A RANDOMIZED CONTROLLED TRIAL
OF THE EFFECTS OF THE BATH IN LABOUR

by

Janet Patricia Brown Rush

A thesis submitted in conformity with the requirements
for the degree of Doctor of Philosophy
Graduate Department of Nursing Science
University of Toronto

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0-612-45760-5
Abstract

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Taking a bath in labour has become increasingly popular, however, the scientific evidence regarding effectiveness has been inconclusive. The purpose of this study was to determine whether a policy to encourage a bath reduced the use of epidural analgesia. Other effects were also evaluated: labour and birth events, fetal/newborn health, women's perceptions of their childbirth experience and, in the experimental group, pain measures pre and post bath immersion. The Gate Control Theory was used to explain the potential benefits of the bath.

In this two-site study, 635 healthy, labouring, women were randomly allocated, with stratification for parity and site, to an experimental group (n = 319) for whom baths were encouraged, and a control group (n = 316) who received conventional care. An intent-to-treat method of analysis was used and a crossover rate of 18% resulted for each group.

There were no differences between groups in the use of epidural analgesia (experimental group, 245/319, 76.8%; control group, 240/316, 75.9%, 1p = .90) and labour and birth events, with the exception that the control group was more likely to experience meconium stained amniotic fluid during labour (62/316, 19.7%, vs. 43/319, 13.6%, 2p = .04). Newborn outcomes between the groups were not significantly different. Mean scores for pain intensity and affect
were significantly lower with bath immersion (intensity: pre, 6.39 ±1.93; post, 5.59 ± 2.19, 2p = <0.0005; affect: pre .760, ± .141; post, .682, ± .202, 2p = <0.0005). The mean scores for women's retrospective rating of overall labour pain intensity and affect were higher for the experimental group (intensity: 7.72 ± 1.7 vs. 7.37 ± 2.1, 2p = .049; affect: .795 ± .118 vs. .756 ± .184, 2p = .005). The experimental group had higher mean scores on a scale that measured the frequency of selected, supportive, nursing activities (45.04 ± 7.6 vs. 43.20 ± 7.3, 2p = .005).

The most prevalent themes about bathing, from the content analysis of the women's comments, were relaxation and pain relief. Further study should be undertaken to measure the effect of the bath on relaxation and anxiety, given the women's written comments.
Acknowledgements

In undertaking this research, I have been most fortunate to have had the influence and support of countless individuals. Through her mentorship, my thesis supervisor, Dr. Ellen Hodnett, has provided me with extensive insight into the process of scientific evaluation. My committee members, Dr. Bonnie Stevens, Dr. Karyn Kaufman, Dr. Murray Enkin and Dr. Andrew Willan, have strengthened my commitment to scientific rigor and evaluating clinical effectiveness.

The women who agreed to participate in the Tub Trial did so with enthusiasm. Their thoughtful written comments have given rise to my deeper understanding about the experience of childbirth and provoked new questions for my future consideration.

The centre collaborators, Susan Burlock and Susan Kwolek, gave their valuable time to integrate the project into their settings. Their commitment and support was exceptional. The Nurse Managers, Jane Ingall, Lois McInnes and Eileen Bain, maintained momentum and stimulated staff in contributing to nursing research. I was impressed with the energy of the site teams, prenatal educators, and the staff nurses who incorporated research tasks into their busy days. Eileen Williams and Emma Rush were patient and relentless in completing the volume of forms for each study participant. Their contribution was invaluable.

The assistance of Dr. Gary Foster in developing the computer logistics and data entry programs is recognized as is the help from Eric Duku in answering my countless biostatistics queries. Sam Rush was detailed and fastidious in assisting with the data cleaning and the entry of eight months of logbook data. I am fortunate to have had the secretarial and personal support of Maureen Weatherston. Students from McMaster University School of Nursing and the Canadian Job Strategy Program enthusiastically provided help with fieldwork and coding forms.

Gratefully acknowledged are the following institutions who provided financial sponsorship for the study: The Maternal and Infant Health Reproductive Unit (MIRU), Toronto; The Fr. Sean O’Sullivan Research Centre, St. Joseph’s Hospital, Hamilton and The Graduate Department of Nursing Science, University of Toronto. The McNeil Consumer Products Company, Guelph, Ontario, donated the pain scoring tools. Receiving studentship, fellowship and scholarship awards provided personal, financial, assistance throughout my five years of study. I extend my gratitude to the Graduate Department, University of Toronto, the Kathleen King Award, Faculty of Nursing, University of Toronto, the Sisters of St. Joseph, the St. Joseph’s Health Care
Foundation and the Fr. Sean O'Sullivan Research Centre, Hamilton, Ontario.

No effort of this magnitude is ever accomplished alone. I am incredibly fortunate to have a network of family, friends and colleagues who have sustained me throughout my doctoral education. I am continually moved and gratified by their love, care, and support. Above all, I dedicate my efforts to my children, Emma and Sam, and to my parents, Phyllis and Bert.
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CHAPTER 1
THE INTRODUCTION

Background

Encouraging a labouring woman to take a bath is one instrumental comfort measure within the repertoire of activities subsumed within the overall concept of supportive care in labour (Hodnett, 1999). The use of the bath as a non-pharmacologic, supportive intervention has become increasingly popular in labour and delivery units for pain relief (Simkin, 1989; Levitt, Hanvey, Avard, Chance & Kaczorowski, 1995; Rush, Lambert, Burlock, Loosley-Millman, Hutchison, Enkin, 1996; Little, 1998). Early descriptive reports have generated an interest in the possible effects of the bath. These effects include decreased pain intensity, less use of pharmacologic pain relief agents, improved relaxation, decreased anxiety and fatigue, and maternal acceptance (Brown, 1982; Odent, 1983; Goodlin, 1984; Milner, 1988; Church, 1989; Alderhold & Perry, 1991). A systematic review of the randomized controlled trials, however, has provided no significant evidence of benefit or risk from taking a bath in labour (Nikodem, 1999).

Two principal factors have stimulated a continued interest in the effects of the bath in labour. First, childbirth is an important developmental event in a woman’s life (Humenick, 1981), and her mastery of the event is closely tied to her feelings of satisfaction, fulfillment and self-worth (Affonso, 1987; Bramadat & Driedger, 1993; Mackay, 1995; Brown & Lumley, 1994). Many women approach childbirth with a desire to avoid pharmacologic pain relief agents or keep them to a minimum (Brownridge, 1994; Christensen-Szalanski, 1984; Beaton & Gupton, 1990; Green, 1993; Lowe, 1989). Women plan, read, take classes and prepare items and resources to help them cope with the stress of labour and control pain using non-pharmacologic measures.
However, the majority of women in Ontario receive pharmacologic pain relief agents, particularly epidural analgesia, during labour (Levitt et al., 1995; Oyston, 1995). Epidural analgesia is a highly effective pain relief method but it is associated with longer labour, increased labour augmentation with intravenous oxytocic agents, fetal malposition, a higher rate of operative birth and an increased likelihood of neonatal hypoglycemia (Howell, 1999). Associations between epidural analgesia and hypotension, fever, pruritis, fetal distress and postpartum backache and urinary dysfunction have been reported (Howell, 1994; Thorp & Breedlove, 1996). Some women may have feelings of disappointment, anger, guilt and a sense of failure associated with their use of epidural analgesia (Morgan, Bulpit, Clifton & Lewis, 1982; Robinson, Rosen, Evans Revill, David & Rees, 1980; Melzack, 1984). These feelings have extended to expressions of non-achievement or lack of fulfillment as a woman and a deprivation of the experience of childbirth (Morgan, Bulpit, Clifton & Lewis, 1982). Evaluating strategies that reduce the rate of epidural analgesia may serve to improve childbirth outcomes.

In a previous randomized controlled clinical trial about the bath in labour (Rush et al., 1996), we observed a non-significant reduction in use of pharmacologic pain relief agents (epidural analgesia and/or intramuscular opioid injection) in the bath group (n = 235/393, 59.8%) compared to the control group (n = 259/392, 66.1%, 2p = 0.06). Further study was warranted to answer various methodologic and theoretical issues. Exploring the theoretical mechanisms linking labour, pain and hydrotherapy was considered important in understanding the possible analgesic effects of the bath.
Statement of the Problem

Taking a bath in labour, while increasingly popular and prevalent in labour and delivery units, lacks conclusive evidence from rigorous clinical trials regarding the effects on pain relief, the use of pharmacologic analgesia and other labour and birth events. Additional scientific study is required to provide evidence upon which to develop sound policies and protocols for safe, responsive, and supportive care.

Objectives

The overall objective of the study was to evaluate the practice of facilitating a woman’s use of a bath in labour. The primary outcome was the use of epidural analgesia. The secondary outcomes included the effects of the bath on labour and birth events, maternal, fetal and neonatal morbidity and on women’s evaluations of their experience. Secondary objectives were to describe the affective and intensity dimensions of pain (pre and post bath immersion), and the effects of selected physiologic markers related to bathing such as body temperature, fluid balance and changes in blood pressure.

Review of the literature

This section will review the process of labour and labour pain. Two pain relief interventions will be reviewed: taking a bath in labour and epidural analgesia. Their use, mechanisms of action and the scientific evidence regarding effectiveness will be described. The Gate Control Theory will then be presented as an explanatory framework about the experience of labour pain and the possible beneficial effects of taking a bath in labour.
The process of labour and labour pain

Labour is a process where progressively stronger uterine contractions result in dilation of the cervix and culminate with the expulsion of the fetus and the placenta. Associated with the process are tissue tension, damage, stretching, shearing, fatigue, pressure and the psychological stress induced by an unfamiliar setting and an unknown birth outcome (Bonica, 1990; Lowe, 1996). Labour pain is nociceptive (Britt & Pasero, 1999). The various effects can provoke fear, anxiety, exhaustion and profound pain. Pain is an unpleasant sensory and emotional experience associated with actual or potential tissue damage. Pain is always subjective (Merskey, Albe-Fessard, Monica et al., 1979). It becomes overwhelming, demands immediate attention, is disruptive and motivates a person into actions which aim to stop the pain as quickly as possible (Melzack, 1983).

While there is wide variation in the location, intensity, quality and predictability of labour pain, most women’s labours are accompanied by acute to severe pain intensity; labour has been reported as one of the most intensely painful and agonizing pain syndromes known (Melzack, 1984; Brown, Campbell & Kurtz, 1989; Brownridge, 1994; Britt & Pasero, 1999). Contributing to the nature and intensity of the response are a combination of physical, physiological, personal and contextual variables. Physical variables include fetal size, stage of labour, maternal height/weight, parity, and labour complications such as dystocia and abruption. Physiological variables are those influences and responses during the time of stress such as the pressure of the uterus on the surrounding structures. Also included are the chemical compounds released with tissue damage and associated with pain (histamine, 5-hydroxytriptime, bradykinen, substance P, prostaglandin, potassium, acetylcholine, and serotonin [Brownridge, 1994; Bonica & McDonald, 1990; Lowe, 1996]). Personal influences may include the woman’s previous pain experience,
culture, education, childbirth preparation, anxiety, effectiveness of pain coping strategies and personal control. Contextual, or situational variables include the warmth of and familiarity with the setting, the amount of labour support, noise, and the staff attributes.

The sources of pain during labour are visceral and somatic. Visceral stimuli originate from the contraction and stretching of smooth muscle of the uterus and the stretching and resulting tissue damage from the dilating cervix (Bonica, 1984; Bonica, 1990; Brownridge, 1994). These sensations emanate predominantly from the small-diameter, nociceptive, non-myelinated C-fibers carried by the uterine, cervical, hypogastric, and aortic plexes. The resulting discomfort and pain can be referred, or felt, in other parts of the body. In the case of the uterus, pain can be felt in the lower back and sacrum, the upper thighs, lower abdomen, and bowels. The experience is described as dull and aching.

Somatic inputs are carried by large-diameter, myelinated, A-delta fibers and are due to the stretching of structures, pressure from the presenting fetal part on the perineal area, and tearing of the fascia and ischemia during the descent of the fetus during the later stages of labour and birth. The nociceptive fibers from the perineal structures course through the pudendal nerve. The sensations are sharp, stinging and localized in the vagina, rectum, and perineum.

