the Caesarean groups [47-53].

A prospective observational cohort study evaluating the long-term effects of vaginal delivery on moderate to severe urinary incontinence in primiparas only delivering vaginally, demonstrated that the risk of stress urinary incontinence was nearly four times the baseline risk at five and ten years from the index delivery [54].

The Childbirth and Pelvic Symptoms (CAPS) study was a prospective study designed to evaluate the risk factors for urinary and fecal incontinence after childbirth [55]. Women were enrolled immediately postpartum and then were interviewed six months postpartum using validated questionnaires. Of the original 921 women enrolled, 82% were interviewed postpartum. Risk factors for postpartum urinary incontinence were antenatal incontinence (OR 3.5, 95% CI 2.4-5.2) and higher body mass index (OR 1.2, 95% CI 1.1-

1.4). This study demonstrated that Caesarean delivery was protective against urinary incontinence (OR 0.5, 95% CI 0.3-0.9).

The first prospective cohort study to evaluate the risk of urinary incontinence in primiparas after Caesarean delivery without labour separate from other methods of delivery demonstrated that Caesarean delivery without labour was protective against urinary incontinence when compared to spontaneous vaginal delivery at six months postpartum (RR 0.6, 95% CI 0.3-1.0) [56].

Limited randomized controlled trial data exist which assesses the difference in pelvic floor symptoms after Caesarean delivery without labour or vaginal birth. A follow-up evaluation of outcomes by mode of delivery in the Term Breech Trial specifically evaluating urinary and fecal incontinence, resumption and comfort during sexual activity and other factors was performed at three months and two years following delivery [57, 58]. At three months, women in the planned Caesarean delivery group reported less urinary incontinence than those in the planned vaginal birth group (4.5% versus 7.3%, RR 0.62, 95% CI 0.41-0.93). Other outcomes did not differ significantly [57]. At two years, there were no differences in incontinence in women after planned vaginal delivery compared to planned Caesarean delivery [58].

1.7 THE INFLUENCE OF TYPE OF LABOUR AND ROUTE OF DELIVERY ON ANAL INCONTINENCE

Studies utilizing magnetic resonance (MR) imaging and endo-anal ultrasound have demonstrated that the incidence of anal sphincter disruption (from a laceration or injury) is as high as 35% in women after vaginal birth of one child and 44% in women after multiple vaginal births [29-31]. Burgio et al, in 2007 clearly demonstrated that severe obstetrical perineal tears were a risk factor for the development of anal incontinence (OR 2.6, 95% CI (1.6-4.2)) [55].

Postpartum anal incontinence is known to be common following childbirth, with an estimated prevalence from 5% to 26% in the first year following delivery [59]. However, how mode of delivery factors in the development of anal incontinence is very controversial [60-63], and there are numerous mitigating factors such as high body mass index (BMI), operative vaginal delivery or severe perineal lacerations and bowel issues such as chronic constipation. These all may increase the risk of anal incontinence [64, 65]. One meta-analysis of 18 studies with 12,237 women, the risk of anal incontinence was demonstrated to be significantly greater after spontaneous vaginal delivery when compared to Caesarean delivery (OR 1.32, 95% CI 1.04-1.68) [66]. These studies all consistently had short-term follow-up. Handa et al, in their study with 5 and 10 years of follow-up did not show any significant differences in risk [34].

There are few clinical studies evaluating anal (fecal and flatal) incontinence by mode of delivery. The Evanston-Northwestern Twin Sister study evaluated the identical twin sister pairs for risk factors in the development of anal incontinence by validated questionnaires. Caesarean delivery after initiation of labour was associated with a lower prevalence of fecal incontinence (4%) when compared to vaginal deliveries (17%) but this difference was not statistically significant. Prevalence rates of flatal incontinence were not significantly different among women who had Caesarean delivery only and those who had at least one vaginal birth (27% compared with 35%, OR 0.92, 95% CI 0.52-1.56, P=.71). Women undergoing only Caesarean sections without labour did not report anal incontinence. Significant independent risk factors for anal incontinence were increasing age (age > 40), menopause, obesity, increasing parity, and concomitant stress urinary incontinence [44, 67].

Similarly, Guise evaluated mode of delivery and fecal incontinence in postpartum women at 3 to 6 months and demonstrated that fecal incontinence was associated with higher parity, mode of delivery, severe perineal tears and smoking [68].

The results from prospective studies have been mixed. Fynes [69] demonstrated by unadjusted analyses that women delivering via any type of Caesarean section (Caesarean with and without labour) did not have any fecal incontinence postpartum, yet those women in the same period of time delivering vaginally had altered fecal continence of 19%. Farrell [70] examined peri-partum risk factors for anal incontinence after eliminating the confounding factor of antepartum anal incontinence and distinguishing between Caesarean delivery with and without labour. The rates of flatal incontinence were 17% for spontaneous vaginal delivery, 18% for Caesarean delivery, 33% after vacuum delivery, and 44% after forceps delivery. Caesarean delivery during labour was associated with an increased risk over Caesarean delivery without labour, 21% versus 0%, respectively. Rates of fecal incontinence were 3% in the Caesarean delivery group, 4% for spontaneous vaginal delivery and 9% for forceps assisted vaginal delivery. The incidence of fecal incontinence among those women with third degree or greater tear was 10%. The authors concluded that the anal continence mechanism is compromised by forceps delivery, increasing the risk of flatal and fecal incontinence when compared to any Caesarean deliveries, and Caesarean deliveries without labour were protective of the anal continence mechanism. The CAPS study established risk factors for postpartum anal incontinence with identifiable anal sphincter tears at time of delivery [55]. They were unable to demonstrate that Caesarean delivery was protective against anal incontinence. The Term Breech Trial did not demonstrate any significant difference in the rates of anal incontinence in women delivering vaginally versus those who were delivered by Caesarean section at three months or two years postpartum [57, 58].

One review of the literature examining anal incontinence and route of delivery concluded that Caesarean section without labour has not been shown to decrease the risk of anal incontinence and that the recent studies lack the power, matched controls and also the long-term follow-up necessary to be able to make any clear recommendations on how route of delivery impacts the risk of anal incontinence [59].

1.8 THE INFLUENCE OF TYPE OF LABOUR AND ROUTE OF DELIVERY ON PELVIC ORGAN PROLAPSE

There are few studies evaluating the incidence of pelvic organ prolapse and route of childbirth. The majority of women present with symptoms of pelvic organ prolapse at or after menopause. Since pelvic organ prolapse is not routinely evaluated at examinations during regular health check-ups, it may not be diagnosed until symptoms are quite pronounced. The length of follow-up required to evaluate the occurrence of pelvic organ prolapse following childbirth presents a significant methodological challenge and may be associated with prohibitive study costs. In a follow-up publication by Buchsbaum and colleagues, they reported on the role of vaginal delivery and the development of pelvic organ prolapse in nulliparous postmenopausal women and the corresponding rates in their biological sisters who had at least one vaginal delivery [71]. The same eligible sister pairs who were asked to complete questionnaires regarding urinary incontinence had also answered similar questions regarding symptoms of pelvic organ prolapse and also invited to undergo examination. Once again, there was a high concordance of pelvic organ prolapse between the sisters. Where there was discordance regarding prolapse, the parous sister had more severe prolapse in 80% of cases.

One recent cross-sectional study of over 1000 women, investigated the etiologies of pelvic organ prolapse and stress urinary incontinence and found that having delivered by caesarean section was protective against the future development of pelvic organ prolapse by three fold (OR 0.33, 95% CI 0.13-0.85) [72].

1.9 SUMMARY

The gold standard for evidence-based medicine is the randomized clinical trial (RCT). In the evaluation of long-term pelvic floor health outcomes after childbirth, the ability to conduct a randomized controlled trial is limited by an incomplete understanding of the full spectrum of etiological factors for development of pelvic floor disorders, the feasibility of prolonged follow-up needed to truly understand the impact of childbirth on pelvic floor disorders in women, and the ethical concerns in randomizing a patient to a treatment that may adversely affect her or her fetus.

Retrospective and prospective studies evaluating urinary and anal incontinence thus far have demonstrated inconsistent findings in terms of the effect of type of labour and mode of delivery on long-term pelvic floor health outcomes. Review of the literature has demonstrated that pelvic floor disorders are very common and increasing age, pregnancy, and increased parity are independent risk factors for the development of these disorders. Vaginal route of delivery would appear to increase this risk but no studies have been able to successfully compare those women who have vaginal delivery with those women who have Caesarean deliveries without labour.

One systematic review assessed the prevalence of postpartum urinary incontinence after Caesarean section [73]. The authors of this study demonstrated that Caesarean section reduced the risk of postpartum stress urinary incontinence from 16 to 9.8% (OR 0.56, 95% CI 0.45-0.68) in cross-sectional studies, and from 22 to 10% (OR 0.48, 95% CI 0.39-0.58) in cohort studies. The numbers of Caesarean sections needed to prevent one case of stress urinary incontinence according to this study were 10-15.

The literature to date continues to have significant methodological limitations. Much of the data on urinary incontinence and pelvic organ prolapse is based on patient self-report surveys or questionnaires which are limited by volunteer selection and recall bias. Variable response rates between age groups may bias study results towards higher age groups. These studies are also restricted by analysis of Caesarean delivery as a group and have been unable to appropriately distinguish between Caesarean subtypes including

Caesarean delivery without labour and Caesarean delivery following labour, which is an important limitation in that a portion of the damage that is believed to lead to pelvic floor disorders occurs during labour and Caesarean during labour would likely be less protective than Caesarean without labour. In addition, questionnaire data on urinary incontinence has not distinguished type of urinary incontinence, and this is a significant drawback to existing studies because stress urinary incontinence is believed to occur as a result of disruption of the pelvic floor, while urge urinary incontinence, although not well understood, is not believed to be related to pelvic support concerns. Information on childbirth and incontinence obtained from randomized trials has not been based on primary outcome measures, and analyses have not accounted for potential, biologically feasible confounding variables. The Term Breech Study [7, 8, 57, 58] results were limited by the large number of women in the planned vaginal birth group who delivered by Caesarean (over 40%) which may lead to difficulties in interpreting outcomes by actual mode of delivery. Breech deliveries may be inherently different from cephalic deliveries since the fetal buttocks and or feet presentation presents a smaller diameter for the length of first and second stage of delivery than the fetal head and may cause less damage to pelvic floor tissues.