Labour provokes a stress response manifested by increased tension in skeletal muscles, respiratory rate and sympathetic tone. Subsequently, there is a release of carbon dioxide, and increases in blood pressure, metabolic rate and oxygen consumption. These responses are intended to maintain homeostasis; however, the prolonged physical stress, exhaustion and anxiety may prove deleterious and counter-productive (Bonica, 1984; Lederman, Lederman, Work and McCann, 1978; Lederman et al., 1981; Lowe, 1996). Excessive muscle tension may be caused by
or be a result of stress, anxiety and mental and physical fatigue. Blood vessels constrict and the heart works harder and faster. At rest, a person breathes six litres of air per minute. During uterine contractions, the volume increases to 25-35 litres per minute (Brownridge, 1994). The calcium ion is increased, which stimulates the sensory nerves to become more excitable, influencing the painful sensations. Hormones released in response to the various forms of physiological and psychological stressors (fear, anxiety) include adrenaline, noradrenalin, cortisone and endorphin. The release of stress hormones promote glucose utilization and a breakdown of glycogen. If insufficient energy is available once glycogen stores are utilized, protein and fat will start to break down. With the breakdown of fat to cope with the energy needs, the subsequent release of fatty acids into the circulation can contribute to an acidotic state (Bonica & McDonald, 1990). The stress response is normal and protective; however, if prolonged and unrelieved either through pharmacologic or non-pharmacologic methods, the effects can include a decreased blood supply to certain organs, including the uterus and the placenta (Lederman et al, 1991). Contractions may become ineffective, lengthening the process of labour. The decreased blood supply to the placenta and prolonged labour may precipitate fetal distress.

**Pain relief interventions**

**Taking a bath in labour**

Taking a bath is a form of hydrotherapy. The principal, clinically-driven reasons for hydrotherapy are to gain the therapeutic value of heat (Walsh, 1990), buoyancy (hence joint flexibility and freedom of movement) and the soothing or relaxing effects of the water (Hall, Bisson & O’Hare, 1990). Heat provides analgesic, antispasmodic and sedative effects (Lee, Itoh,
Thermal afferent receptors are triggered with the perfusion of heat via convection and
conduction (Sekins & Emery, 1990; Walsh, 1990). Cited in various animal studies and
observational human studies, are descriptions that heat produces an increase in the extensibility of
collagen tissue, a decrease in joint stiffness, relief of muscle spasm, an increased blood flow and
assists in the resolution of inflammatory infiltrates, edema, and exudates (Lehman & DeLatour,
1990). The underlying mechanism suggests that superficial heating of the skin (to approximately
38 degrees Celsius) will increase the temperature of collagen and muscles and produce changes in
tissue metabolism, neuromuscular, and enzyme activity. Reflexogenic changes in muscular
activity, such as relaxation in striated muscle and in the smooth muscle of gastrointestinal tract
and uterus, can occur. While immersed in water, the pressure on the body’s surface increases by
22.4 mm. Hg for each foot of water in a bath or pool (Hall et al., 1990), thus facilitating venous
return, and consequently, increased urinary output.

Taking a bath is a time-honoured form of stress relief and relaxation in virtually all
cultures (Donegan, 1986). Water has inherent forces of buoyancy, pressure, cohesion and
viscosity. Thus, stress on the joints, muscles, and great vessels is minimized. This is especially so
for pregnant women as the water can lift the gravid abdomen, relieving pressure on the inferior
vena cava, possibly improving circulation to the fetus. Archimedes’ principle of buoyancy is that
objects with a specific gravity <1 will float. The specific gravity of the body is .974. Water exerts
a perpendicular pressure against the surface of the body. This hydrostatic pressure is equal to the
ratio of the magnitude of the force exerted by the fluid per body surface area. Hydrostatic
pressure increases with the depth of the submerged part and the density of the liquid (Walsh,
As a result of the hydrostatic pressure gradients experienced during immersion, 400-500 ml. of blood pooling in the limbs is redistributed (Hall et al., 1990). Should the bath have the added feature of whirlpool jets, the water’s agitation may contribute to additional sedative and analgesic effects (Walsh, 1990).

Offering tangible, instrumental, ‘hands-on’ assistance, such as encouraging a bath, to provide comfort and decrease pain, is one of the five categories of activities within the concept of nursing support (Hodnett, 1996; Hodnett, 1998). The other four categories are emotional support, advocacy, supporting the husband/partner and information/advice. A systematic review of the trials of labour support from skilled care givers (Hodnett, 1998) concluded that, given the benefits, and no associated risks, efforts should be extended to ensure that all labouring women receive support. The benefits of the continuous presence of a trained support person included decreases in operative vaginal birth, cesarean section, use of analgesia and fewer newborns with Apgar scores <7. Women experiencing continuous labour support tended to rate their childbirth experiences more favourably.

In a Canadian hospital survey of maternity services and practices, a question was included requesting participants to note if a bath or shower was available to labouring women for pain relief (Levitt et al., 1995). Seventy-two percent (364/508) of hospitals responded that baths and/or showers were available. A second part of the question asked that respondents to report the proportion of women who actually used a bath or shower. Forty percent was the average estimate and wide variations were apparent. In previous national surveys conducted in 1980 and 1985, the question about baths and showers was not included (Post, 1981; Post & Hanvey, 1986).
Studies of the use of the bath in labour

The use of the bath in labour is increasing despite the paucity of scientific evidence of effectiveness. Evaluation of selected, specific effects of the bath in labour has been subjected to five randomized controlled trials (Table 1). In her systematic overview of three of the trials, Nikodem (1999) concluded that the studies provided no significant evidence of benefit or risk from a bath during labour.

Two of the studies (Cammu, Clasen, VanVelstere & Derde, 1992; Schorn, McAllister & Blanco, 1993) were relatively small and the other (Rush et al., 1996), while larger, observed a 46% crossover effect in the experimental group. There were various inconsistencies among the protocols. The Belgian study (Cammu et al., 1992) involved nulliparous women only. Timing of the bath was restricted to specific cervical dilations in the Belgian study (3-5 centimeters) and the American study (4-7 centimeters, Schorn et al., 1993). Cervical dilation for the Canadian study (Rush et al., 1996) was only specified as approximately 3 centimeters and greater; their criteria for admission to the labour unit. Only a few outcomes were reported in more than one trial. The focus for one study was pain (Cammu et al., 1992), overall childbirth events in another (Schorn et al., 1993) and use of analgesia in the third study of the review (Rush et al., 1996). The recommendation of Nikodem’s review was that routine use of the bath in labour should be undertaken with care. She suggested that baths in labour be limited to controlled trials or situations where ongoing audit of outcomes and possible complications was a component of care. Figure 1 details the meta analysis results.

Not included in the systematic review are two other randomized controlled trials. The
first (Bastide, 1992) was conducted in Quebec and included 295 healthy, labouring women, 152 of whom received four baths lasting between 26 and 32 minutes each. The outcome of interest was length of labour. The experimental group experienced a longer mean length of labour than controls (600 vs. 552 minutes). The effect was more pronounced for nulliparous women (767 vs. 632 minutes).

A small randomized trial (n=18) was conducted on the effects of the bath in labour on pain intensity, anxiety, and various physiological markers of hydrotherapy (Benfield, 1993). The bath was offered when the woman’s cervix was ≥4 centimeters dilated. Pain intensity and anxiety were measured at comparable intervals in both groups using visual analogue scales. The experimental group experienced statistically significantly lower pain intensity and anxiety at the fifteen minute mark following bath immersion. A plasma volume increase occurred in the experimental group, after 15 minutes in the bath, as measured by serum hematocrit and hemoglobin values. The author postulated that the increase in plasma volume could improve uteroplacental function. Her explanation for this was based on the suggestion that the hemodilution would decrease the concentration of beta-endorphins which are oxytocin antagonists, and dilute levels of epinephrine. The decreases in these levels would, according to Benfield’s model, reverse the effects of stress and improve uteroplacental function. An assessment of urinary catecholamines showed no differences between groups in this small study.
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<td>@ end of protocol (p = .001)</td>
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<td></td>
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<td>Satisfaction</td>
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<td>@ Cx 3-5 cm</td>
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<td>Nulliparas</td>
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<td>1 bath, &lt;1hr</td>
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<td>Bastide,</td>
<td>1992, Canada</td>
<td>E = 295</td>
<td>Length of labour</td>
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<td>(690 vs 552 min)</td>
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<td>events</td>
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<td>Only intact memb.</td>
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<td>Showers allowed for controls</td>
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<td>Benfield,</td>
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<td>Pain</td>
<td>15 min post immersion Pain score lower with bathers @ 15 and 90 min post immersion.</td>
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<td>@ Cx 3-5 cm</td>
<td></td>
<td></td>
<td>Plasma volume shift</td>
<td>Increased plasma volume @ 15 minutes post immersion.</td>
<td></td>
</tr>
<tr>
<td>1 bath, 2-3 hrs</td>
<td></td>
<td></td>
<td>Urine catecholamine</td>
<td>No difference in urine catecholamine</td>
<td></td>
</tr>
<tr>
<td>Rush et al.,</td>
<td>1996, Canada*</td>
<td>E = 393</td>
<td>Epidural analgesia</td>
<td>Lower instrumental births in experimental group (2p = .05)</td>
<td>Large cross-over rate (46%)</td>
</tr>
<tr>
<td>C = 392</td>
<td></td>
<td></td>
<td>IM opioids</td>
<td></td>
<td></td>
</tr>
<tr>
<td>@ Cx, ~3 cm</td>
<td>bath time</td>
<td></td>
<td>Labour and birth</td>
<td></td>
<td></td>
</tr>
<tr>
<td>54 min (avr)</td>
<td>events</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
A randomized controlled trial has been published of early (cervix > 5 centimeters dilated) labor versus late beginning in the first stage of labor (Rikhsian et al., 1997). Labor was defined by the presence of regular contractions only, with cervical dilatation > 5 centimeters. The early group

![Diagram showing data and comparisons.](Diagram)

Figure 1: Immersion vs. no Immersion in labor: comparison of outcomes (adapted from Nikodem, 1999)
100) used more epidural analgesia (p = <0.001), had longer labours (p = <0.004) and used more oxytocin (p = <0.01) than the late group (n = 100). The study stimulated interest in the timing of bathing. The absence of a no-bath cohort limits the understanding of the bath's specific effects.

A non-randomized trial in Sweden (Lenstrup, Schantz, Berget, Feder, Roseno & Hertel, 1987) was conducted with 160 women, 88 of whom requested a bath, and a control group (n = 72) who did not wish to take a bath during labour. Pain intensity scores, using a 100mm. visual analogue scale, showed statistically significantly lower scores for bath users while immersed in the tub (p = <0.05) than the controls at comparable time periods. During the following 90 minutes post immersion, the pain intensity levels were similar between groups. This study reported an increase in dilation during the bathing period compared with the control group (2.5 cm/hr versus 1.25 cm/hr., p = <0.05). No differences in analgesic use, maternal complications and neonatal Apgar scores were found. The authors concluded that the differences in pain intensity scores may have been related to volunteer bias. A follow-up study (Gradert, Hertel, Lenstrup, Christenses & Roseno, 1987) used the same protocol for 20 women and explored the effects of the bath on newborn levels of stress hormone in the cord blood. No statistically significant differences were reported.

Other non-randomized studies (Waldenstrom & Nilsson, 1992; Burns & Greenish, 1992) suggested that taking a bath may decrease pain intensity, shorten (or lengthen) labour, decrease the need for analgesia, reduce episiotomies and improve breastfeeding outcomes. The early descriptive reports about the bath in labour generated an interest in the effects of the bath, encouraged its use and suggested possible reasons for the overwhelmingly positive maternal
responses. These reasons include decreased pain intensity, promotion of relaxation, improved overall comfort and decreased muscle tension and fatigue. The reports encouraged the bath as a labour pain relief option owing to its universal familiarity, and because it was an intervention in which the woman could participate and experience a sense of personal control (Brown, 1982; Odent, 1983; Milner, 1988; Church, 1989; Aderhold & Perry, 1991; Goodlin, Hoffman, Williams & Buchan, 1984). A survey in England and Wales was conducted about the number of women who had laboured or given birth in water and any resulting problems. During the 2-year period (1992-1993), 8,255 women were reported to have used the bath for labour or birth. Twelve stillbirths or neonatal deaths had occurred and each situation was subjected to individual follow-up by the authors. No death was directly attributable to use of the bath (Alderice, Renfrew, Marchant, Ashurst, Hughes, Berridge & Garcia, 1995)

Taking a bath appears to be a sensible, feasible, and inexpensive comfort measure which can be administered without apparent risk to the woman or fetus. The bath's measurable beneficial outcomes, however, remain to be determined.

**Epidural Analgesia**

Epidural analgesia, a regional motor block, has become the primary pharmacological pain relief intervention used in most large maternity hospitals in Canada (Levitt et al., 1995). A survey of maternity practices in Canadian hospitals occurred in 1993. Ontario had the largest use of epidural analgesia. The hospitals were asked to estimate the proportion of women who used epidural analgesia. The respondents noted that the use was as low as 15 % in some units and as
high as 90% (average, 33%, SD = 25, Levitt et al., 1995). Larger birthing units (>300 births per year) and teaching or university affiliated hospitals were more likely to be associated with higher use of epidural analgesia. From the survey data, the actual number of women who use epidural analgesia is difficult to ascertain. The overall use, as reported by varying sizes of hospitals, under-represents the actual volume of women experiencing epidural analgesia. Sixty percent of Ontario’s births (about 86,000 births) occur in the larger hospitals. A survey of Labour and Delivery Unit Managers at Ontario’s hospitals with obstetrical beds was conducted in 1994, to obtain data about the availability of regional anaesthesia for cesarean section and labour (Oyston, 1995). Epidural analgesia for labour, with and without the adjunct of an opioid, was used in 75% of hospitals. The overall mean epidural analgesia rate was 38% with the larger hospitals reporting rates of 60% or higher. In the two settings for the current trial, the use of epidural analgesia administration during the year prior to the study was approximately 70%. This represents 5,200 women who experienced epidural analgesia.

The local anaesthetic agents, such as bupivacaine, reversibly prevent generation and conduction of electrical impulses in autonomic sympathetic fibres by decreasing the transient increase in the permeability to sodium. Nerve axons and other excitable membranes utilize sodium channels as the primary means of action potential generation (Miller, 1998). Sensitivity usually depends on the size of the fibre; small fibres are more sensitive than larger fibers. Visceral, C-fibres are usually blocked first, followed by fibres that transmit sensations of temperature, touch and deep pressure. Higher concentrations of local anesthetic also block sympathetic somatic sensory and motor fibres (Bonica, 1984). The onset of action is rapid (5-10 minutes) and the duration of action is 3-7 hours (Gelman & Rumack, 1996). Moderate to
complete motor blockade can be achieved with 0.5% solutions of bupivacaine in doses of 10-20 ml (50-100mg). Partial to moderate motor blockage is achieved with 0.25% in doses of 10-20 ml (25-50mg).

The addition of opioids to the epidural anesthetic agents has become more prevalent over the past decade. Opioid analgesics, such as morphine or fentanyl, produce analgesia by interacting with opiate receptors in the central nervous system, possibly by mimicking endogenous endorphins (Gelman & Rumack, 1996; Way, Fields & Way, 1998). A number of opiate receptors have been identified and opiates can be classified according to their relative affinities and potencies at the different receptors. Opiates interact with binding sites in the central nervous system involved in the transmission and modulation of pain, and other tissues, but with the highest concentration in the limbic system, thalamus, striatum, hypothalamus, mid brain and spinal cord (Way, Fields & Way, 1998). Fentanyl citrate (the usual opioid in epidural analgesia protocols) is an opioid analgesic with similar pharmacological effects to morphine and meperidine. Fentanyl 0.1 mg has equivalent activity to 10 mg of morphine or 75 mg of meperidine (Gelman & Rumack, 1996). The greater lipid solubility of fentanyl, in comparison to morphine (580:1), results in more rapid onset of analgesia. High lipid solubility also causes rapid clearance from the cerebral spinal fluid, resulting in a relatively short duration of action and a decreased incidence of side effects. Systemic absorption of opioid does occur which can cause euphoria, sedation, nausea, vomiting or fetal heart rate variability (ACOG, 1996).
Studies of epidural analgesia in labour

In a review of the scientific evidence from eight randomized controlled trials related to epidural analgesia versus other pharmacologic methods for labour and birth, Howell (1999) concluded that epidural analgesia is more effective than alternate forms of pain relief in labour. However, it is associated with various risks. Epidural analgesia is linked with an increase in the length of the first and second stage of labour. Epidural analgesia users experience an increase in the need for labour augmentation with oxytocic agents. Also associated is an increase in the incidence of fetal malposition and an increase in the use of instrumental delivery if the motor block is maintained beyond the first stage of labour. The meta-analysis reported an increase in the need for cesarean section for failure to progress and that neonates were more likely to experience hypoglycemia. Howell concluded that confirmation from larger studies is needed to understand the long-term effects on both the neonate and the woman. Howell commented that the review spanned twenty years and that the epidural techniques varied from study to study. Various concentrations of anaesthetic agents were used, with and without opioids, via continuous, patient-controlled or intermittent administration. Table 2 provides a summary of six randomized controlled trials from Howell’s review. The studies relating primarily to the effects on the newborn are not included in this table. Figure 2 shows the meta analysis results.
### Table 2: Studies of the use of epidural analgesia in labour (from Howell, 1999)

<table>
<thead>
<tr>
<th>Author</th>
<th>Subjects</th>
<th>Intervention</th>
<th>Major Outcome(s)</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Thalme et al.,</td>
<td>E = 14</td>
<td>E = B, .25mg, Int</td>
<td>Length of labour</td>
<td></td>
</tr>
<tr>
<td>1974 Sweden</td>
<td>C = 14</td>
<td>C = P, 100 mg. x1, Chl, 12.5 mg x1, N20/02, pudendaral</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Swanstrom et al.,</td>
<td>E = 37</td>
<td>E = L .4% Cont., or L .5%, Int.</td>
<td>Length of labour</td>
<td></td>
</tr>
<tr>
<td>1981 Sweden</td>
<td>C = 43</td>
<td>C = paracervical block off L .5% or 50% N20/02</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Philipsen &amp; Jensen</td>
<td>E = 57</td>
<td>E = B .375, Int</td>
<td>Pain, hypotension, neonatal outcomes Length of labour:</td>
<td></td>
</tr>
<tr>
<td>1989 Denmark</td>
<td>C = 55</td>
<td>No use in 2nd stage C = P 75 Mg x 1-2, pudendaral for 2nd stage</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Thorpe et al.,</td>
<td>E = 48</td>
<td>E = B .25% bolus then .25% Cont.</td>
<td>Length of labour Pain</td>
<td></td>
</tr>
<tr>
<td>1993 USA</td>
<td>C = 45</td>
<td>C = P 75mg and 25 mg Prom. IV every 90 min. if required</td>
<td>Apgar scores Cord blood Neurological adaptive scores</td>
<td></td>
</tr>
<tr>
<td>Ramin et al</td>
<td>E = 664</td>
<td>E = B .25, with 2 mcg F. (Cont)</td>
<td>Length of labour Labour and birth events Cord gases</td>
<td>Large crossover, data published as secondary analysis</td>
</tr>
<tr>
<td>1995 USA</td>
<td>C = 666</td>
<td>2nd stage = ½ infusion dose C = P 50 mg. IV with Prom. 25 mg (Inf)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Muir,</td>
<td>E = 28</td>
<td>E = B .125 plus P. 25 mg (PCA) or B .125, 4ml boluses</td>
<td>Pain scores Regional block Length of labour Cervical dilation Augmentation Delivery Maternal satisfaction Apgar scores</td>
<td>50% crossover to epidural analgesia</td>
</tr>
<tr>
<td>1996 Canada</td>
<td>C = 22</td>
<td>C = P 1mg/Kg load then 10 mg buses (PCA)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Legend: E = Experimental group (epidural analgesia); C = Control group; B = Bupivacaine; L = Lignocaine; P = Pethidine; Prom = Promethazine; F = Fentanyl; Int = Intermittent doses; Cont = Continuous infusion; PCA Patient controlled analgesia via IV infusion

Note: Studies relating primarily to neonatal outcomes are not included
Figure 2: Epidural vs. no epidural in labour: comparison of outcomes (adapted from Howell, 1999)

<table>
<thead>
<tr>
<th>Review: Epidural vs non-epidural analgesia in labour</th>
<th>Peto Odds Ratio (95%CI)</th>
<th>WMD (95%CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Epidural vs non-epidural analgesia in labour</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1st stage of labour not painless</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2nd stage of labour not painless</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Failed analgesia in first stage</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Failed analgesia in second stage</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Length of first stage of labour (hours)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Length of second stage of labour (minutes)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Oxytocin augmentation</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Motor blockade</td>
<td></td>
<td></td>
</tr>
<tr>
<td>FHR abnormalities/meconium</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Malrotation</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Forceps/ventouse delivery</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Caesarean section</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Caesarean section for dystocia</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Caesarean section for fetal distress</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Caesarean section/forceps for dystocia</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Apgar Score &lt;7 at 5 minutes</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cord blood pH</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Umbilical artery pH &lt;7.2 at delivery</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Neonatal jaundice</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hypoglycaemia (&lt;1.67 mmol/l)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Two reviews (Howell, 1994; Thorp & Breedlove, 1996) provide summaries of other side effects of epidural analgesia based on retrospective and descriptive studies. Many of these relationships to epidural analgesia remain controversial in the absence of rigorous, prospective clinical trials: fetal distress, hypotension, fever, movement of the epidural catheter, pruritus (with opioids), postpartum headache, backache and urinary dysfunction. These reviews have been criticized in that the dose of analgesia used was relatively high, compared to current practices. Procedural problems have been reported such as multiple attempts or ineffective block (Lucy, 1993; Munoz, Dagnine, Allende et al, 1994). Faulty equipment, a “higher” block than required,
and broken or internally lodged catheters have also been reported (Dunn, Steinberg, O'Sullivan et al, 1992; Health Devices Alert, 1996).

More recently, “low-dose epidurals” that use a combination of anesthetic and opioid agents and the combined spinal-epidural (CSE) analgesia have been implemented in some settings (Abouleish, Abouleish & Camann, 1994; Ramin, Gambling, Lucas, Sharma Sidawi & Leveno, 1995; Muir, Shulkla, Liston & Writer, 1996; ACOG, 1996). The addition of the opioid generally allows for a smaller dose of local anaesthetic via the epidural route, and therefore, a reduction in the motor block and a decrease in the likelihood of local anaesthetic complications (ACOG, 1996).

Administered usually earlier in labour, the CSE method purports similar effects to the standard epidural analgesia but allows the woman to walk about in relative comfort during the early stages of her labour. Theoretically, the effects of the ambulation should prevent malposition and decrease the length of labour. A randomized controlled trial of CSE (n = 616) versus intravenous meperidine (n = 607) revealed no statistically significant differences in the rates of cesarean section for dystocia between the groups (Gambling, Sharma, Ramin, Lucas, Leveno, Wiley & Sidawi, 1998). The rate of forceps delivery was significantly higher in the CSE group (p = 0.036) as was the incidence of postanalgesia oxytocin augmentation (p = 0.01). The incidence of profound fetal bradycardia within sixty minutes of initial administration was more prevalent in the CSE group (p = <0.005). A recent Task Force on obstetrical anesthesia reported that the use of CSE techniques, when compared with standard techniques, results in a higher incidence of pruritis and nausea. The Task Force was equivocal regarding improved analgesia or maternal benefits in the absence of specific, rigorous trials (American Society of Anesthesiologists Task
Two recent RCT’s evaluating anaesthetic with opioid agents via the epidural route, versus intravenous meperidine have been reported. Sharma and colleagues (1997) found no differences in labour and birth events. The compliance with the protocols was 68% in the epidural analgesia group (n = 358) and 73% among the controls (n = 357). Protocol compliance was an issue in another trial of the two regimens (Clark, Carr, Loyd, Cook & Spinnato, 1998), specifically among the women allocated to the intravenous meperidine group (84/162, 52% crossover, versus 147/156, 6% crossover for the epidural analgesia group). In this trial, no differences were found in the rates of augmentation, operative birth, length of labour or neonatal outcomes using the intent-to-treat method of analysis.

In summary, the primary indication for epidural analgesia is the patient’s desire for pain relief (Levitt et al., 1995; American Society of Anesthesiologists Task Force on Obstetrical Anesthesia, 1999). The advantages of epidural analgesia are pain relief, continuous use (given the indwelling catheter and an infusion pump) and that it can be maintained for operative births (Bonica, 1984). The presence of epidural analgesia requires strict care procedures and close monitoring of the woman and the fetus for signs of adverse effects. The adverse effects are well-documented (Yarmush & Carlson, 1992; ACOG, 1996; Howell, 1998; American Society of Anesthesiologists Task Force on Obstetrical Anesthesia, 1999). Pain relief, while a compelling reason for epidural analgesia, may not confer childbirth satisfaction for some women (Robinson, Rosen, Evans, Revill, David & Rees, 1980; Morgan et al, 1982). From a behavioural or emotional perspective, the woman may lose her sense of control, her fear and stress may escalate with the various interventions and with her concern for her baby. She may feel dissatisfied and frustrated
by her childbirth experience and poor adaptation during the postpartum period may follow. Women have been reported to have feelings of anger, guilt and sense of failure associated with the use of epidural analgesia (Melzack, 1984). Some women have reported being deprived of the experience of childbirth, had no sense of achievement or did not fulfill their function as a woman (Morgan et al., 1982). No clinical trial has shown that epidural analgesia is without risk (Chestnut, Laszewski & Pollack et al., 1990; Howell, 1999).