CHAPTER 2 OBJECTIVES

The purpose of this study was to estimate influence of type of labour and maternal, obstetrical and neonatal factors on long-term pelvic floor sequelae with obstetrical deliveries in Nova Scotia. Specifically, women who underwent Caesarean section without labour ("no labour" group) were compared with women who underwent labour, regardless of mode of delivery ("labour" group). This population-based cohort study utilized comprehensive pregnancy data extracted from the Nova Scotia Atlee Perinatal Database with linkage to physician billing databases and hospital discharge abstract databases to employ general practitioner and specialty physician visits and hospital admissions and procedures, in order to investigate the relationship between no labour and labour on long-term incontinence and pelvic organ prolapse.

Primary objectives:

1. To determine the frequency of delivery by Caesarean section without labour.
2. To determine the relationship between type of labour and clinically relevant maternal, obstetrical and neonatal characteristics.
3. To estimate the risk of pelvic floor disorders, including urinary incontinence (a combination of stress, urge or mixed urinary incontinence), anal incontinence (a combination of fecal or flatal incontinence), pelvic organ prolapse (a combination of cystocele, rectocele/enterocele, uterine prolapse, or vaginal vault prolapse) and urogenital fistula, relative to type of labour.

Secondary objective:

1. To provide pregnant women and health care providers with information to understand and guide effective preconception counseling, antenatal management, management during labour and delivery, and care in the postpartum period, to optimize future reproductive and pelvic floor health.

CHAPTER 3 METHODS

3.1 STUDY DESIGN

This is a retrospective population-based cohort study designed to estimate the influence of type of labour on long-term pelvic floor health outcomes using three data sources, from 1988-2007. The analysis was performed on two related data sets, including women with pregnancies identified in the Nova Scotia Atlee Perinatal Database and who were eligible for MSI coverage during the timeframe where relevant codes for pelvic floor disorders were available in both the MSI and CIHI databases. Women were considered eligible to receive MSI health coverage if they were registered in the MSID.

3.1.1 Primary Objective 1:

All women in the NSAPD database were categorized according to their type of labour (no labour, labour). Women undergoing Caesarean section without labour were defined as the no labour group, while the women having labour and any method of delivery were defined as the labour group.

3.1.2 Primary Objective 2:

Data on clinically relevant maternal, obstetrical and neonatal characteristics were extracted from the Nova Scotia Atlee Perinatal Database and categorized by type of labour. Summary characteristics for women with no labour were compared with women who underwent labour, regardless of mode of delivery.

3.1.3 Primary Objective 3:

Data on diagnoses and procedures related to physician visits or hospitalizations for pelvic floor disorders, including urinary incontinence (a combination of stress, urge or mixed urinary incontinence), anal incontinence (a combination of fecal or flatal incontinence), pelvic organ prolapse (a combination of cystocele, rectocele/enterocele, uterine prolapse, or vaginal vault prolapse) and urogenital fistula were extracted from the MSID and CIHI DAD. Rates of these outcomes in the two study groups were estimated using univariate and multivariate analyses. Pelvic floor disorder outcomes among women delivering with no labour (Caesarean section without labour) were compared to women undergoing labour (spontaneous onset of labour, induction of labour), regardless of mode of delivery (Caesarean section in labour, operative vaginal delivery such as forceps or vacuum, and spontaneous vaginal delivery).

3.1.4 Secondary Objective 1:

Information obtained from objectives 1, 2, and 3 was summarized to provide appropriate information to women and their healthcare providers.

3.2 STUDY POPULATION

The study population included all women who were residents of Nova Scotia, who had a parity of 0 for their first delivery documented in the database and who delivered a least one singleton newborn with birth weight ≥ 500 grams or a gestational age of ≥ 20 weeks from April 1, 1988 to March 31, 2007 (subsequent pregnancies with multiple gestation were included). Women were considered for inclusion in the study if they were eligible to receive MSI health coverage (if they were registered in the MSID and accessed health care for any reason), from one year before their first delivery date to at least one year following their last delivery date. Therefore, pregnancies were excluded if they delivered before April 1, 1990 and if they delivered less than one year before March 31, 2007. MSI codes (with 4 or 5 digits) were not available for the outcomes of interest before April 1, 1997. Two populations of women were evaluated for long term pelvic floor health outcomes. First, eligible women with pregnancies identified in the Nova Scotia Atlee Perinatal Database and who delivered during the timeframe where relevant codes for pelvic floor disorders were available in both the MSID and CIHI DAD (April 1, 1998 to March 31, 2006). Second, eligible women with pregnancies identified in the Nova Scotia Atlee Perinatal Database and who delivered during the timeframe where relevant codes for pelvic floor disorders were available in the CIHI DAD (April 1, 1990 to March 31, 2006). Results of analyses using outcome data from the second population of women likely represented more severe disease requiring hospitalization. The analysis in each of these populations was done with two groups: women who had had only one delivery and women who had had one or more deliveries.

3.3 INDEPENDENT VARIABLE

Type of labour was identified as the independent variable (no labour and labour groups). The variable labour is available in the NSAPD and is classified as no labour or labour. Labour may be further classified as spontaneous onset of labour or induced labour.

3.4 DEPENDENT/OUTCOME VARIABLES:

The diagnoses of pelvic floor disorders were determined from family physician and specialty physician (urologists, gynecologists) billings using the MSI Database, which contains administrative records for each insured health service provided by a physician, and from hospital discharge data following admission or for procedures related to pelvic floor disorders using the CIHI DAD, which contains administrative records for each admission to a Nova Scotia hospital facility. Both of these administrative records are coded using ICD-9 and ICD-10 coding, and relevant ICD-9 and ICD-10 codes used to identify diagnoses and procedures associated with selected pelvic floor disorders are summarized in Appendix B. Diagrams of these pelvic floor disorders are provided in Figures 1-6.

Two clinically relevant composite outcome measures were also considered in the analysis. The composite outcome of pelvic floor dysfunction included any occurrence of urinary incontinence, anal incontinence or pelvic organ prolapse. The composite outcome of pelvic floor disorder included any occurrence of urinary incontinence, anal incontinence, pelvic organ prolapse or urogenital fistula.

3.5 POTENTIAL CONFOUNDERS/PREDICTORS:

Determination and inclusion of potential confounders was based on clinical understanding, the medical literature and epidemiologic principles. They included current and previous pregnancy information, obstetrical complications, pre-existing medical conditions, pre-existing incontinence, and neonatal information. All potential confounders were examined in univariate analyses; potential confounders are summarized in Appendix A.

Several maternal and perinatal variables were at specific time points in the obstetrical history based on clinical relevance to the selected pelvic floor outcomes. Maternal age in years at first delivery was considered as a continuous variable. Maternal parity (the number of pregnancies which resulted in one or more infants weighting 500 grams or more at birth or 20 weeks or greater gestational age (regardless of whether such infants lived, were stillborn or died after birth) at last delivery was defined as parity of 1, 2 or three or more. Maternal pre-pregnancy weight at last delivery was considered as continuous variable and was defined as the weight in kilograms of the mother either in first trimester or pre-pregnancy. The first delivery was considered preterm (yes, no) if the first delivery occurred less than 37 weeks gestation. Largest newborn birth weight in grams in any pregnancy was considered as a continuous variable. Smoking at admission for labour in any pregnancy, chorioamnionitis (intrauterine infection by placental pathology or physician diagnosis), and a diagnosis of hypertension or diabetes that pre-existed any pregnancy were binary (yes, no). Pre-pregnancy urinary and anal incontinence were defined (yes, no) if these occurred before the first pregnancy. Relevant complications in pregnancy were binary (yes, no) and included Caesarean or postpartum hysterectomy (the last delivery complicated by postpartum surgical removal of the uterus), intra-operative maternal trauma in any pregnancy (surgical injury to bladder, bowel and surrounding structures), and wound infection or dehiscence in any pregnancy (infection or breakdown of perineal or abdominal incisions or wounds).

3.6 SOURCES OF DATA

Information on all women who had an obstetrical delivery in Nova Scotia from 1988 to 2007 were obtained from clinical and administrative databases; the clinical Nova Scotia Atlee Perinatal Database (NSAPD) and the administrative Canadian Institute for Health Information's Discharge Abstract Database (CIHI DAD, hospital discharge data) and the Medical Services Insurance Database (MSID, physician billings). Procedures for linking these databases are well-developed, tested and formalized. Because women are diagnosed and managed by both family practitioners and specialists, these health databases permit the capture of all diagnosed cases of PFD in both the outpatient and hospital settings.

3.6.1 The Nova Scotia Atlee Perinatal Database

The Nova Scotia Atlee Perinatal Database (managed by the Reproductive Care Program of Nova Scotia) was used to create a population-based dataset identifying all pregnancies categorized by mode of delivery. The Nova Scotia Atlee Perinatal Database is a high quality, provincial population-based database containing clinical information on all births at a gestational age of at least 20 weeks or having a birth weight of at least 500 grams. It contains maternal and newborn information, including demographic variables, procedures, interventions, maternal and newborn diagnoses and morbidity and mortality information for every pregnancy and birth occurring in Nova Scotia hospitals and to residents of Nova Scotia since 1988. Information in the database is abstracted by trained health records personnel from standardised forms and hospital medical records across the province of Nova Scotia. Detailed information on several hundred variables is collected on medical conditions, labour and delivery events and neonatal outcomes (including follow-up information on death and cause of death in the first year of life). Information is also collected on specific lifestyle and other patient characteristics. All information is entered into the database soon after the time of collection. The database has been shown to be reliable; it has been used previously for several studies and has been used to validate other sources of data [74]. In this latter validation study, stillbirth and linked live birth-infant death files in the Statistics Canada database were shown to be 92% and 99% complete for stillbirths and infant deaths, respectively, when evaluated against the Nova

Scotia Atlee Perinatal Database. Variables to be obtained from the Nova Scotia Atlee Perinatal Database are listed in Appendix A.

3.6.2 Provincial Administrative Health Databases

Other databases relevant to this project included the administrative databases housed at the Health Data Nova Scotia (HDNS) in the Department of Community Health and Epidemiology, Dalhousie University. The databases include population-level administrative health data for the Province of Nova Scotia. The Medical Services Insurance (MSI) Database contains data from provincial billing information. The Canadian Institute for Health Information's (CIHI) Discharge Abstract Database contains information on medical diagnoses and procedures from hospital discharge data. Nine facilities provide regional or tertiary level obstetrical services in Nova Scotia; in 6 of these facilities, the data abstractor who codes and abstracts information is the same coder for both CIHI DAD and NSAPD data, while in 3 facilities, the data are collected for the CIHI system and the RCP system by two different individuals. Each data abstractor is registered with the Canadian Health Information Management Association and is qualified and knowledgeable about data collection in either system.

These health databases permitted the capture of all diagnosed cases in both outpatient and hospital settings. The Canadian Institute for Health Information's Discharge Abstract Database (CIHI DAD) contains information on medical diagnoses and procedures from hospital discharge data. Discharge diagnoses are coded using the International Classification of Diseases, Injuries and Causes of Death (9th revision, 1987-2001, and

10th revision, 2001-present) codes and surgical and other procedures are coded using the Canadian Classification of Procedures (1987-2001) and the Canadian Classification of Health Interventions (2001-present). The Nova Scotia Medical Services Insurances (MSI) Database records outpatient visits and diagnoses through physician billing. Information on physician specialty is included in this database. In Nova Scotia, clinical fees for obstetrical services are coded separately for prenatal visits, admission to hospital, care for labour and delivery, and postpartum care. Variables to be obtained from the CIHI and MSI databases are listed in Appendix B.

3.7 DATABASE LINKAGE

Information from the Nova Scotia Atlee Perinatal Database was sent to Atlantic Blue Cross Care for encryption of Health Card Numbers and Medical Services Insurance Numbers. Each file also contained a Reproductive Care Program of Nova Scotia–Population Health Research Unit-Patient Admission ID Number. Based on approved request, the required fields were extracted from the Nova Scotia Atlee Perinatal Database (electronic form) and forwarded to the HDNS with the Reproductive Care Program of Nova Scotia-HDNS-Patient Admission ID Number attached but with no other identifiers present (a "cross-walk" file). The required fields from the HDNS databases were extracted and linked to the records selected from the Nova Scotia Atlee Perinatal Database and stored on the HDNS computer with encrypted Health Card Numbers and Reproductive Care Program of Nova Scotia-HDNS-Patient Admission ID Numbers intact. Encrypted Health Card Numbers and Reproductive Care Program of Nova Scotia–HDNS-Patient Admission ID Number were then removed prior to release of the file for data analysis and replaced by a project-specific identifier unique to the patient.

Analyses were performed on a secure HDNS computer. Only aggregated data from SAS output files are reported.

This linkage allowed evaluation of patient utilization of physicians (such as urologists, gastroenterologists and gynaecologists) who provided care for incontinence and pelvic organ prolapse. It captured conservative as well as surgical interventions.

3.8 MISSING VALUES:

The Nova Scotia Atlee Perinatal Database has a low rate of missing information for most key variables (e.g., almost no missing information on maternal age, birth-weight, perinatal death etc). Records with missing information (e.g., 4% of subjects have no information regarding smoking status) were excluded from regression analyses.

3.9 DATA ANALYSIS

Descriptive analyses examined the relationship between type of labour and clinically relevant maternal, obstetrical and neonatal factors in order to gain an understanding regarding potential confounders. Crude and adjusted analyses were performed to estimate the influence of labour on the selected four selected pelvic floor health outcomes and the two composite outcomes. Relationships were examined separately for women who had only one delivery in the study period, and for women who had one or more deliveries in the study period. Time-to-event analyses were performed to obtain hazard ratios using proportional hazards regression; follow-up for each individual pelvic floor health outcome occurred until the date of the first diagnosis of that pelvic floor health outcome, or at the end of the study period. Data for each individual pelvic floor health outcome was censored if a woman moved away from Nova Scotia since eligibility for MSI coverage stopped.

3.9.1 Univariate Analyses:

Continuous variables between groups were compared using t-tests. Categorical data were compared using chi-square and Fisher's exact tests, where appropriate. Statistical significance level was $P<.05$. Crude measures of the effect of type of labour were estimated in the analysis. Odds ratios were used to estimate the strength of the association and express the magnitude of the effect. Univariate comparisons were made between women with pelvic floor disorders by type of labour.

3.9.2 Regression analyses:

Logistic regression analyses were used in order to determine whether maternal, obstetrical or neonatal characteristics explained relationships between type of labour and dichotomized pelvic floor health outcomes. Clinically relevant variables were included in the regression models. Multivariate logistic regression analysis was performed in a backward, stepwise fashion (factor retained if it changed the point estimate of the type of labour variable by 5% or more) to generate adjusted odds ratios for all outcomes by type of labour (no labour, labour) accounting for potential confounding variables. The most parsimonious model was obtained using the difference in –2 log likelihood, X^2. Since the women in the study could have had multiple deliveries and we were interested in capturing the information on all deliveries, the general estimating equation (GEE) procedure provided standard errors corrected for non-independence of multiple pregnancies to the same woman. Odds ratios and 95% confidence intervals were determined. Statistical significance level was $P<.05$. Statistical analyses were performed using OpenEpi (Version 3.01) and SAS for windows Version 9.3 (SAS Institute, Cary, NC).

3.10 CONFIDENTIALITY AND ETHICS

All necessary precautions were taken to ensure confidentiality. The development and maintenance of study databases such as those used in this study is consistent with the Tri-Council's guidelines pertaining to database linkages under their Code of Ethical Conduct for Research Involving Humans. Application to and approval from the Joint Data Access Committee of the Perinatal Epidemiology Research Unit, Health Data Nova Scotia (HDNS), formerly known as Population Health Research Unit (PHRU), and the Reproductive Care Program (RCP) of Nova Scotia (which has strict rules governing data access and use), as well as approval by the Dalhousie University/IWK Health Centre Research Ethics Boards was obtained before the project was initiated by the investigators. These approvals were to ensure the privacy and confidentiality of the women, care-providers, institutions and vulnerable sub-populations. Unique identifiers were not released to study investigators. Investigators committed to establish secure systems of data management and analysis so that no individual patient, care provider, person or institution was identified. In this study, analysis was done on secure Health Data Nova Scotia computers.

Data was reported in aggregate form only. As per Reproductive Care Program of Nova Scotia rules, cells in tables which contain less than five subjects were suppressed. Given the confidential nature of the data in the Nova Scotia Atlee Perinatal Database and other databases relevant to this project, measures and procedures were undertaken in order to ensure data confidentiality. Information in these databases is routinely analyzed and used for research and other purposes on an ongoing basis. The institutions that maintain these databases have already developed stringent rules to ensure that data confidentiality is not violated. All data are maintained in locked and secure premises.

CHAPTER 4 RESULTS

Out of a potential study population of 183,268 pregnancies to residents of Nova Scotia identified by the NSAPD from 1988-2007, linkage of databases was available for 27,861 eligible women in the time frame when both MSI and CIHI medical and procedure codes (April 1, 1998 to March 31, 2006) were available, and for 61,005 eligible women in the time frame when CIHI medical and procedure codes (April 1, 1990 to March 31, 2006) were available.

<u>Analysis of pelvic floor outcomes including both CIHI and MSI medical and procedure codes:</u>

Table 1 summarizes maternal, obstetrical and neonatal characteristics among women for whom there was information using both MSI and CIHI medical and procedure codes. Of the 27,861 deliveries that were captured in the linkages of the NSAPD, CIHI DAD and MSID, 1,720 (6.2%) deliveries were Caesarean sections without labour among nulliparous women (parity=0) and 26,141 were deliveries that included labour. The characteristics were classified by type of labour (no labour and labour).

The no labour group was more likely to be older at first delivery, be primiparous at last delivery, have a higher pre-pregnancy weight at last delivery, have a first delivery that was preterm (earlier than 37 weeks gestational age), to have pre-existing hypertension or diabetes in any pregnancy, to have a Caesarean or postpartum hysterectomy in their last pregnancy, and to have had a wound infection or dehiscence in any pregnancy ($P<.001$ for all comparisons). They were more likely to have had pre-pregnancy anal incontinence and shorter duration from first to last pregnancy (P=.02). Women with no labour had smaller babies, were more likely to smoke, and have a severe perineal laceration in any pregnancy (P<.001 for all comparisons). No statistically significant differences were seen for the characteristics of chorioamnionitis in any pregnancy, intraoperative maternal trauma in any pregnancy, or urinary incontinence prior to the first pregnancy (P>.05 for all comparisons).

Individual pelvic floor health outcomes of interest occurred at a rate of less than 2% in the no labour group. In the labour group, the outcomes of interest occurred at rate of less than 3%. Table 2 summarizes univariate and adjusted comparisons of the four selected long-term pelvic floor outcomes and the two composite outcome measures among the two groups, for women who had only one delivery in the study period, using logistic regression. Of the original 1720 women in the no labour group, 69.3% (n=1192) had only one delivery. Among the women with labour, 61.5% had only one delivery (n=16087). Crude analyses demonstrated a statistically significant protective odds ratio for anal incontinence (P=0.01, OR suppressed due to cell size <5), pelvic floor dysfunction, and any pelvic floor disorder, among women with no labour. Although the relationship between delivery without labour and anal incontinence and any pelvic floor disorder were no longer significant once adjusted for confounders, no labour remained protective for pelvic floor dysfunction (40% reduction).

Table 3 summarizes the univariate and adjusted comparisons of the four selected pelvic floor outcomes and the two composite outcome measures among women with no labour and those with labour in the initial pregnancy, where all deliveries were considered and multiple observations were accounted for using GEE. The crude association between delivery without labour and urinary incontinence was in the direction of being protective, but only reached borderline statistical significance. This relationship became statistically significant once adjusted for confounders (32% reduction). Crude analysis demonstrated a statistically significant protective odds ratio for anal incontinence, pelvic floor dysfunction, and any pelvic floor disorder, among women with no labour. No labour remained protective for anal incontinence (74% reduction), pelvic floor dysfunction (37% reduction) and any pelvic floor disorder (32% reduction) once adjusted for confounders.

Table 4 summarizes univariate and adjusted time-to event analyses using proportional hazards regression for the selected long-term pelvic floor health outcomes for the women with no labour compared to the labour group in their first delivery to the first pelvic floor disorder diagnosis for each disorder during the study period. Crude analyses showed that women with no labour were less likely to have anal incontinence over the duration of follow-up; this relationship did not remain significant with adjusted analyses. Following multivariate analysis, no labour became protective for urinary incontinence (HR 0.68, 95% CI 0.47-0.995) over the duration of follow-up.