**The Gate Control Theory**

The Gate Control Theory (Melzack & Wall, 1965; Melzack, 1996; Wall, 1996) provides a possible explanation as to why a bath in labour might work to provide comfort to the mother. Figure 3, below, provides a schematic representation of the interrelatedness of the excitatory, afferent nerve inputs, the spinal cord, and the brain, all of which transmit, discriminate, analyze, modulate, evaluate and respond to the event(s). The Gate Control Theory proposes that pain is a multidimensional, subjective, and uniquely personal experience (McGuire, 1992).

The Gate Control Theory suggests that a mechanism in the dorsal horns of the spinal cord, along the substantia gelatinosa, acts like a gate that inhibits or facilitates ascending and descending transmissions. The facilitation or inhibition depends on the balance of inputs from competing afferent nerve fibers in systematic association with interrelated brain processes (Melzack & Wall, 1965; Melzack, 1996). According to the Gate Control Theory, the brain plays a major role in the phenomenon of pain by way of three influencing systems which work in dynamic interplay to analyze and modulate inputs and responses. First, the evaluative system (central control) accounts for neocortical, or higher central nervous system, processes such as the
influence of meaning and past experience. Secondly, the motivational-affective system is subserved by the reticular and limbic mechanisms which generally ascribe unpleasantness of the experience, expectations, desires, and goals. Finally, the sensory-discriminatory system function is determined by the relative balance of spinal activity and addresses location and intensity. The three systems work in association with the spinal gating mechanism (Melzack & Casey, 1968; Melzack, 1996). The systems support the notion that pain is a multidimensional, subjective phenomenon. The individual’s pain response, then, is not only governed by noxious stimuli (or inputs) and internal chemical, hormonal, behavioural, and reflexic regulation, but also by personal and contextual variables such as prior conditioning, experience, culture, education, environment, age and the immediate situation at the time of the pain or stress.

A summary of the propositions underlying the Gate Control Theory follows. Afferent transmissions to the spinal cord transmission (T) cells are modulated by a gating mechanism in the dorsal horn of the spinal cord. The mechanism is influenced by the relative amount of activity in the large and small afferent fibers. The large fibers inhibit, or close, the gating mechanism and the small fibers excite/facilitate, or open, the gating mechanism. The specific gating mechanism is influenced by impulses from the brain. A specialized large-fibre descending system from the brain acts as a controlling mechanism, influences afferent conduction, and exerts control over sensory input. Once the output of the T cells (in the spinal cord) exceeds a critical level, an action system is provoked and the complex and individual pattern of behaviour, also called the action or the response to pain is experienced. The body is felt as a unitary system where inputs, central influences and responses are in dynamic activity (Melzack, 1996; Wall, 1996).
Figure 3: Gate Control Theory of Pain (adapted from Melzack, 1996; Wall, 1996)

Legend:
1. Central Control Processes (evaluative/meaning); 2. Motivational (affective/unpleasantness); 3. Sensory (discriminatory/intensity); GCS: Gate Control System – spinal cord; (T) – T-cells – transmission of ascending/descending stimuli; L – Large fibre afferents; S – small fibre afferents.
Application of the Gate Control Theory to the bath in labour

The Gate Control Theory provides an explanation of how therapies for pain relief might work. The Gate Control Theory has been consistently identified as the theoretical mechanism as to why a bath may provide relief, physically and emotionally (Newton, 1990; Simkin, 1989a; Simkin, 1989b; Lehman & DeLatour, 1984). Taking a bath excites tactile and thermal afferent fibres, acts upon the physical structures such as skin, muscles, collagen and circulation, and stimulates the descending influencing systems.

The apparently innocuous stimulation of immersion in a warm bath excites thermal and tactile receptors transmitted along large, high-velocity afferent nerve fibers. For the purposes of this study, the bath, through its properties of thermal energy, hydrostatic pressure, innocuous counter-stimulation and relaxation (physical and emotional) may modify pain intensity and unpleasantness, and specifically affect the relative balance of fast to slow afferent inputs to the central nervous system. An increase in the innocuous stimuli coursing along the large-diameter afferent fibers should, by competing with the small, noxious, afferent fibers, decrease painful inputs by inhibiting the “gate”. Vibration, (from whirlpool jets) activates fibres of all diameters but activates a larger proportion of A-fibres, since they tend to adapt during constant stimulation whereas C-fibre firing is maintained. The added feature of agitation from the vibration of the water in a whirlpool bath, therefore, sets the gate in a more closed position (Melzack & Wall, 1965). Other variables may combine to enhance the effects of the bath at a central level such as experience, meaning, culture, situational support, and the stage of labour. The critical level at which the T-cells activate a response may be dependent on this combination of factors.

Any central nervous system conditioning that increases the flow of the descending,
modulating inputs would facilitate the closing of the gate (Melzack & Wall, 1965). More slowly rising temporal patterns of stimuli, such as the process of labour, are susceptible to central control and allow the individual to use strategies to keep pain under control (Melzack & Wall, 1965).

Taking a bath need not be learned at a time of distress. Most women are aware of and have used a bath in other contexts than labour for comfort, coping and stress relief. Women may have the belief that taking a bath might comfort, relax, or distract them during labour. More importantly, taking a bath in labour may facilitate the woman’s feelings of participation in, or control over, her labour experience, which may be a precursor to childbirth satisfaction and postpartum health (Humenick, 1981; Littlefield, 1990; Brown & Lumley, 1994; Lowe, 1991; Mander, 1992).

**Primary Research Question**

Does a policy of encouraging a bath in labour decrease the use of epidural analgesia?

**Secondary Research Questions**

1. What are the effects of encouraging a bath in labour on:

   a) Maternal labour and birth outcomes, including: length of labour, labour augmentation, cervical dilation at the time of epidural analgesia administration, other analgesia, abnormalities in temperature and blood pressure, perineal trauma, operative birth?

   b) Fetal/neonatal morbidity including: fetal distress (meconium stained amniotic fluid during labour), Apgar score, temperature at birth, admission to a special care nursery, signs of infection while in hospital and

   c) Women’s evaluations of their childbirth experiences, including: recall of nursing support in labour, recall of the labour pain experience, perceptions of control during childbirth,
comments and preferences regarding pain relief methods in subsequent labours and their opinions about being study participants?

2. In those who took a bath during labour what was their pain pre and post immersion?
CHAPTER 2
DESIGN AND METHODS

Design

This study was a randomized controlled trial with prognostic stratification for parity and site. Randomization was undertaken using a central computerized system at the data coordinating centre. After obtaining consent from the eligible women, the nurse telephoned the centre and a computerized message guided the nurse in entering identification numbers and parity, following which the computer voice indicated the woman's study group.

Settings

The settings for the study were two birthing units in southern Ontario. A summary of the features of the sites from 1997 data follows:

<table>
<thead>
<tr>
<th>FEATURE</th>
<th>SETTING #1</th>
<th>SETTING #2</th>
</tr>
</thead>
<tbody>
<tr>
<td>Location</td>
<td>Central West, Ontario</td>
<td>Central East, Ontario</td>
</tr>
<tr>
<td>Regional designation</td>
<td>Level II</td>
<td>Level II</td>
</tr>
<tr>
<td>Births/Year</td>
<td>3800</td>
<td>3900</td>
</tr>
<tr>
<td>Epidural Analgesia Rate</td>
<td>70.6%</td>
<td>65%</td>
</tr>
<tr>
<td>Cesarean Section Rate</td>
<td>13%</td>
<td>22%</td>
</tr>
<tr>
<td>Policy for routine use of continuous electronic fetal monitoring?</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>Policy for continuous support in labour?</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>#Labour Birth Recovery rooms (LBR's)</td>
<td>11</td>
<td>6 (+4LR's)</td>
</tr>
<tr>
<td># Tubs</td>
<td>4 (2 in LBR's, 2 communal)</td>
<td>4 (in LBR's)</td>
</tr>
<tr>
<td>Preadmission Policy?</td>
<td>Assessment Area (admission: Cx=--3-cm, contractions and/or mother considered &quot;active&quot;)</td>
<td>Triage Area (admission: Cx=--3-4cm and/or mother considered &quot;active&quot;)</td>
</tr>
<tr>
<td>Attendants</td>
<td>Obstetricians = 80% of births</td>
<td>Obstetricians = 75% of births</td>
</tr>
<tr>
<td>Ethnic/Immigrant Population?</td>
<td>Yes, Western European and Central American (10%)</td>
<td>Yes, Asian (30%)</td>
</tr>
</tbody>
</table>
Inclusion and Exclusion Criteria

The inclusion criteria were as follows: normal low risk pregnancy (as per Ontario Antenatal Record I), competent to give informed consent (Appendix A), at term (≥37 weeks) and in labour (as defined by the usual Labour Assessment/Triage protocols at the sites). It was permissible to obtain consent during the prenatal period. This could occur during a prenatal tour or at a visit to the hospital. Randomization occurred only when the woman was considered to be in labour and if a bathtub was available.

The exclusion criteria were: planned cesarean delivery, booked medical induction of labour, febrile, medical orders for continuous fetal monitoring or immediate epidural analgesia or if the woman was deemed at such medical high risk that a bath during labour was not advisable. Women who indicated a firm preference for pharmacologic pain relief as soon as possible after admission or stated a strong preference for taking a bath in labour were also not approached to consent and participate.

An Admissions Log tracked the participants and non-participants in the trial.

Manoeuvre

Prior to Randomization

Large, colourful posters of the study design were placed in the Assessment Areas and the Birthing Units for perusal by staff and those participating in the Prenatal Tours. Physicians and midwives were provided with information during meetings, at rounds and individually through a pre-study mail-out. Flyers that announced the study and invited participation were mailed to physicians’ offices, available at prenatal classes and hospital tours. A small Project Committee was in place at each site composed of a centre collaborator and volunteer representatives from front-line staff. The Principal Investigator provided special education sessions to nursing staff not
only to review the study procedures but also to reinforce the importance of providing nursing activities which respected the woman’s wishes about their pain medication preferences. For the purposes of popularizing the study among the staff, a logo (mermaid) was selected for all flyers, forms and posters and a short title of the study was used (“The Tub Trial”).

At each site, the labour nurse approached the woman when she came into the hospital for labour assessment, to ascertain her interest in the study. If she was interested and met the eligibility criteria, she was asked to review and complete the consent form. After ascertaining that a bath tub was available, randomization was accomplished by making a telephone call to the central data control centre, the group was assigned and the woman was told of her allocation. The hospital record and study documents were flagged appropriately.

The Experimental Group (The Tub Group)

The nursing staff assigned the woman to an appropriate labour room. If the woman was allocated to the experimental group, a room outfitted with a tub was provided. All women in the experimental group were offered a bath in their own labour room or in the other communal areas (in the case of the Central West site). While the staff was expected to actively encourage the woman to try the bath, they were advised not to use coercion. If the woman did not wish to use the bath, the reasons for non-use were documented. When the bath was used, data were collected about the frequency and duration in the bath. Prior to and about 15-20 minutes following immersion in the bath (initial time only), pain intensity and affect scores were documented. The temperature of the water in the tub was pre-set, however, if a conventional bathtub was used (ie, not the whirlpool tubs), the temperature was ascertained by staff and was not to exceed 39°C.

The woman’s request or the physician’s orders for epidural analgesia or other
pharmacologic intervention were followed as per usual custom.

Control Group

Women allocated to the control group were admitted to rooms not equipped with a tub. At Site 1, all rooms were decorated in a similar manner with two of the rooms equipped with a whirlpool bath. At Site 2, the four rooms with whirlpool baths were larger and newly renovated as birthing suites. If a woman was admitted to their conventional labour room, the staff at Site 2 made every attempt to move her so the birth would occur in the birthing suite (rather than their less-desirable “case room”). This was feasible for the vast majority of births. The control group women’s plans for labour and birth were respected, and care was managed in the conventional manner but without actively offering a bath. Women in the control group could use any other means of comfort or pain relief, including a shower.

Both Groups

The care of women and newborns followed the usual practice patterns of the hospitals. All hospital record data were collected by the principal investigator or by trained project assistants (Appendix B). For the purpose of group comparisons and other statistical analyses, data were collected as follows:

1. The Primary Outcome: use of epidural analgesia, agent(s) used, time of administration and cervical dilation at the time of the procedure;
2. Background variables: parity, maternal age, time of admission to hospital, gestational age, rupture of membranes (ROM), vaginal birth after cesarean (VBAC), fetal position;
3. Labour and birth outcomes: labour length (from when the woman stated it had begun and
from the time of admission), cervical dilation at admission, length of first and second stages of labour, oxytocin use during labour (augmentation), meconium-stained amniotic fluid, birth position, method of delivery, status of the perineum, any other analgesia/anaesthesia use, attendant for pregnancy (family physician, obstetrician, shared care or midwife), maternal temperature, blood pressure, fluid balance (outcomes of interest relative to hydrotherapy) and presence of ketones in the urine as recorded in the woman’s chart;

4. Information about use of the tub (frequency and duration of use, use of the whirlpool jets), measures of pain intensity and affect pre and post use;

5. Newborn outcomes: newborn weight, sex, first temperature, Apgar score, signs of newborn infection and any admission to the neonatal intensive care unit;

6. Maternal postpartum outcomes: maternal signs or symptoms of infection (with or without swabs, identified organism or treatment) were to be obtained from the health record;

7. Women’s evaluations of their experiences: from a questionnaire package provided to women during their postpartum hospital stay, data were obtained about their feelings and experience of control in labour and their perceptions of nursing support during labour, their overall recall of pain in labour and their opinions about the bath, epidural analgesia and being a study participant.