<u>Analysis of pelvic floor outcomes using only CIHI medical and procedure codes:</u>

Table 5 summarizes maternal, obstetrical and neonatal characteristics among women for whom there was linked information using only CIHI medical and procedure codes. Of the 61,005 deliveries that were captured in the linkages of the NSAPD and the CIHI DAD, 3,066 (5.0%) deliveries were with no labour among nulliparous women (parity=0), and 57,939 were deliveries that included labour. The characteristics were classified by type of labour (no labour and labour).

Women with no labour were more likely to be older at first delivery, be primiparous at last delivery, have a higher pre-pregnancy weight at last delivery, have a first delivery that was preterm (earlier than 37 weeks gestational age), to have pre-existing hypertension or diabetes in any pregnancy, to have a Caesarean or postpartum hysterectomy in their last pregnancy, and to have had a wound infection or dehiscence in any pregnancy ($P<.001$ for all comparisons). Women with no labour were less likely to have large babies, to smoke, to have a severe perineal laceration in any pregnancy and to have a long duration between first and last pregnancies ($P<.001$ for all comparisons). No statistically significant differences were seen for the characteristics of chorioamnionitis in any pregnancy, intraoperative maternal trauma in any pregnancy, or pre-pregnancy urinary or anal incontinence ($P>.05$ for all comparisons).

Individual pelvic floor health outcomes of interest occurred for the labour group at a rate of less than 4% and at a rate of 1% or less for the no labour group. Table 6 summarizes the univariate and adjusted comparisons of four selected long-term pelvic floor outcomes and the two composite outcome measures among the two groups, for women who had only one delivery in the study period, using logistic regression. Crude analyses demonstrated a statistically significant protective odds ratio for anal incontinence, pelvic floor dysfunction, and any pelvic floor disorder, among women with no labour. Although the relationships between delivery without labour and anal incontinence and any pelvic floor disorder were not significant once adjusted for confounders, no labour remained protective for pelvic floor dysfunction (45% reduction) and became significant for pelvic organ prolapse (55% reduction).

Table 7 summarizes the univariate and adjusted comparisons of the four selected pelvic floor outcomes and the two composite outcome measures among women with no labour and those with labour in the initial pregnancy, where all deliveries were considered and multiple observations were accounted for using GEE. Crude analyses demonstrated a statistically significant protective odds ratio for urinary incontinence, anal incontinence, pelvic organ prolapse, pelvic floor dysfunction, and any pelvic floor disorder, among women with no labour. No labour remained protective for urinary incontinence (45% reduction), pelvic organ prolapse (45% reduction), pelvic floor dysfunction (36% reduction) and any pelvic floor disorder (31% reduction) once adjusted for confounders.

Table 8 summarizes the univariate and adjusted time-to-event analyses of selected long-term pelvic floor health outcomes among women with no labour compared to women having labour in the initial pregnancy in their first delivery to first pelvic floor disorder diagnosis for each disorder during the study period. Crude analyses showed that women with no labour were less likely to have anal incontinence and pelvic organ prolapse over the duration of follow-up; the relationship with anal incontinence did not remain significant with adjusted analyses. Following multivariate analysis, no labour remained protective for pelvic organ prolapse (HR 0.63, 95% CI 0.41-0.97), and became protective for urinary incontinence (HR 0.61, 95% CI 0.38-0.88) over the duration of follow-up.

CHAPTER 5 DISCUSSION

The long term implications of the sequelae resulting from childbirth become relevant in a health care climate of ongoing financial constraints, longer wait-times for specialty consultation and operating room time, and the reality of an aging Canadian population. There is an increasing understanding that women who undergo labour are at higher risk for pelvic floor dysfunction than women who do not labour. Although not life-threatening, pelvic floor dysfunction often negatively influences quality of life, and may result in changing social interactions with family and friends, and physical activity, and professional challenges with time away from work.

This study was performed in an attempt to better inform the question of the impact on long-term pelvic floor health for women who have a Caesarean section on maternal request in their first pregnancy. Caesarean section without labour in the first pregnancy was used as a surrogate for maternal request (elective Caesarean section), because there were too few women who opted for elective caesarean in the Nova Scotia Atlee Perinatal Database to permit a meaningful analysis. Pre-labour Caesarean section done for other indications, may involve other health conditions and obstetrical factors that might have an influence on long-term pelvic floor health. Differences in the engagement of the presenting part in the maternal pelvis, with term breech fetuses or with increased fetal weight, for example, may not be representative of the pelvic floor environment in women choosing caesarean delivery in the absence of obstetrical indications; this group, however, still provides the best option to gain insight into the maternal risk of elective Caesarean section beyond the usual risks associated with first obstetrical delivery. The estimates found in the study are likely therefore conservative ones.

In order to address this question, this retrospective cohort study linked the comprehensive provincial, population-based Nova Scotia Atlee Perinatal Database, to the Nova Scotia Medical Services Insurance (physician billings) Database and the Canadian Institute for Health Information Discharge Abstract (hospitalization) Database. By using both MSI codes that captured ambulatory care and CIHI codes that captured hospital admissions and procedure codes, presumably to undergo surgery, this study was able to provide comprehensive coverage of a range in severity of the outcomes under investigation.

Analysis of linked data from using CIHI DAD codes from 1990 to 2006, a sixteen year period, demonstrated reassuringly low rates of long-term pelvic floor health outcomes requiring hospitalization in a cohort of women identified by type of labour (no labour, labour) in their first pregnancy. Despite this, the large numbers available from the NSAPD allowed estimation of the influence of labour on clinically important long-term pelvic floor outcomes. Caesarean section without labour was found to be protective, in particular, for the composite outcome of pelvic floor dysfunction, which combined occurrences of urinary incontinence, anal incontinence or pelvic organ prolapse. This finding is supported by a cross-sectional questionnaire study conducted in 2006 [75]. The authors demonstrated that in a group of women aged 25-84 years, the prevalence of one or more PFDs was 37%, with an increased risk if the respondent had at least one vaginal delivery as compared to caesarean delivery, OR 1.85 (95% CI 1.42-2.41).

For the population of women identified by including both MSID and CIHI DAD codes, long-term pelvic floor health outcomes were diagnosed in both outpatient and inpatient settings, and therefore included the conditions with a range in severity; the size of the effect of type of labour may have been underestimated if women were first diagnosed, and then treated in a conservative fashion not requiring surgery.

The finding of a significant reduction in risk for urinary incontinence in the no labour group is supported by the findings in other studies [33-35, 42, 44, 47-56]. The Term Breech Study did not demonstrate a difference in urinary incontinence at two years of follow-up in women who had had planned Caesarean section compared to women with planned vaginal delivery; this may in part be explained by the loss-to follow-up and analysis done on initial randomization categories [58].

This study demonstrated a significant reduction in risk for urinary incontinence and pelvic organ prolapse for those women who delivered without labour for the duration of follow-up. This study was not able to estimate the impact of these conditions on quality of life or to determine if menopause had occurred, which is known to influence progression of pelvic floor disorders. Onset of menopause has been found to be a risk factor for new urinary incontinence [37, 38]. Evaluation of the study duration and maternal age at first delivery suggests, however, that these diagnoses likely occurred before the onset of menopause, and are more likely to be influenced by type of labour in the first pregnancy. These findings are highly relevant to young women considering having an elective Caesarean section to prevent pelvic floor disorders. The group of women in this study who had pelvic floor dysfunction that was severe enough to require hospitalization and surgical correction were unlikely to have reached menopause in the study interval; the implications of these findings include important quality of life issues related to pelvic floor dysfunction associated with multiple consultations, multidisciplinary care, and the possibility of requiring multiple procedures. This study was not able to address the additional influence of menopause on pelvic floor health outcomes evaluated by type of labour.

There was a statistically and clinically significant difference in severe (3^{rd} or 4^{th} degree) perineal lacerations in any pregnancy, with a higher proportion of severe lacerations seen in the group with labour (5.2% and 6.1%, respectively) compared to the group without labour in their first delivery (0.8% and 1.2%, $P<.001$). Lacerations involving the anal sphincter (3^{rd} degree) or the rectal mucosa (4^{th} degree), are known to be associated with short-term anal incontinence and require special training to surgically correct [55]. Other studies have shown a relationship with anal incontinence with disruption of the anal continence mechanism following operative vaginal delivery (delivery with forceps or vacuum) [24].

This study did demonstrate a higher risk of anal incontinence over the long term in this group among the dataset with physician billings only (MSI). In women who required hospitalization and presumably surgical correction we did not see this difference. This could mean that the majority of women who are diagnosed with anal incontinence may not necessary seek surgical correction but rather choose to manage their symptoms conservatively. Several other studies have failed to demonstrate a protective effect from Caesarean delivery without labour [55, 57, 58] and are consistent with the results of this large cohort study when taking account of relevant clinical factors. This study's evaluation of time from obstetrical delivery to first diagnosis of anal incontinence also demonstrated no difference in risk for anal incontinence for the duration of follow-up. Studies have shown that flatal incontinence rates are considerably higher than fecal incontinence after EAS injury [70]. While flatal incontinence has significant impact on quality of life, it is much less likely that a patient will seek medical help for flatal incontinence as compared to fecal incontinence. This may explain the lack of difference in anal incontinence rates found in this study.

No significant difference was demonstrated for the outcome of pelvic organ prolapse in the cohort identified by including both MSI and CIHI data. There was, however, a significant 55% reduction in the risk for pelvic organ prolapse in the no labour group in the cohort identified by including only CIHI data. Few studies have examined the influence of type of labour or type of delivery on prolapse outcomes. Buchsbaum had shown no influence of pregnancy (including labour and mode of delivery) on risk for pelvic organ prolapse [71]. This large cohort study reports the first information on the protective effects of Caesarean section without labour on the development of pelvic organ prolapse.

Regardless of whether the outcomes included inpatient or outpatient diagnoses, or whether the population was restricted to those who had only one delivery or multiple deliveries, there was a trend for labour to be protective for the risk for urogenital fistula, in contrast to all other pelvic floor outcomes. Postpartum fistulas are rare in developed nations, which was confirmed in this study (rates less than 0.5%), though they do still occur following traumatic vaginal deliveries with severe lacerations and also following difficult caesarean deliveries.

Higher rates for pelvic floor health outcomes than those shown in the current study have been reported in the literature. This study was able to follow women for a duration longer than the immediate postpartum period, but likely before the onset of menopause. Both of these time frames have been shown be associated with higher rates of pelvic floor health outcomes, with recovery of function noted postpartum [47, 53, 57, 58], and then subsequent decline in function with menopause, [46, 48, 60] which may explain the lower rates seen in this study.