Instruments

Data collection packages

The data collection tools (Appendices D and E) were created to conform to a software program for the purpose of scanning into a computer database. The computer-sensitive data
forms were developed with the assistance of the staff at the Maternal, Infant and Reproductive Health Research Unit (MIRU), Toronto.

The Entry Form contained information to validate the women’s eligibility, parity (the stratification variable), staff instructions about the randomization service and procedure and the group assignment. A bedside form for bath users had places for the most recent cervical dilation prior to entering the bath, times in the bath, reasons for non-use, pain measurements pre and post bath immersion. The instruction for staff on this form was that a vaginal examination need not be performed unless indicated prior to tub use. There were forms for collecting Health Record information regarding the labour, birth and maternal/newborn postpartum outcomes.

The postpartum questionnaire package (containing the Labour Agentry Scale to assess childbirth feelings and experiences, the survey of opinions about using the bath, epidural analgesia and about being a study subject and the woman’s recall of the nursing supportive activities) was packaged separately for delivering to the woman’s bedside. All project forms included the study number and the woman’s hospital identification number.

**Pain measures: intensity and affect**

There were two pain assessment measures. The first measured pain intensity by requesting the woman to look at a colour analogue scale (McGrath, Seifert, Speechley, Booth, Stitt & Gibson, 1996). The colours intensified from white indicating no pain through red-brown for worst pain imaginable (Appendix B). The woman was asked to rate the intensity of the pain by sliding a marker along the coloured scale. The nurse recorded the number, from 0-10, that corresponded to the placement of the marker. A high internal consistency (r = .90) has been reported with the use of a visual analogue scale for pain intensity (Melzack, 1975). The color and visual analogue scales have been compared with use in children (McGrath et al., 1996) and showed a high level of correlation ($R^2 = .921$). The use of a vertical scale has been reported to be
easier to use, especially for those under stress (Cline, Herman, Shaw & Morton, 1992).

The second instrument measured the affective dimension of pain, (aversion, distress or unpleasantness feelings), and the woman was to choose from nine faces, ranging from happy to grimacing/crying, the one that described her feelings as they related to the pain (Appendix C). Each face corresponded to a numerical value from .04 to .97 and the values were read by the nurse from the reverse of the card. In the development of the values, children (3-17 years) rated their feelings, on brightness and visual analogue scales, that corresponded to the various faces. Each value represents the geometric mean of 400 responses averaged over 200 children. The mean values were transformed to a 0-1 scale on which the maximum negative affective value equals 1 and the maximum positive value equals 0 (McGrath, et al., 1996). Studies about the use of the pain affect measure in adults were not found. Prior to this study, a small group of postpartum women (n = 10) were asked their opinion about the faces tool by a nursing student. The women felt that the measure would be easy to use, not intrusive during labour and that they would be able to indicate their feelings about the pain via the faces. For this study, each tool was administered prior to entering the tub and again, after 15-20 minutes of immersion. The recording was to correspond to the pain felt at the height of the last contraction.

The same set of faces was presented in the postpartum questionnaire package for all participants to complete. Because the colour analogue scale was difficult to reproduce for the self-administered questionnaire, a visual analogue scale (a horizontal, 10cm. line) was used for assessing overall labour pain intensity. Women were asked to reflect on, recall, and rate their overall experience of pain intensity and affect in labour.

Labour Agentry Scale

The Childbirth Experience Form (The Labour Agentry Scale, Hodnett, 1983) assessed the participants’ experience of personal control during labour and birth. The Labour Agentry Scale
(LAS) is a ten-item, unifactorial, Likert-type rating scale. Women with high LAS scores have reported high childbirth satisfaction \((r > .88, \text{Hodnett, 1983})\).

**Nursing support in labour questionnaire**

The Nursing Support in Labour Questionnaire was included in the postpartum package. The questionnaire began with the woman’s assessment of the overall amount of time their nurse was with them. There were five categories from “small amounts of time only” up to “about 90% of the time”. A more lengthy section followed and asked women to recall their experiences of both the type and the frequency of nursing supportive activities during labour from a list of 21 items. The woman then rated whether the activity occurred often, occasionally or never. In a study of 201 women, the Support in Labour questionnaire had a Cronbach’s alpha coefficient of .87 (Hickey, 1992).

**Survey of postpartum opinions and comments**

Questions were included in the postpartum package about the participants’ opinions about pain relief measures. Women were asked to evaluate whether they were pleased, neutral or disappointed about having epidural analgesia (or not), and having had a bath (or not). There were lines on the form for written comments and questions about whether they would be likely to choose epidural analgesia or a bath in subsequent labours. Similarly, they were asked to comment about being in the study and to reflect on their choice about participating.

**Compliance**

Of importance to the study was the issue of respect for the woman’s pain medication preferences. It could have been possible for staff to influence a woman in her decisions about the type and timing of pain relief medications. Staff meetings and education sessions stressed the need for very strict protocol adherence especially as it related to the explanation of the study, obtaining
of consent, adherence to group allocation and the staff role in advocacy for the woman’s labour plans. A staff project team, the Principal Investigator and the centre collaborators maintained this emphasis during the study period.

Some crossover was expected. It was hoped that, by careful explanation of the study to potential study participants and strict monitoring, the women would be satisfied with their assigned groups and crossover would be minimized. Women were to be neither coerced into the tubs nor prevented from using them (in the case of control group allocation).

Co-intervention

In this effectiveness trial, the women in the two groups were exposed to other interventions that were associated with the outcomes. It was anticipated that the randomization process would distribute the interventions and activities equally between the two groups. The provision of continuous, one-to-one support during labour by a trained caregiver has been linked with similar outcomes as those claimed by bathing in labour (Hodnett, 1997; Rush et al, 1996). It was possible that women in the experimental, or “Tub” Group, could receive more support due to the presence of the nurse during the bath. For this reason, the amount of nursing support during labour was ascertained via postpartum questionnaire.

Non-randomized patients

Because women who participate in trials may differ from those who do not, data were collected on the overall population in terms of some variables and outcomes of this study (incidence of epidural analgesia, cesarean section, episiotomy rates and Neonatal ICU admission rates). These data are regularly collected and reported in the hospitals in an aggregate fashion. Names and other identification were not required for the purposes of this comparison.
Sample Size

A two-month audit of all births was conducted at both sites during 1997. The overall rate of epidural analgesia was 70.6% at Site 1 and 65.0% at Site 2. The use of epidural analgesia among women in the control group of our previous trial was 66% (Rush et al., 1996). The sample size was based on the mean epidural analgesia rate of these sites: 68%. The estimation of the sample size was based on the hypothesis that labouring women who are offered and encouraged to take a bath would experience a 10% absolute reduction in the use of epidural analgesia compared to women in the control group. Because epidural analgesia is associated with some adverse labour and birth outcomes (Howell, 1999) and has been related to other physical and emotional adverse effects, a 10% reduction in the use of epidural analgesia would make a considerable contribution toward the goals of improved birth outcome and maternal satisfaction.

A one-tailed test of the hypothesis was chosen, since the question of primary interest related to the issue of the bath’s beneficial effects on the decreased use of epidural analgesia for women in the experimental group. The total sample size needed to detect a 10% reduction in the use of epidural analgesia (for a one-sided, 5% level test of the hypothesis with 80% power) was 300 per group. The figure was adjusted to 320/group to account for the possibility of losses (women discharged home, not in labour) and to correct for the potential crossover effect.

Data Analysis

All women randomized were included in the final analysis. The analysis proceeded in the following manner.

1. All data forms were checked for consistency of identifiers (the hospital identification
number and the corresponding study numbers) and completeness of information. The
participants’ Health Records were checked for missing data.

2. The Admission Logs from the two sites were coded and analyzed to ascertain the
proportion of women who were eligible and ineligible during the dates of the study period
including the reasons for inclusion or exclusion.

3. The frequencies and distributions of all demographic, baseline variables, labour, birth and
postpartum outcomes were compared using chi square tests or Fisher’s exact for
categorical variables and 2-sample t-tests for between group means at the 0.05 level of
significance (0.10 level for epidural analgesia). The data collectors were provided with
parameters for indicating the presence or absence of the various outcomes:

*Augmented during labour:* administration of intravenous oxytocin during labour;

*Maternal B/P normal:* no elevations or decreases in either systolic or diastolic B/P in
excess of 20 mm Hg. during the labour period;

*Meconium noted during labour:* any notation of meconium-stained fluid during labour but
not to include notations of meconium at delivery;

*Maternal temperature normal during labour:* temperatures <37.5°C were considered
normal;

*Balanced intake and output:* considered unbalanced if a difference of 500 ml was
observed in the fluid balance record during the course of the labour;

*Ketones detected:* any presence of ketones (trace to 4+) noted in the labour notes;

*Temperature (newborn):* temperature as noted within the first hour of life;

*Infection (maternal or newborn):* any notations in the mothers’ or newborns’ post delivery
nursing records from a listing of signs, symptoms or diagnoses provided to the data
collectors(such as inflamed, mucky, reddened, pus, GBS, pneumonia, endometritis).
4. Using the methods of content analysis (Krippendorf, 1980; Kelly & Sime, 1990), a numbering system was developed for themes that emerged from the written comments noted in the first one hundred postpartum questionnaires. Themes were developed independently, first by a project assistant and then by the Principal Investigator. For example, the name “relax” was ascribed for written comments about taking a bath where such words as relax, soothe or calm appeared. The naming of the theme related to the word most frequently used in the comment, or in some themes such as “disclaim” or “suggest”, the overall impression or intent of the writer’s comment. One code per comment was allowed, therefore the primary expression or thought was selected for the coding. Where a comment did not fit into a major theme, or seemed unrelated to the area for comment, it was coded as “other”. A system for agreement was developed for comparing mutually consistent codes. One comment from each of the 100 packages was selected and the coding was compared. The level of agreement between the two evaluators was high (92%). The numerical coding was undertaken by trained project assistants and audited for accuracy and consistency by the principal investigator.

5. The appropriate items of the Labour Agency Scale (LAS) were reverse-coded (items 2, 3, 4, 6, 7 and 9). Each of the ten items has a possible score from 1 to 7. All scales but 6 were completely filled out (2 scales missed 3 items, 2 scales missed 2 items and 1 missed 1 item). For these, a mean score for these scales was assigned by computing and inserting the mean from the answered items. The item scores were summed and the mean scores were analyzed using independent sample t-tests.

6. The Nursing Support in Labour tool had two sections. Section 1 related to the amount of nursing support. The mother’s choice from the five categories about the percentage of direct nursing time spent during labour was analyzed using chi square analysis for linear
trend. Section 2 concerned the type of nursing support. This section had twenty-one items and the selected response was assigned the number 1 (never), 2 (occasionally) or 3 (often). Scales with at least 17 completed items were included. A sum out of 63 was calculated. Group means were calculated deleting item #19 (“Helped me to use a tub bath or shower of Jacuzzi as a way to relieve pain or relax”) for the purpose of reporting, given that this item corresponded to the intervention of the study. The mean scores were compared and analyzed using independent sample t-tests.

7. To describe her overall impression of labour pain intensity, the mark placed by the mother on a line was assigned a number from zero to ten using the software program. The face that described the woman’s overall labour pain affect was scored using the same values as the intrapartum measurement. The group means for both scales were compared and analyzed using t-tests for independent means.

8. Analysis of the change in the mean pain scores, pre and post bath immersion, was computed using paired t-tests for difference of means (same group).

9. To ascertain the predictors for epidural analgesia, logistic regression was undertaken using the pre-randomization variables (age, gestational age, attendant, hospital site, prelabour rupture of the membranes, prior cesarean section, twins and group assignment).

10. For the statistically significant predictors of epidural analgesia from the logistic regression (in this analysis, parity and hospital site), interaction effects were analyzed to explore whether the level of one factor affected the relationship between the other factor on epidural analgesia.

11. An analysis of the labour and birth events of early versus late bath users (intervention taken at < 5 centimeters and ≥ 5 centimeters of cervical dilation) was undertaken using chi square tests.
Ethics

Women were informed about the study during the prenatal period (prenatal visits, tours, flyers, posters, hospital registration procedures, assessment/triage areas) and had the study reviewed and explained at the time of labour assessment, if eligible. Only if the woman was adequately informed and in agreement was she asked to sign a consent form (Appendix A). At the educational sessions prior to the study, staff nurses were instructed on the appropriate approach for obtaining consent. Respecting the women's individual plans for the birth was emphasized. At no time was the woman to be urged to participate if she was ambivalent. Baths had been used in both sites for several years. While baths were not absolutely prohibited for women in the control group, women were informed that a bath would not be encouraged if they were allocated to that group. If a woman wished to include the option of the bath, she was advised not to participate in the study. At Site 2, one birthing suite was left free, if feasible, for the possibility of study participant use. Women were advised of this but if they were insistent on trying a bath in labour, and did not wish to be randomized, the “free” room would be made available for them. Any question could be directed to the Principal Investigator, Centre Collaborator, project assistants or members of the staff project team.

The project did not proceed until written approval was received from a Human Subjects Review Committee at the University of Toronto and from each participating institution.

Following all data collection, the documents were collected and maintained by the Principal Investigator and secured in a cabinet and locked office. Confidentiality was maintained by the use of study numbers on all data collection sheets. Only the Study Log identified the names of participants against their study numbers and this Log was carefully secured at the completion of the project.
CHAPTER 3

RESULTS

Timeline for the study and derivation of the sample

Pre-study activities were undertaken from June to December, 1997. The research proposal obtained approval in January, 1998. The study began on February 2, 1998, in both sites. The Central East site completed recruitment by August 17, 1998, and, the Central West site, by September 16, 1998. The overall number of births during this period was 4,323 (this figure excludes the elective cesarean sections [n = 234]). Women presenting for obstetrical assessment were entered into logbooks at the respective sites.

In total, 6,482 women arrived at the hospitals for obstetrical assessment during the study period. About one-half (n = 3,019, 46.6%) were not eligible for reasons of prematurity (n = 111); medical reasons such as fever, orders for electronic monitoring and risk issues (n = 842); or non-admission or transfer to the antenatal unit or another hospital following assessment (n = 2,066). Of the women meeting the eligibility criteria (n = 3,463, 53.4%), many were not approached (n = 1,695) owing to the activity of the unit, unavailability of a bathtub or if the birth was imminent. Language barrier (n = 281) was given as another reason for not approaching an eligible woman. Some women who were approached, refused (n = 847). The reasons documented for refusal were that they wanted the option of the bath, requested immediate epidural analgesia administration or were not interested. For three, eligible, consenting women, their pre-numbered study package was discarded because of documentation errors during the set up of the forms and another package was used for the randomization procedure. The spoiled originals were discarded. Two women were assigned to a group (one each per group) without using the randomization service and their forms were subsequently not entered into the analysis. Six hundred and thirty five (635) women were randomized following consent: 319 to the Tub or
experimental group and 316 to the control group. Figure 4 summarizes the recruitment of the sample.

Figure 4: STUDY DESIGN AND DERIVATION OF THE SAMPLE

Study Period: February 2-September 16, 1998
Women presenting to Labour and Delivery (n = 6,482)

Not Eligible (n = 3,019, 46.6%)
- <37 weeks gestation (n = 111)
- medical orders/problems (n = 842)
- home after assessment (n = 2,066)

Eligible (n = 3,463, 53.4%)
- missed, unit busy, precipitous (n = 1,695)
- refused (n = 847)
- language barrier (n = 281)
- consenting to study (n = 640)

Eligible, Consented (n = 640)
- forms spoiled/not used (n = 3, 1 tub, 2 control)
- assigned, not randomized (n = 2, one/group)

Randomized (n = 635)

TUB GROUP* (n = 319)
- Offered tub, did not use (n = 58, 18%)
- Offered tub, used the tub (n = 261, 81.8%)

CONTROL GROUP** (n = 316)
- Requested and took tub (n = 59, 18.6%)
- Usual care without use of tub (n = 257, 81.3%)

- shower use in experimental group = 12 (3.8%); **shower use in control group = 53 (16.7%)
Compliance

The crossover rate was 18.4%. Fifty-eight women in the tub group did not have a bath and fifty-nine women in the control group requested and took a bath (Figure 4). The reasons for not having a bath were: maternal/fetal complications (n = 8), mechanical difficulties (no hot water/tub malfunction, n = 3), epidural given before bath taken (n = 38), the woman changed her mind or the delivery occurred before the bath could be taken (n = 9).

The majority of women who used the tub did so only one time and the mean time in the tub was 51 (SD = 37) minutes. Twenty-five women used the tub twice and four women used the tub 3 times. The whirlpool jets were used by almost all of the women (92%).

The postpartum questionnaire package containing the various scales and survey forms was delivered to the bedside of participants while on the postpartum unit. It was expected that the women would complete the documents prior to leaving the hospital. In total, 529 (83.3%) women completed the package. There were 106 women (16.7%; 54 in the tub group and 62 in the control group) who did not complete the package despite up to 3 follow-up phone calls to their home and/or mail-outs within the first two weeks postpartum.

Group comparisons at randomization

Table 3 contains the data and analysis for the background variables by assigned group. Overall, there were slightly more nulliparas (n = 332, 52.3%) than multiparas (n = 303, 47.7%). The women’s mean age was 29.8 years (SD = 1.3). Most women were under the sole care of an obstetrician for their care in pregnancy (446, 70.2%) and others providing care were: general practitioner (n = 107, 16.8%), shared care (n = 76, 11.9%) and midwives (n = 5, 0.79%). The mean gestational age was 39.8 weeks (SD = 1.1). Twenty-six women had had a cesarean delivery previously. There was one case of a diagnosed twin pregnancy and this occurred in the tub
group. A woman with twins did not meet the eligibility criteria for low-risk but she was randomized and, therefore, included in the analysis. Overall, no important differences were found between the two groups.

### Table 3. Group comparisons at randomization*

<table>
<thead>
<tr>
<th>MEASURE</th>
<th>TUB GROUP** (N = 319)</th>
<th>CONTROL GROUP (N = 316)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Maternal Age</td>
<td>29.9 ±1.5</td>
<td>29.7 ±1.1</td>
</tr>
<tr>
<td>Gestational Age</td>
<td>39.8 ±1.1</td>
<td>39.7 ±1.1</td>
</tr>
<tr>
<td>Parity:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>nullipara</td>
<td>167 (52.3)</td>
<td>165 (52.2)</td>
</tr>
<tr>
<td>multipara</td>
<td>152 (48)</td>
<td>151 (47.8)</td>
</tr>
<tr>
<td>VBAC</td>
<td>12 (3.8)</td>
<td>14 (4.5)</td>
</tr>
<tr>
<td>Twins</td>
<td>1 (0.3)</td>
<td>0</td>
</tr>
<tr>
<td>Attendant:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>obstetrician</td>
<td>223 (70)</td>
<td>223 (70.6)</td>
</tr>
<tr>
<td>GP</td>
<td>53 (16.6)</td>
<td>54 (17.1)</td>
</tr>
<tr>
<td>GP-OB</td>
<td>40 (12.5)</td>
<td>36 (11.4)</td>
</tr>
<tr>
<td>Mwife</td>
<td>3 (0.9)</td>
<td>2 (0.6)</td>
</tr>
<tr>
<td>other</td>
<td>0</td>
<td>1 (0.3)</td>
</tr>
</tbody>
</table>

*Plus-minus values are means ± SD (standard deviation)

**"TUB GROUP" refers to the experimental group

### Primary Research Question: Use of epidural analgesia

The primary question of the study was the effect of the tub bath on the use of epidural analgesia. Table 4 provides the group comparisons. The overall rate of epidural analgesia was 76.4% (485/635). The difference between the groups was not statistically significant (tub group 245, 76.8%; control group 240, 75.9%, 1p = 0.80). The epidural solution which used an anaesthetic agent only was given in 160 cases (tub group, n = 79, 24.8%, control group, n = 81, 25.6%, 2p = 0.58) while anaesthetic and opioid agents or a combined spinal-epidural analgesia
was provided to 327 women (tub group, n = 167, 52.4%; control group n = 160, 50.6%, 2p = .66).

Table 4. Methods of analgesia and anaesthesia during labour and birth.

<table>
<thead>
<tr>
<th>METHOD</th>
<th>TUB GROUP</th>
<th>CONTROL GROUP</th>
<th>2p</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>(N = 319)</td>
<td>(N = 316)</td>
<td></td>
</tr>
<tr>
<td>Frequency (percent)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Epidural analgesia</td>
<td>245 (76.8)</td>
<td>240 (75.9)</td>
<td>.900***</td>
</tr>
<tr>
<td>anaesthetic agent only*</td>
<td>79 (24.8)</td>
<td>81 (25.6)</td>
<td>.580</td>
</tr>
<tr>
<td>+ opioid agent**</td>
<td>167 (52.4)</td>
<td>160 (50.6)</td>
<td>.664</td>
</tr>
<tr>
<td>IM Opioid</td>
<td>34 (10.7)</td>
<td>35 (11.1)</td>
<td>.865</td>
</tr>
<tr>
<td>Pudendal/Local</td>
<td>27 (8.5)</td>
<td>29 (9.2)</td>
<td>.751</td>
</tr>
<tr>
<td>General</td>
<td>1 (0.1)</td>
<td>0</td>
<td>.310</td>
</tr>
<tr>
<td>Nitrous oxide</td>
<td>1 (0.1)</td>
<td>0</td>
<td>.319</td>
</tr>
<tr>
<td>“Other” ***</td>
<td>16 (5.0)</td>
<td>16 (5.0)</td>
<td>.978</td>
</tr>
<tr>
<td>No analgesia</td>
<td>45 (14.1)</td>
<td>42 (13.3)</td>
<td>.765</td>
</tr>
</tbody>
</table>

Cervical dilation (at epidural analgesia administration):

<table>
<thead>
<tr>
<th>Cervical Dilation</th>
<th>TUB GROUP</th>
<th>CONTROL GROUP</th>
<th>2p</th>
</tr>
</thead>
<tbody>
<tr>
<td>0-2 centimeters</td>
<td>36 (14.7)</td>
<td>40 (16.7)</td>
<td>.920</td>
</tr>
<tr>
<td>3-4 centimeters</td>
<td>100 (40.8)</td>
<td>99 (41.3)</td>
<td></td>
</tr>
<tr>
<td>5-6 centimeters</td>
<td>64 (26.1)</td>
<td>60 (25)</td>
<td></td>
</tr>
<tr>
<td>7-10 centimeters</td>
<td>45 (18.4)</td>
<td>41 (17.1)</td>
<td></td>
</tr>
<tr>
<td>mean dilation ±SD</td>
<td>2.48 ±.95</td>
<td>2.42 ±.96</td>
<td>.300</td>
</tr>
</tbody>
</table>

* only an anaesthetic agent was administered for epidural block
** fentanyl or morphine added either in epidural space or intrathecally for combined spinal epidural. Two women who had spinal anaesthesia are included, one per group
*** “other” includes acetaminophen, gravol, phenergan, sterile water injections and hydrotherapy
----- Only the use of epidural analgesia was analysed using a one-sided test; all other tests were 2-sided

No statistically significant difference was observed in the timing of epidural analgesia as measured by the cervical dilation at the time of the procedure. The mean cervical dilation was 2.48 (SD = .95) centimeters for the tub group and 2.42 (SD = .96) centimeters dilation for the control group. The data were grouped by those having epidural analgesia from 0-4 centimeters (early epidural) and those who had epidural analgesia at ≥ 5 centimeters dilation. “Later” epidural
analgesia was administered to 45.5% of the tub group, while the control group rate was 42.1%, a non-significant difference.

For both sites, the overall use of epidural analgesia for the entire population was 69.4% during the period of the study.

Secondary Research Question #1:

Effects on birth outcomes, perinatal morbidity and mothers’ evaluations

Labour and birth events

The mean cervical dilation on admission to the labour and delivery unit was 2.9 (SD = 1.6) centimeters. The mean length of labour according to the women’s reports was 815.3 (SD = 579) minutes and the mean length of time from admission to delivery, 582.3 (SD = 404) minutes. There were no significant differences between groups in these times or in the lengths of the second and third stages of labour (Table 5).