Since information identifying successive births to the same woman is available in the Nova Scotia Atlee Perinatal Database, pelvic floor health outcomes to women across consecutive pregnancies were uniquely estimated in this study. Some of the women who had a Caesarean section without labour in their first pregnancy may have had a subsequent vaginal delivery. The impact of a subsequent vaginal delivery on a woman who delivered in her first pregnancy by Caesarean section may have lead to an underestimation of the protective effect of no labour on long-term pelvic floor health outcomes. In addition, the large proportion of women in this Nova Scotia population having only one delivery during the study period may limit generalizability to populations consistently having more than one delivery.

A limitation to this study includes the introduction of new provincial health card numbers (HCN) after 1995. Before this time, women had their father's (if under 18) or their husband's (if married) social insurance number plus a suffix, for a health card number (HCN), while after 1995 they were assigned their own HCN. Both the HDNS and the RCP have optimized mapping of the old to the new HCN; however, there may be occurrences where mapping may be incomplete. This would lead to women appearing in the data as left censored or lost to follow-up when the old MSI number is changed, and would underestimate the prevalence of pelvic floor disorders.

The value of a linked comprehensive validated perinatal database with administrative databases in estimating risks of pelvic floor health outcomes cannot be understated; using these databases minimizes the methodologic challenges for acquiring this information that have been consistently demonstrated in past studies, including cost, recall bias, selection bias and loss to follow-up. This study used a large dataset that allowed analyses by type of labour and controlling for other relevant maternal, obstetrical and perinatal factors. Previous studies have been limited by lack of information on type of labour and presence or absence of confounding variables. While the data in the Nova Scotia Atlee Perinatal Database has been shown, through data re-abstraction (with a high level of agreement for most routine variables) and validation studies, to contain reliable information, retrospective studies are limited to available data and so there may be other variables relevant to the present study that are not routinely captured in the database, such as BMI, which was only consistently collected after the study period, conditions associated with poor healing, such as diabetes, or dietary details, workplace requirements such as heavy lifting, chronic conditions such as constipation, sexual dysfunction, or information on type of pelvis. Ethnic variations in rates of pelvic floor dysfunction were not able to be evaluated give the homogenous ethnic composition of the Nova Scotian population.[76]. In addition, changes in obstetric practice patterns, such as the decreasing use of forceps or vacuums in operative vaginal delivery, may have contributed to rates of pelvic floor health outcomes during the study period. Since relevant information on physician billings (from the MSID) was not available before 1997, there was a gap from the start of available pregnancy data from the NSAPD (available from 1988) to the time of available outcome information (available from 1997).

In a subset of women whose risks for pelvic floor health outcomes were identified using hospital discharge data (likely representing more severe disorders), rates for urinary incontinence appeared lower, and for anal incontinence appeared higher than those in the subset of women whose risks were identified using physician billing information as well as hospital discharge data. A change from the ICD-9 to ICD-10 coding system occurred in April 1997 in Nova Scotia, and may have affected the determination of relevant diagnoses using both MSI and CIHI codes (1998-2006) compared to using only CIHI codes (1990-2006). This observation may be a result of inclusion of additional years in the study, and improved coding with experience with new coding systems, [77] balanced with increasing reimbursement for medical services using alternate funding programs established by the government of Nova Scotia. This change in funding, with an inconsistent requirement for shadow billing demonstrate clinical care deliverables, may have resulted in decreased accuracy in coding. In particular, there was an increase in alternate funding programs in the tertiary care centres in Nova Scotia in later years of the study. It has been demonstrated that detection of chronic disease is more likely with hospitalization, but that these diseases are less likely to be detected in surveillance programs dependent on administrative data algorithms in non-fee-for-service settings [78].

These study findings have implications for women, health care providers, and policy makers. Comparison of pelvic floor health outcomes in Nova Scotia women classified by type of labour demonstrated the protective influence of no labour in the first delivery, even accounting for multiple deliveries, and this uniquely determined information contributes to the current available information regarding benefits and risks of attempted vaginal delivery. Careful evaluation of progress in pregnancy and identification of concerns or complications are necessary when considering planned mode of delivery. Counseling that includes education regarding the importance of this evidence to women by health care providers is also essential; this study was performed in a homogeneous ethnic population employing data related to caesarean sections performed without labour for maternal, obstetrical or fetal reasons, with considerable follow-up post delivery but likely prior to the onset of menopause. Administrative appeals for the reduction in caesarean delivery rates must take into account changing population and obstetrical characteristics, such as increasing maternal age at first delivery, increasing BMI and increasing birth weight [79], changing obstetric practice patterns, and establishing goals and clinical audits to optimize management during labour and delivery, in order that caesarean section rates are safely reduced. The additive influence of menopause and type of labour on pelvic floor health outcomes remains unclear; longer follow-up through menopausal ages would be necessary to complete this picture.

CHAPTER 6 CONCLUSION

The current study was designed to estimate long-term pelvic floor health outcomes in women undergoing obstetrical delivery categorized by type of labour in the first pregnancy. The absolute risks for the pelvic floor outcomes of urinary incontinence, anal incontinence, pelvic floor disorders and fistula disorders were small (regardless of type of labour in the first pregnancy), although this may have been explained by the study duration, with possible recovery of function after the immediate postpartum period and the likely exclusion of the effects of menopause. Women undergoing obstetrically indicated caesarean section without labour in their first delivery had reduced risks of important pelvic floor health disorders, even after multiple deliveries. The results obtained from this study contributes important information for health care providers when counseling women and their families who are weighing the risk of long-term pelvic floor disorders against the benefits of spontaneous vaginal delivery on maternal and perinatal outcomes, as well as for policy makers in order to achieve safe reductions in caesarean delivery rates.