Over one-half of the women (n = 364, 56.8%) had their membranes ruptured artificially while the remainder experienced spontaneous rupture of membranes during (19.5%) or before labour actually started (21.9%). Virtually all (96.2%) fetuses presented in the vertex position. Six women were noted to have fetuses in the breech position (tub group, n = 2; control group, n = 4), and, despite not being eligible for a low-risk classification, were randomized and included in the analysis. It is not known if the position of the fetus had been diagnosed at the time of randomization. The intravenous oxytocin augmentation rate was 42.1% (n = 267). Most women maintained a normal temperature throughout labour (n = 545, 85.8%). Blood pressure remained normal for the majority of women (n = 534, 84.1%). While fluid balance and the presence of ketones in the urine were included in the data collection forms, these were generally not recorded in the women’s hospital charts. Showers were taken by 12 women in the tub group and by 53 controls (3.7% vs. 16.7%, 2p = <0.0005). Apart from the use of showers, there were no
statistically significant differences between the groups (see Table 5).

Table 5: Group comparisons: Labour events*

<table>
<thead>
<tr>
<th>MEASURE</th>
<th>TUB GROUP (N = 319)</th>
<th>CONTROL GROUP (N = 316)</th>
<th>2p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Admission Dilation (cm)</td>
<td>2.90 ± 1.5</td>
<td>3.07 ± 1.7</td>
<td>.216</td>
</tr>
<tr>
<td>Length of labour (minutes):</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>From women’s estimations</td>
<td>814.1 ± 52</td>
<td>816.4 ± 634</td>
<td>.964</td>
</tr>
<tr>
<td>From admission</td>
<td>579.7 ± 390</td>
<td>584.9 ± 418</td>
<td>.83</td>
</tr>
<tr>
<td>Length of Second stage</td>
<td>67.7 ± 71.9</td>
<td>62.4 ± 60.9</td>
<td>.35</td>
</tr>
<tr>
<td>Length of Third stage</td>
<td>8.9 ± 7.8</td>
<td>9.5 ± 9.2</td>
<td>.32</td>
</tr>
<tr>
<td>Rupture of Membranes**</td>
<td></td>
<td></td>
<td>.110</td>
</tr>
<tr>
<td>PROM</td>
<td>78 (24.7)</td>
<td>60 (18.9)</td>
<td></td>
</tr>
<tr>
<td>SROM</td>
<td>66 (20.7)</td>
<td>58 (18.6)</td>
<td></td>
</tr>
<tr>
<td>AROM</td>
<td>171 (53.6)</td>
<td>193 (61.1)</td>
<td></td>
</tr>
<tr>
<td>Presentation:</td>
<td></td>
<td></td>
<td>.741</td>
</tr>
<tr>
<td>Vertex</td>
<td>309 (97.8)</td>
<td>302 (95.5)</td>
<td></td>
</tr>
<tr>
<td>Breech</td>
<td>2 (.6)</td>
<td>4 (1.3)</td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td>5 (1.5)</td>
<td>7 (2.2)</td>
<td></td>
</tr>
<tr>
<td>Augmented during labour</td>
<td>138 (44.7)</td>
<td>129 (42.2)</td>
<td>.531</td>
</tr>
<tr>
<td>Temperature &lt;37.5°C</td>
<td>275 (86.5)</td>
<td>270 (85.4)</td>
<td>.707</td>
</tr>
<tr>
<td>B/P normal</td>
<td>271 (85.5)</td>
<td>263 (84)</td>
<td>.543</td>
</tr>
<tr>
<td>Intake and Output:</td>
<td></td>
<td></td>
<td>.109</td>
</tr>
<tr>
<td>balanced</td>
<td>130 (40.8)</td>
<td>103 (44.2)</td>
<td></td>
</tr>
<tr>
<td>not balanced</td>
<td>7 (2.2)</td>
<td>8 (2.5)</td>
<td></td>
</tr>
<tr>
<td>not recorded</td>
<td>182 (57.1)</td>
<td>204 (64.5)</td>
<td></td>
</tr>
<tr>
<td>Ketones:</td>
<td></td>
<td></td>
<td>.872</td>
</tr>
<tr>
<td>Present</td>
<td>8 (2.5)</td>
<td>6 (1.9)</td>
<td></td>
</tr>
<tr>
<td>absent</td>
<td>155 (48.5)</td>
<td>153 (48.4)</td>
<td></td>
</tr>
<tr>
<td>not measured</td>
<td>156 (49)</td>
<td>156 (50)</td>
<td></td>
</tr>
<tr>
<td>Shower</td>
<td>12 (3.8)</td>
<td>53 (16.9)</td>
<td>&lt;0.0005</td>
</tr>
</tbody>
</table>

*Plus-minus values are means ±SD. There were a small number of missing values and percentages do not always total 100; **PROM: pre-labour rupture of the membranes; SROM: spontaneous rupture of the membranes; AROM: artificial rupture of the membranes.

The usual position for giving birth was on the back in a Semi-Fowler's position (n = 627, 98.7%). This figure includes the women who experienced an operative birth (n = 241).

Spontaneous births occurred in 393 (61.8%) women. The operative birth rates were as follows: forceps, 8.8% (n = 56); vacuum, 15.9% (n = 101) and cesarean section 13.2% (n = 84). The
primary cesarean section rate for the overall population of the two sites was 13.86% during the study period. About thirty percent (n = 189) of women had an intact perineum or a first or second-degree laceration (n = 243, 38.3%). Third and fourth-degree lacerations occurred in eleven (1.7%) cases and the number of women with episiotomies was 180 (28.4%). As detailed in Table 6 there were no statistically significant differences between the two groups.

Table 6: Group comparisons: Birth events

<table>
<thead>
<tr>
<th>MEASURE</th>
<th>TUB GROUP</th>
<th>CONTROL GROUP</th>
<th>2p</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>(N = 319)</td>
<td>(N = 316)</td>
<td></td>
</tr>
<tr>
<td>frequency (percent)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Back/Semi-Fowler’s position for delivery*</td>
<td>314 (98.4)</td>
<td>313 (98.1)</td>
<td>.485</td>
</tr>
<tr>
<td>Method of Delivery</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Spontaneous</td>
<td>192 (60.2)</td>
<td>201 (63.6)</td>
<td>.808</td>
</tr>
<tr>
<td>Forceps</td>
<td>29 (9.1)</td>
<td>27 (8.5)</td>
<td>.428</td>
</tr>
<tr>
<td>Vacuum</td>
<td>52 (16.3)</td>
<td>49 (15.5)</td>
<td>.784</td>
</tr>
<tr>
<td>C-Section</td>
<td>45 (14.1)</td>
<td>39 (12.3)</td>
<td>.511</td>
</tr>
<tr>
<td>Condition of the perineum</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Intact</td>
<td>98 (30.7)</td>
<td>91 (28.8)</td>
<td>.596</td>
</tr>
<tr>
<td>1° laceration</td>
<td>53 (16.6)</td>
<td>53 (16.8)</td>
<td>.957</td>
</tr>
<tr>
<td>2° laceration</td>
<td>61 (19.1)</td>
<td>76 (24.1)</td>
<td>.131</td>
</tr>
<tr>
<td>3° laceration</td>
<td>4 (1.3)</td>
<td>6 (1.9)</td>
<td>.514</td>
</tr>
<tr>
<td>4° laceration</td>
<td>1 (.1)</td>
<td>0</td>
<td>.319</td>
</tr>
<tr>
<td>Episiotomy</td>
<td>76 (23.8)</td>
<td>76 (24.1)</td>
<td>.946</td>
</tr>
<tr>
<td>Epis+Laceration</td>
<td>17 (5.3)</td>
<td>11 (3.5)</td>
<td>.256</td>
</tr>
</tbody>
</table>

*Includes forceps, vacuum and cesarean deliveries

Intramuscular opioids were administered to 10.9% (n = 69) of the women. For the birth, 56 women were given either a local or pudendal block. General anaesthesia was given to one woman (tub group). The use of nitrous oxide occurred in one situation (a tub group woman). There was space for indicating “other” analgesia and this was filled out for 32 participants (16 in
each group). The various other methods included acetaminophen, gravol or phenergan (given in combination with injected opioids) and sterile water injections. There was no between-group difference (see Table 4).

The nurses’ notes of all hospital records were read to ascertain any signs of postpartum infection (see Table 8). In total, 31 women were identified as having signs of infection and these were for maternal temperature, >37.5°C (tub group, 12; control group 18), and one reddened cesarean section incision (tub group). The findings regarding maternal signs of infection were not statistically significant.

Fetal/Newborn Events

Table 7 details the fetal and newborn outcomes by maternal group assignment. Meconium was noted to have been present during labour in 105 cases (16.5%). There was a statistically significant difference noted between the study groups (tub group, 13.6%, control group, 19.7%, 2p = .04).

There were no other statistically significant differences between the groups in terms of newborn outcomes (Table 7). The mean birthweight was 3483 (SD = 474.3) grams and the majority of newborns were being breastfed (88.8%). The overall percentage of males born was 57.9%, and females, 42.1%. The mean one and five-minute Apgar scores were 8.3 (SD = 1.2) and 9.0 (SD = .59) respectively. Apgar scores <7 were assigned to 58 newborns at one minute and 4 newborns at 5 minutes. Newborn temperatures were taken within the first hour of life and the mean temperature was 36.8°C (SD = .46°C). Fifty newborns were admitted to the Neonatal Intensive Care Unit (tub group, n = 25, 7.9%; control group, n = 25, 7.9%, p = .98) and the most prevalent reason was observation of transient respiratory problems.
Table 7: Group comparisons: Newborn outcomes

<table>
<thead>
<tr>
<th>MEASURE</th>
<th>TUB GROUP N = 319</th>
<th>CONTROL GROUP N = 316</th>
<th>2p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Birthweight (Gms)</td>
<td>3476 ± 481</td>
<td>3489 ± 467</td>
<td>.729</td>
</tr>
<tr>
<td>Apgar: 1 minute</td>
<td>8.34 ± 1.13</td>
<td>8.25 ± 1.38</td>
<td>.340</td>
</tr>
<tr>
<td>Apgar: 5 minute</td>
<td>9.01 ± .49</td>
<td>8.98 ± .69</td>
<td>.428</td>
</tr>
<tr>
<td>First temperature**</td>
<td>36.86 ± .43</td>
<td>36.84 ± .49</td>
<td>.550</td>
</tr>
<tr>
<td></td>
<td>frequency (percent)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Meconium in labour</td>
<td>43 (13.6)</td>
<td>62 (19.7)</td>
<td>.040</td>
</tr>
<tr>
<td>Apgar ≤ 7: 1 minute</td>
<td>26 (8.15)</td>
<td>32 (10.12)</td>
<td>.411</td>
</tr>
<tr>
<td>Apgar ≤ 7: 5 minutes</td>
<td>2 (.62)</td>
<td>2 (.63)</td>
<td>.100</td>
</tr>
<tr>
<td>Sex</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>182 (57.2)</td>
<td>185 (58.5)</td>
<td>.738</td>
</tr>
<tr>
<td>female</td>
<td>136 (42.8)</td>
<td>131 (41.5)</td>
<td></td>
</tr>
<tr>
<td>Breastfeeding</td>
<td>282 (88.4)</td>
<td>282 (89.2)</td>
<td>.737</td>
</tr>
<tr>
<td>NICU admission</td>
<td>25 (7.9)</td>
<td>25 (7.9)</td>
<td>.981</td>
</tr>
<tr>
<td>NICU Reason:</td>
<td></td>
<td></td>
<td>.355</td>
</tr>
<tr>
<td>From L&amp;D</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>respiratory sign</td>
<td>13 (4.1)</td>
<td>19 (6)</td>
<td></td>
</tr>
<tr>
<td>other reason</td>
<td>5 (1.6)</td>
<td>2 (.6)</td>
<td></td>
</tr>
<tr>
<td>From Postpartum</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>hyperbilirubinemia</td>
<td>2 (.6)</td>
<td>1 (.3)</td>
<td></td>
</tr>
<tr>
<td>hypoglycemia</td>
<td>2 (.6)</td>
<td>3 (.9)</td>
<td></td>
</tr>
<tr>
<td>other reason</td>
<td>3 (.9)</td>
<td>0</td>
<td></td>
</tr>
</tbody>
</table>

* plus-minus values are means ± SD
** first temperature: as recorded within the first hour of life

The nursing notes of 27 (4.3%) newborns had comments regarding indicators of infection (Table 8). A first temperature of >37.5°C was noted in 14 newborns (tub group, n = 6; control group, n = 8). Respiratory signs that may indicate an infection accounted for 12 cases (tub group, n = 4; control group, n = 8). Pustules were observed in one baby in the control group. There were no statistically significant differences between the groups.
Table 8: Group comparisons: Maternal and newborn signs of infection

<table>
<thead>
<tr>
<th>MEASURE</th>
<th>TUB GROUP</th>
<th>CONTROL GROUP</th>
<th>2p</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>N = 319</td>
<td>N = 316</td>
<td></td>
</tr>
<tr>
<td></td>
<td>frequency (percent)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Maternal infection</td>
<td>13 (4.1)</td>
<td>18 (5.7)</td>
<td>.588</td>
</tr>
<tr>
<td>Sign noted:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Temperature (&gt;37.5)</td>
<td>12 (3.7)</td>
<td>18 (5.7)</td>
<td>.513</td>
</tr>
<tr>
<td>C-section incision (red)</td>
<td>1 (.3)</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>Newborn infection</td>
<td>10 (3.1)</td>
<td>17 (5.4)</td>
<td>.160</td>
</tr>
<tr>
<td>Sign noted:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Temperature (&gt;37.5)</td>
<td>6 (1.8)</td>
<td>8 (2.6)</td>
<td>.278</td>
</tr>
<tr>
<td>Respiratory sign</td>
<td>4 (1.3)</td>
<td>8 (2.5)</td>
<td></td>
</tr>
<tr>
<td>Pustules</td>
<td>0</td>
<td>1 (.3)</td>
<td></td>
</tr>
</tbody>
</table>

Postpartum Evaluations

Nursing support in labour

There were no significant between-group differences in women's reports of the amount of
time nurses spent with them in labour. Approximately 30% of the women reported that the
nurses were with them 90% of the time and another 30% of respondents reported time spent at
the 75% level. Sixteen percent noted that the nurses spent 50% of the time with them, and the
remaining 12% indicated "small amounts to 25%" of their labour time with them (Table 9).