Figure 1: Urinary incontinence

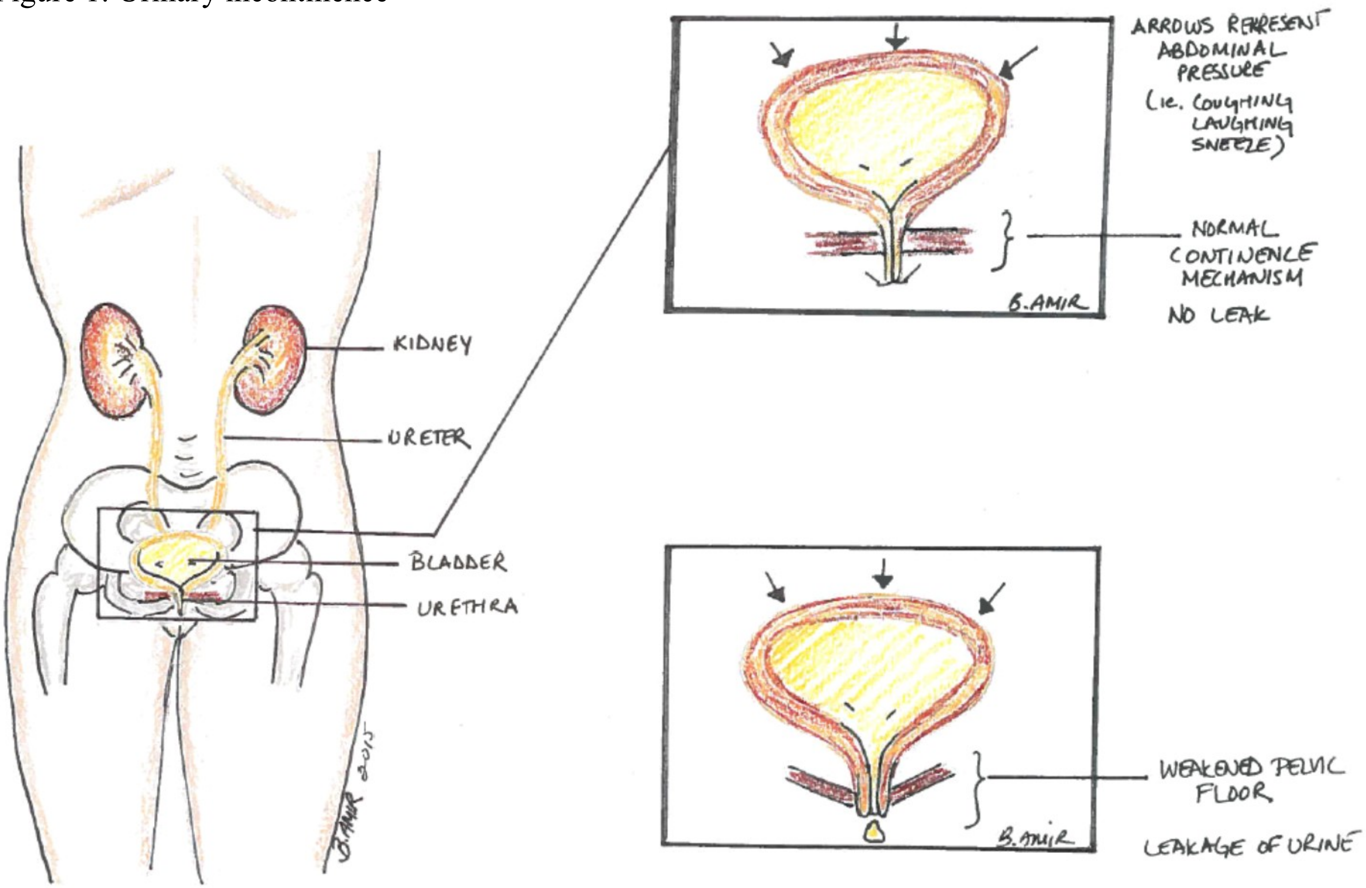

Figure 2: Uterine Prolapse

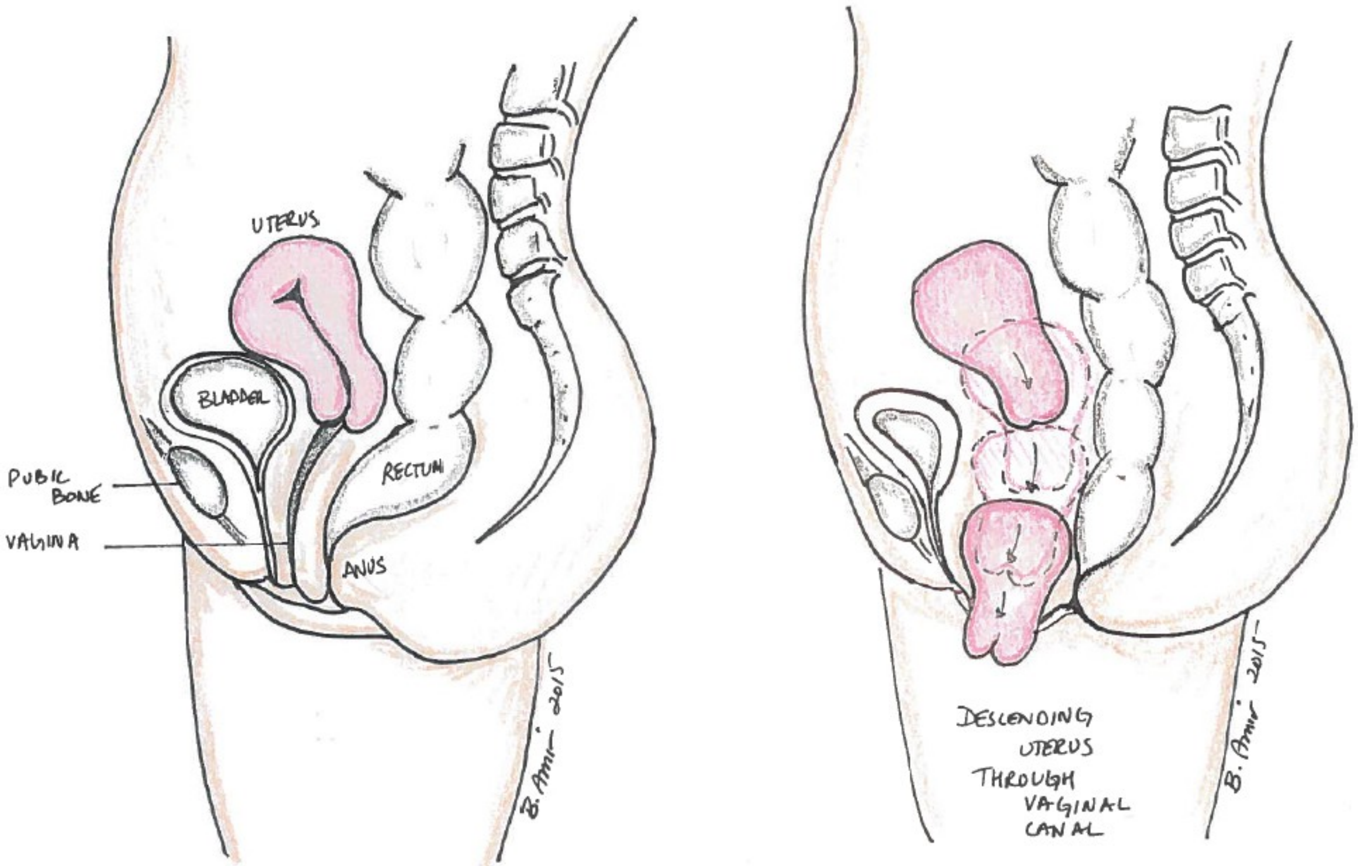

Figure 3: Bladder Prolapse/Cystocele

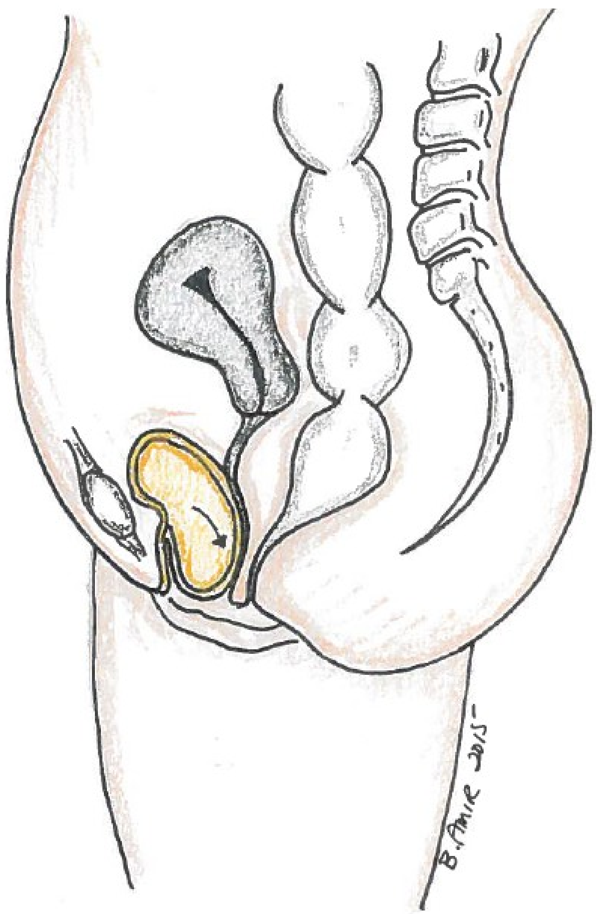

Figure 4: Rectocele

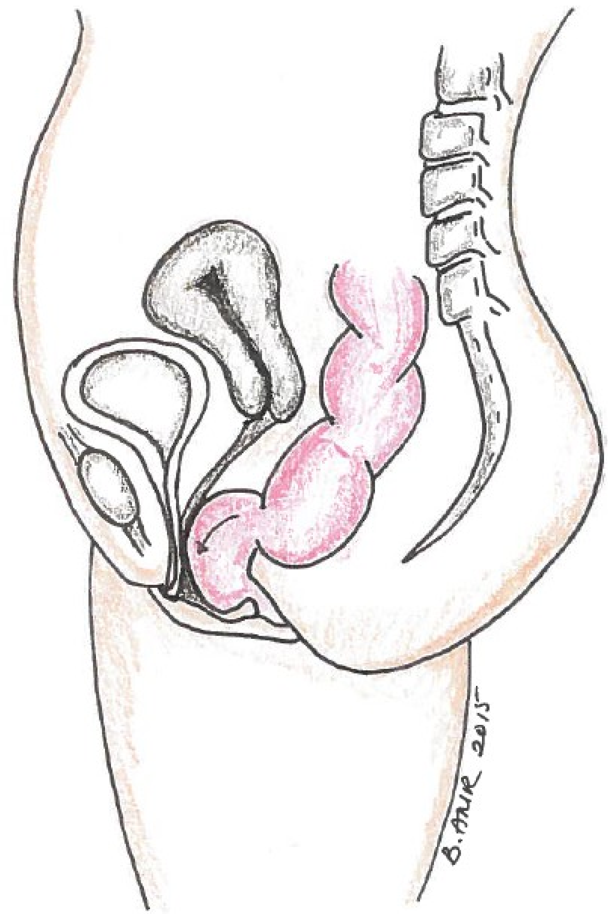

Figure 5: Anal Incontinence

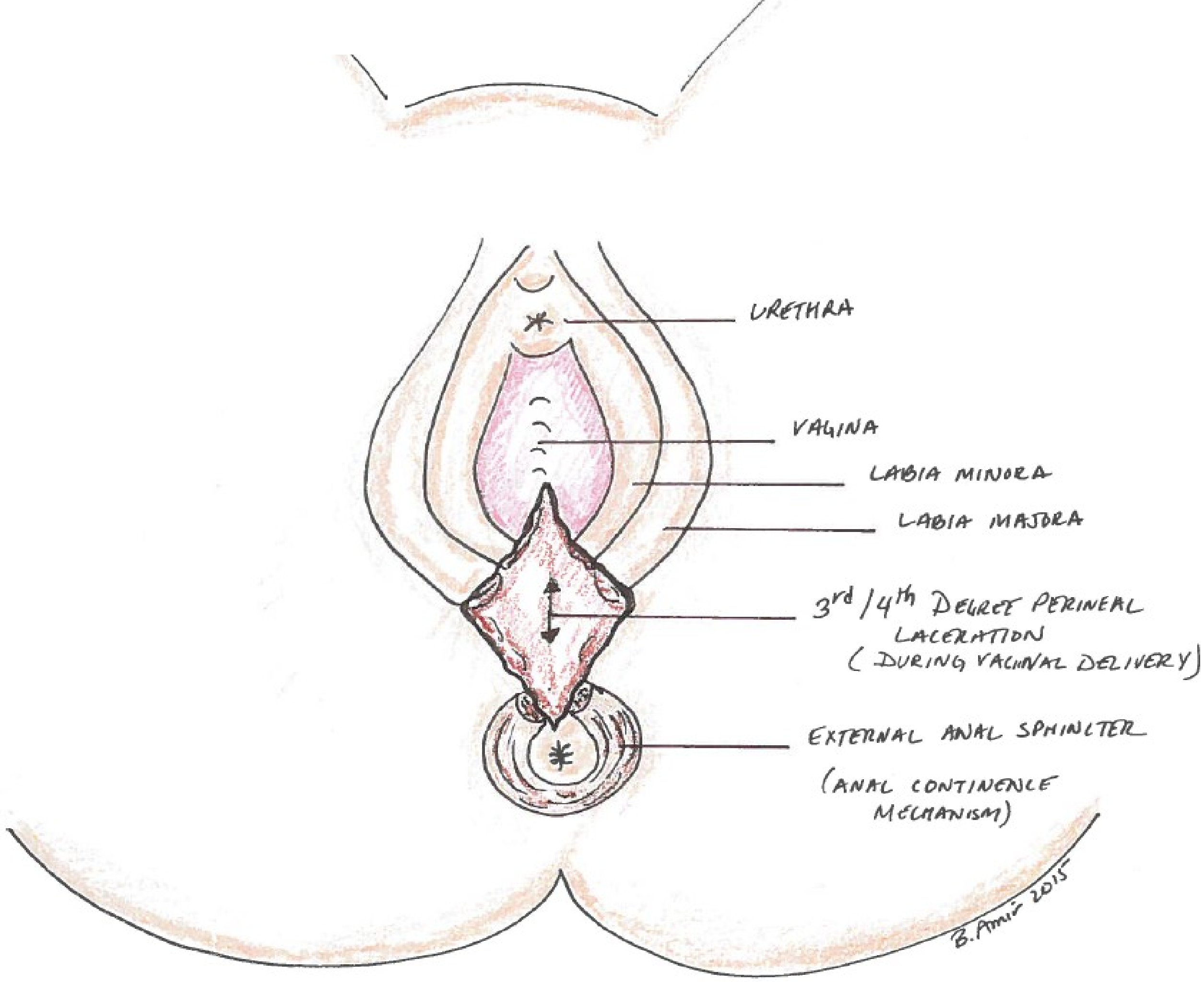

Figure 6: Urogenital Fistula

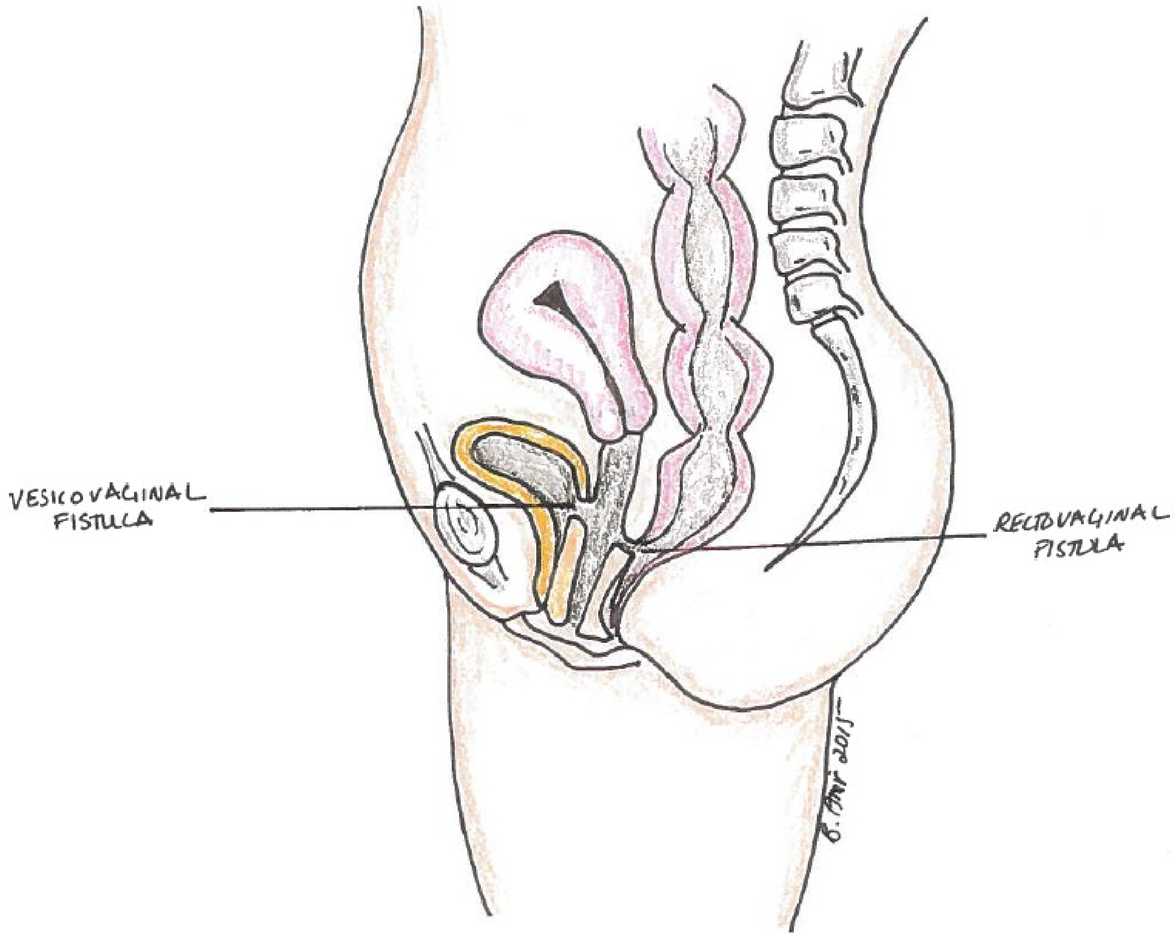

Table 1: Maternal, obstetrical and newborn characteristics of women with no labour and women having labour in Nova Scotia, including both MSI and CIHI medical and procedure codes, 1998-2006.

	No labour n=1720	Labour n=26141	P value
Mean maternal age at first delivery, years (SD)	28.9 (5.7)	26.9 (5.7)	<.001
Maternal parity at last delivery (%)			
1	1192 (69.3)	16087 (61.5)	<.001
2	476 (27.7)	8717 (33.4)	
3 or more	52 (3.0)	1337 (5.1)	
Mean maternal pre-pregnancy weight at last delivery, kg (SD)	72.1 (17.8)	69.8 (17.2)	<.001
First delivery < 37 weeks gestation (%)	296 (17.4)	1788 (6.9)	<.001
Mean of largest birth weight, grams (SD)	3323 (790)	3533 (567)	<.001
Smoking at admission for labour in any pregnancy (%)	321 (19.1)	5647 (22.2)	.003
Chorioamnionitis in any pregnancy (%)	21 (1.2)	271 (1.0)	.46
Pre-existing hypertension in any pregnancy (%)	42 (2.4)	326 (1.3)	<.001
Pre-existing diabetes mellitus in any pregnancy (%)	98 (5.7)	998 (3.8)	<.001
Caesarean or postpartum hysterectomy in last pregnancy (%)	7 (0.4)	18 (0.1)	<.001
Severe perineal laceration in any pregnancy (%)	14 (0.8)	1369 (5.2)	<.001
Intra-operative maternal trauma in any pregnancy (%)	15 (0.9)	341 (1.3)	.15
Wound infection or dehiscence in any pregnancy (%)	20 (1.2)	139 (0.5)	.002
Pre-pregnancy urinary incontinence in first pregnancy (%)	20 (1.2)	204 (0.8)	.09
Pre-pregnancy anal incontinence in first pregnancy (%)	< 5 (< 0.3)	7 (0.03)	.02
Mean duration between first and last pregnancy, years (SD)	2.9 (1.3)	3.03 (1.4)	.02
Mean duration of observation after first pregnancy, years (SD)	4.6 (2.3)	4.9 (2.3)	<.001

Table 2: Univariate and adjusted comparisons of selected long-term pelvic floor health outcomes among women with no labour and women having labour, for women who had only one delivery, in Nova Scotia, including both MSI and CIHI medical and procedure codes, 1998-2006.

Outcome	No labour n = 1192	Labour n = 16087	Univariate			Adjusted		
	n (%)	n (%)	OR	95% CI	P value	OR	95% CI	P value
Urinary incontinence[a]	17 (1.4)	318 (2.0)	0.72	0.44-1.17	.19	0.65	0.40-1.07	.09
Anal incontinence[b]	< 5 (< 0.4)	183 (1.1)	*	*	.01	0.71	0.09-5.35	.74
Pelvic organ prolapse[a]	6 (0.5)	136 (0.9)	0.59	0.26-1.35	.21	0.53	0.23-1.20	.13
Urogenital fistula[c]	< 5 (< 0.4)	18 (0.1)	*	*	.30	1.87	0.42-8.24	.41
Pelvic floor dysfunction[a]	21 (1.8)	586 (3.6)	0.47	0.31-0.74	<.001	0.60	0.39-0.94	<.001
Any pelvic floor disorder[d]	23 (1.9)	599 (3.7)	0.51	0.33-0.78	.002	0.66	0.43-1.02	.06

Analysis using logistic regression
[a]Adjusted for type of labour, maternal age at first delivery, severe perineal laceration in any pregnancy
[b]Adjusted for type of labour, pre-existing hypertension in any pregnancy, severe perineal laceration in any pregnancy, wound infection or dehiscence in any pregnancy
[c]Adjusted for type of labour, smoking at admission for labour in any pregnancy, severe perineal laceration in any pregnancy
[d]Adjusted for type of labour, maternal age at first delivery, smoking at admission for labour in any pregnancy, severe perineal laceration in any pregnancy

*Suppressed since cell size < 5

Table 3: Univariate and adjusted comparisons of selected long-term pelvic floor health outcomes among women with no labour and women having labour in the initial pregnancy in Nova Scotia, including both MSI and CIHI medical and procedure codes, 1998-2006, accounting for multiple observations.

Outcome	No labour n =1720	Labour n = 26141	Univariate			Adjusted		
	n (%)	n (%)	OR	95% CI	P value	OR	95% CI	P value
Urinary incontinence[a]	29 (1.7)	624 (2.4)	0.70	0.48-1.02	.06	0.68	0.47-0.99	.047
Anal incontinence[b]	< 5 (< 0.3)	493 (1.9)	*	*	<.001	0.26	0.07-0.93	.04
Pelvic organ prolapse[a]	14 (0.8)	310 (1.2)	0.68	0.40-1.17	.16	0.66	0.38-1.13	.13
Urogenital fistula[d]	< 5 (< 0.3)	35 (0.1)	*	*	.30	1.90	0.63-5.69	.25
Pelvic floor dysfunction[a]	41 (2.4)	1302 (5.0)	0.47	0.34-0.64	<.001	0.63	0.46-0.88	.01
Any pelvic floor disorder[e]	44 (2.6)	1326 (5.1)	0.49	0.36-0.67	<.001	0.68	0.49-0.94	.02

Analysis using GEE

[a]Adjusted for type of labour, maternal age at first delivery, parity, severe perineal laceration in any pregnancy

[b]Adjusted for type of labour, parity, severe perineal laceration in any pregnancy

[c]Adjusted for type of labour, maternal age at first delivery, smoking at admission for labour in any pregnancy, severe perineal laceration in any pregnancy

[d]Adjusted for type of labour, maternal age at first delivery, parity, smoking at admission for labour in any pregnancy, severe perineal laceration in any pregnancy

*Suppressed since cell size < 5

Table 4: Univariate and adjusted time-to-event analyses of selected long-term pelvic floor health outcomes among women with no labour and women having labour in the initial pregnancy from first delivery to first pelvic floor disorder diagnosis for the study duration, in Nova Scotia, including both MSI and CIHI medical and procedure codes, 1998-2006.

Outcome	Univariate			Adjusted		
	HR	95% CI	P value	HR	95% CI	P value
Urinary incontinence[a]	0.75	0.52-1.09	.13	0.68	0.47-0.995	.047
Anal incontinence[b]	0.09	0.03-0.29	<.001	0.90	0.44-1.83	.77
Pelvic organ prolapse[c]	0.74	0.43-1.26	.27	0.67	0.39-1.15	.15
Urogenital fistula[d]	1.80	0.64-5.05	.27	1.94	0.68-5.58	.22

Analysis using proportional hazard regression
laceration in any pregnancy
[b]Adjusted for type of labour, parity, severe perineal laceration in any pregnancy,
[c]Adjusted for type of labour, maternal age at first delivery, parity, Caesarean or postpartum hysterectomy in last pregnancy, severe perineal laceration in any pregnancy
[d]Adjusted for type of labour, maternal age at first delivery, smoking at admission for labour in any pregnancy, severe perineal laceration in any pregnancy

Table 5: Maternal, obstetrical and newborn characteristics of women with no labour and women having labour in Nova Scotia, including only CIHI medical and procedure codes, 1990-2006.

	No labour n=3066	Labour n=57939	P value
Mean maternal age at first delivery, years (SD)	28.3 (5.6)	26.2 (5.5)	<.001
Maternal parity at last delivery (%)			
1	1695 (55.3)	25832 (44.6)	<.001
2	1121 (36.6)	24427 (42.2)	
3 or more	250 (8.2)	7680 (13.3)	
Mean maternal pre-pregnancy weight at last delivery, kg (SD)	70.8 (17.6)	68.7 (16.5)	<.001
First delivery < 37 weeks gestation (%)	539 (17.8)	3658 (6.4)	<.001
Mean of largest birth weight, grams (SD)	3352 (775)	3583 (564)	<.001
Smoking at admission for labour in any pregnancy (%)	714 (23.8)	15992 (28.2)	<.001
Chorioamnionitis in any pregnancy (%)	35 (1.1)	689 (1.2)	.83
Pre-existing hypertension in any pregnancy (%)	114 (3.7)	769 (1.3)	<.001
Pre-existing diabetes mellitus in any pregnancy (%)	196 (6.4)	2488 (4.3)	<.001
Caesarean or postpartum hysterectomy in last pregnancy (%)	11 (0.4)	40 (0.1)	<.001
Severe perineal laceration in any pregnancy (%)	36 (1.2)	3519 (6.1)	<.001
Intra-operative maternal trauma in any pregnancy (%)	49 (1.6)	942 (1.6)	1.0
Wound infection or dehiscence in any pregnancy (%)	72 (2.4)	725 (1.3)	<.001
Pre-pregnancy urinary incontinence in first pregnancy (%)	<5 (< 0.2)	66 (0.1)	.78
Pre-pregnancy anal incontinence in first pregnancy (%)	0 (0)	12 (0.02)	1.0
Mean duration between first and last pregnancy, years (SD)	3.8 (2.3)	4.1 (2.5)	<.001
Mean duration of observation after first pregnancy, years (SD)	7.9 (4.6)	9.0 (4.7)	<.001

Table 6: Univariate and adjusted comparisons of selected long-term pelvic floor health outcomes among women with no labour and women having labour, for those women who had only one delivery, in Nova Scotia, including CIHI medical and procedure codes, 1998-2006.

	No labour n=1695	Labour n=25832	Univariate			Adjusted		
Outcome	n (%)	n (%)	OR	95% CI	P value	OR	95% CI	P value
Urinary incontinence[a]	11 (0.7)	191 (0.7)	0.88	0.48-1.61	.67	0.70	0.37-1.33	.27
Anal incontinence[b]	< 5 (< 0.3)	611 (2.4)	*	*	<.001	0.75	0.10-5.56	.77
Pelvic organ prolapse[c]	8 (0.5)	223 (0.9)	0.55	0.27-1.10	.09	0.45	0.21-0.90	.04
Urogenital fistula[b]	< 5 (< 0.3)	35 (0.1)	*	*	.66	1.94	0.58-6.52	.28
Pelvic floor dysfunction[d]	14 (0.8)	927 (3.6)	0.22	0.13-0.38	<.001	0.55	0.32-0.96	.04
Any pelvic floor disorder[d]	17 (1.0)	950 (3.7)	0.27	0.16-0.43	<.001	0.63	0.38-1.04	.72

Analysis using logistic regression
[a]Adjusted for type of labour, maternal age at first delivery, smoking at admission for labour in any pregnancy, wound infection or dehiscence in any pregnancy
[b]Adjusted for type of labour, prepregnancy weight for last delivery, smoking at admission for labour in any pregnancy, intra-operative maternal trauma in any pregnancy, severe perineal laceration in any pregnancy
[c]Adjusted for type of labour, maternal age at first delivery, smoking at admission for labour in any pregnancy, severe perineal laceration in any pregnancy
[d]Adjusted for type of labour, maternal age at first delivery, smoking at admission for labour in any pregnancy, intra-operative maternal trauma in any pregnancy, severe perineal laceration in any pregnancy

*Suppressed since cell size < 5

Table 7: Univariate and adjusted comparisons of selected long-term pelvic floor health outcomes among women with no labour and women having labour in the initial pregnancy in Nova Scotia, including only CIHI medical and procedure codes, 1990-2006, accounting for multiple observations.

	No labour n=3066	Labour n=57939	Univariate			Adjusted		
Outcome	n (%)	n (%)	OR	95% CI	P value	OR	95% CI	P value
Urinary incontinence[a]	21 (0.7)	655 (1.1)	0.60	0.39-0.93	.02	0.55	0.35-0.87	.01
Anal incontinence[b]	25 (0.8)	2109 (3.6)	0.22	0.15-0.32	<.001	0.87	0.51-1.51	.62
Pelvic organ prolapse [c]	24 (0.8)	844 (1.5)	0.53	0.35-0.80	.002	0.55	0.36-0.83	.01
Urogenital fistula[d]	7 (0.2)	95 (0.2)	1.39	0.65-3.00	.40	1.78	0.81-3.91	.15
Pelvic floor dysfunction[e]	59 (1.9)	3190 (5.5)	0.34	0.26-0.44	<.001	0.64	0.48-0.85	.002
Any pelvic floor disorder[e]	65 (2.1)	3250 (5.6)	0.36	0.28-0.47	<.001	0.69	0.53-0.90	.01

Analysis using GEE
[a]Adjusted for type of labour, maternal age at first delivery, parity, smoking at admission for labour in any pregnancy, pre-existing diabetes in any pregnancy
[b]Adjusted for type of labour, prepregnancy weight for last delivery, parity, severe perineal laceration in any pregnancy, wound infection or dehiscence in any pregnancy
[c]Adjusted for type of labour, maternal age at first delivery, parity, smoking at admission for labour in any pregnancy, severe perineal laceration in any pregnancy
[d]Adjusted for type of labour, maternal age at first delivery, prepregnancy weight for last delivery, smoking at admission for labour in any pregnancy, severe perineal laceration in any pregnancy, wound infection or dehiscence in any pregnancy
[e]Adjusted for type of labour, maternal age at first delivery, parity, smoking at admission for labour in any pregnancy, severe perineal laceration in any pregnancy, wound infection or dehiscence in any pregnancy

Table 8: Univariate and adjusted time-to-event analyses of selected long-term pelvic floor health outcomes among women with no labour and women having labour in the initial pregnancy from first delivery to first pelvic floor disorder for the study duration in Nova Scotia, including only CIHI medical and procedure codes, 1990-2006.

	Univariate			Adjusted		
Outcome	HR	95% CI	P value	HR	95% CI	P value
Urinary incontinence[a]	0.72	0.47-1.11	.14	0.61	0.38-0.88	.04
Anal incontinence[b]	0.22	0.15-0.33	<.001	0.95	0.66-1.37	.78
Pelvic organ prolapse[c]	0.63	0.42-0.95	.03	0.63	0.41-0.97	.04
Urogenital fistula[d]	1.56	0.72-3.36	.26	1.91	0.87-4.15	.11

Analysis using proportional hazard model

[a]Adjusted for type of labour, maternal age at first delivery, prepregnancy weight for last delivery, pre-existing diabetes in any pregnancy

[b]Adjusted for type of labour, maternal age at first delivery, parity, severe perineal laceration in any pregnancy, wound infection or dehiscence in any pregnancy

[c]Adjusted for type of labour, maternal age at first delivery, prepregnancy weight for last delivery, parity, severe perineal laceration in any pregnancy

[d]Adjusted for type of labour, maternal age at first delivery, prepregnancy weight for last delivery, smoking at admission for labour in any pregnancy, severe perineal laceration in any pregnancy, intra-operative maternal trauma in any pregnancy

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APPENDIX A

Variables evaluated from the Nova Scotia Atlee Perinatal Database

Antepartum Variables	**Intrapartum Variables**	**Postpartum Variables**	**Neonatal Variables**
Maternal age	Method of delivery	Wound hematoma	Infant birth year
Maternal parity	Caesarean hysterectomy/ postpartum hysterectomy	Wound dehiscence	Gestational age
Maternal pre-pregnancy weight (kg)	Trial of labour after previous Caesarean delivery	Wound infection	Infant weight
Maternal smoking in pregnancy	Severe perineal laceration		
Pre-existing hypertension	Maternal intra-operative trauma		
Pre-existing diabetes			
Gestational diabetes			
Previous Caesarean delivery			
Multiple gestation			
Chorioamnionitis			

APPENDIX B

Variables evaluated from the HDNS Databases (MSI billing and CIHI)

	ICD-9 Codes	ICD-10 Codes
Incontinence Disorders		
Urinary	625.6, 788.3	N31.2, 31.9, 35.0, 39.3, 39.4
Anal	787.6	R15
Prolapse Disorders	618.0,618.1,618.2,618.3 618.4,618.5,618.7,618.8,61 8.9	N99.3, 81.2-81.5 N81.0, 81.1 K62.2, N81.5, 81.6, 81.8, 81.9
Prolapse in pregnancy	654.4	O34.5. O34.8
Fistula Disorders	596.2, 619.0, 619.1, 619.8	N82.0, N32.2

	ICD-9 Codes	ICD-10 Codes
Incontinence Procedures		
Urinary	59.3,59.4,59.5,59.6, 59.71,59.72,59.79	1.PL.74,1.PM.80, 1.PL.35
Anal	48.79,49.79,75.62	1.NT.80
Prolapse Procedures	69.22,69.23,70.4,70.5,70.77 ,70.79,70.8,96.18,97.74,97. 25 48.79,49.79	1.RM.73,1.RM.74, 1.RS.51 1.PL.74,1.PM.80,1.RS.74,1. RS.80, 1.NQ.73, 1.NT.73
Fistula Procedures	57.84, 70.73	1.PM.86,1.PQ.86,1.NQ.86, 1.NT.86, 1.RS.86,1.RY.80