Women in the tub group reported slightly higher levels of nursing support than mothers in
the control group (Table 9). One of the support items in the scale was related to assisting the
mother to a bath or shower during labour. Given that this was the intervention being studied, the
analysis was done with this item removed. The mean scores for the tub and control groups were
45.05 (SD = 7.6) and 43.2 respectively (SD = 7.3, 2p = .005).
**Table 9:** Group Comparisons: Labour Support Questionnaire

<table>
<thead>
<tr>
<th>MEASURE</th>
<th>TUB GROUP</th>
<th>CONTROL GROUP</th>
<th>2p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Frequency of nursing activities</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sum without #19 (/60)*</td>
<td>45.04 ± 7.6</td>
<td>43.20 ± 7.3</td>
<td>.005</td>
</tr>
<tr>
<td>Amount of direct nursing time</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Time period:</td>
<td></td>
<td></td>
<td>.25</td>
</tr>
<tr>
<td>Nearly 90% of the time</td>
<td>86 (33.1)</td>
<td>65 (25.5)</td>
<td></td>
</tr>
<tr>
<td>About 75% of the time</td>
<td>86 (33.1)</td>
<td>96 (37.6)</td>
<td></td>
</tr>
<tr>
<td>About 50% of the time</td>
<td>53 (20.4)</td>
<td>49 (19.2)</td>
<td></td>
</tr>
<tr>
<td>About 25% of the time</td>
<td>20 (7.7)</td>
<td>22 (8.6)</td>
<td></td>
</tr>
<tr>
<td>Small amounts only</td>
<td>15 (5.8)</td>
<td>23 (9.0)</td>
<td></td>
</tr>
</tbody>
</table>

* item #19 related to offering the women baths or showers for labour pain

**Perceived control during labour**

Table 10 provides a comparison of the group responses. Mean LAS scores were not statistically significant (tub group, mean = 50.46, SD = 9.3; control group, mean = 51.71, SD = 9.6, 2p = .13).

**Table 10:** Comparisons of the Childbirth Experience Tool/ Labour Agency Scale scores.

<table>
<thead>
<tr>
<th></th>
<th>TUB GROUP</th>
<th>CONTROL GROUP</th>
<th>2p</th>
</tr>
</thead>
<tbody>
<tr>
<td>LAS Scores</td>
<td>50.46 ± 9.3</td>
<td>51.71 ± 9.6</td>
<td>.128</td>
</tr>
</tbody>
</table>
Postpartum recall of labour pain

The mean score for pain intensity was higher for the experimental group than the control group (tub group, mean = 7.72, SD = 1.7; control, mean = 7.37, SD = 2.1; 2p = .049). The pain affect scores were higher in the tub group (mean score = .795, SD = .12) than the control group (mean score = .756, SD = .18, 2p = .005) (Table 11).

Table 11: Measures of recall of overall labour pain intensity and affect

<table>
<thead>
<tr>
<th>MEASURE</th>
<th>TUB GROUP</th>
<th>CONTROL GROUP</th>
<th>95% CI</th>
<th>2p</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>N = 269</td>
<td>N = 262</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean ± SD</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pain intensity*</td>
<td>7.72 ± 1.7</td>
<td>7.37 ± 2.1</td>
<td>.002, .703</td>
<td>.049</td>
</tr>
<tr>
<td>Pain affect**</td>
<td>.795 ± .12</td>
<td>.756 ± .18</td>
<td>.012, .006</td>
<td>.005</td>
</tr>
</tbody>
</table>

* as measured by a horizontal visual analogue scale
** as measured by the faces scale

Women’s evaluations of the bath

The majority (74.3%) of women who took a bath and completed this section of the questionnaire (n = 234; tub group, 162; control group, 52) noted they felt pleased with having taken a bath in labour (Table 12). Approximately 18% felt neutral and 8.5% noted disappointment. Written comments were invited under a heading “please explain” and 235 women responded. The most prevalent theme (“relax”, 37.5%) related to how the bath relaxed, calmed, soothed and/or distracted them. Eighteen percent of the women wrote about how the bath relieved the pain and 15% stated that the bath both relaxed them and relieved the pain. Three other themes emerged about how the bath helped labour to progress (n = 14, 6%), slowed

54
their labour (n = 2, 0.85%) or had helped them in earlier labour. (n = 25, 10.6%). Some comments (n = 28, 12%) were organized into an “other” or miscellaneous theme. Examples included how the bath made them feel clean, warm and secure, helped them tolerate labour, that being in warm water was an instinctive thing to do, or that they wished they had the opportunity (control group). Also included in “other” were comments that were suggestions about the construction of the bath for added comfort or mobility. Comments illustrating some of the written responses as they relate to the themes of relaxation and pain relief are contained in Appendix F.

Table 12: Postpartum evaluations and themes from written comments: Bath Taken

<table>
<thead>
<tr>
<th>Survey: bath taken</th>
<th>frequency (percent)</th>
<th>2p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pleased:</td>
<td>162 (75.3)</td>
<td></td>
</tr>
<tr>
<td>Neutral:</td>
<td>37 (17.2)</td>
<td></td>
</tr>
<tr>
<td>Disappointed:</td>
<td>16 (7.4)</td>
<td></td>
</tr>
</tbody>
</table>

Themes from comments:

- Relax: 235
- Pain relief: 88 (37.5)
- Relax and pain relief: 43 (18.3)
- Hastened labour: 52 (22.6)
- Slowed down progress: 14 (6)
- Short-term effect: 29 (13.1)
- Other: 28 (12)

Some women responded to this section who were not labeled as crossovers and may have reported pre-hospital bathing.

Women’s evaluations of not taking a bath

Of the women who responded to this section (n = 190) and who did not take a bath, 62.6% stated they were neutral and 31.6% noted they were disappointed (Table 13). The most common theme from those who wrote comments (52/140, 37.1%) was entitled “disclaim” and
mothers expressed that the bath probably would not have helped them in their particular circumstance. The next theme, “regret” expressed comments where the mother wished that she had tried the bath. The “other” comments held notations such as, “It’s OK”, “It’s no bother”, “I’ll try it out next time.” Selected comments from the disclaim and regret themes are found in Appendix G.

Table 13: Postpartum evaluations and themes from written comments: Bath NOT taken

<table>
<thead>
<tr>
<th></th>
<th>TUB GROUP</th>
<th></th>
<th>CONTROL GROUP</th>
<th></th>
<th>2p</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>N = 45</td>
<td></td>
<td>N = 145</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Survey: bath not taken</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>.16</td>
</tr>
<tr>
<td>Pleased:</td>
<td>4 (8.9)</td>
<td>7 (4.8)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Neutral:</td>
<td>23 (51.1)</td>
<td>96 (66.2)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Disappointed:</td>
<td>18 (40.0)</td>
<td>42 (29.0)</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Themes from comments:

<table>
<thead>
<tr>
<th></th>
<th>Responses</th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Disclaim</td>
<td>52 (37.1)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Regret</td>
<td>47 (33.5)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Alternate (shower, home bath)</td>
<td>7 (5.0)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td>34 (24.9)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Women’s evaluations of epidural analgesia

Of those women who had epidural analgesia and completed this question (n = 278), 70.6% (278/394) were satisfied, 20.3% noted that they were neutral and 9.1% stated they were disappointed with the experience (Table 14). From the written comments that were offered, about 64.5% (187/290) related to the theme “satisfied.” The next themes related to dissatisfaction and disappointment and the final theme contained expressions about the woman’s ability to cope once they had epidural analgesia. Examples of the comments as they relate to the themes are in Appendix H.
Table 14: Postpartum evaluations and themes from written comments: Epidural analgesia taken

<table>
<thead>
<tr>
<th></th>
<th>TUB GROUP</th>
<th>CONTROL GROUP</th>
<th>2p</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>N = 205</td>
<td>N = 189</td>
<td></td>
</tr>
<tr>
<td>frequency (percent)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Survey: epidural analgesia taken</td>
<td></td>
<td></td>
<td>.66</td>
</tr>
<tr>
<td>Pleased:</td>
<td>148 (72.2)</td>
<td>130 (68.8)</td>
<td></td>
</tr>
<tr>
<td>Neutral:</td>
<td>38 (18.5)</td>
<td>42 (22.2)</td>
<td></td>
</tr>
<tr>
<td>Disappointed:</td>
<td>19 (9.3)</td>
<td>17 (9.0)</td>
<td></td>
</tr>
<tr>
<td>Themes from written comments</td>
<td>290</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Responses</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Satisfied</td>
<td>187 (64.5)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cope</td>
<td>23 (7.9)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dissatisfied</td>
<td>32 (11.0)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Disappointed</td>
<td>40 (13.8)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td>8 (2.76)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Women's evaluations of not having epidural analgesia

Of the 150 women who did not experience epidural analgesia, 115 filled in this portion of the survey. Seventy-three percent of women wrote that they were pleased with not having epidural analgesia, 20% were neutral and 7% indicated they were disappointed. Eighty-nine women offered comments in the space provided on the form. The most prevalent theme reflected that the mothers planned or preferred to have natural childbirth (46/89, 51.7%). Other themes were fear of the procedure, their wish to cope or maintain control or that their labours were too fast to consider this method of analgesia. Two women were disappointed about not having epidural analgesia (Table 15). Examples of the comments related to the themes are provided in Appendix I.
Table 15: Postpartum evaluations and themes from written comments: Epidural Analgesia NOT taken

<table>
<thead>
<tr>
<th></th>
<th>TUB GROUP</th>
<th>CONTROL GROUP</th>
<th>2p</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>N = 54</td>
<td>N = 61</td>
<td></td>
</tr>
<tr>
<td>frequency (percent)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Survey: epidural analgesia not taken</td>
<td></td>
<td></td>
<td>.18</td>
</tr>
<tr>
<td>Pleased</td>
<td>34 (66.7)</td>
<td>48 (78.7)</td>
<td></td>
</tr>
<tr>
<td>Neutral</td>
<td>12 (22.2)</td>
<td>11 (18.0)</td>
<td></td>
</tr>
<tr>
<td>Disappointed</td>
<td>6 (11.1)</td>
<td>2 (3.3)</td>
<td></td>
</tr>
<tr>
<td>Themes from written comments</td>
<td>89</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Responses</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Planned/preferred</td>
<td>46 (51.7)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fear (needle/epidural)</td>
<td>14 (15.7)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cope/control</td>
<td>11 (12.4)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fast</td>
<td>9 (10.1)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Disappointed</td>
<td>2 (2.3)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td>7 (7.8)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Participation in the project.

Two hundred and ninety-six women offered comments to the question, “if you had it to do all over again, would you have participated in this study?” About forty percent of the comments (118/296, 39.8%) reflected the theme “help/learn” (Table 16). For some (n = 61), their dominant explanation was that involvement was easy, there was no pressure and that they had a choice as to whether they participated. Other themes included, happy (with their group assignment), some mothers offered a suggestion about the use or construction of the tub. Twelve women wrote comments about how participation provided an opportunity to reflect on their childbirth experience. A small group of women (n = 11) stated they were disappointed because they would have preferred to have had been in the experimental group. Four women wrote that they were influenced to be in the study by their doctor or midwife. Eight women felt the study was not necessary or would not be interested if they were approached in the future. Selected comments
from the predominant themes are found in Appendix J.

Table 16: Postpartum evaluations and themes from written comments: Study Participation

<table>
<thead>
<tr>
<th>Themes from written comments</th>
<th>Frequency (percent)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Responses</td>
<td>296</td>
</tr>
<tr>
<td>Help/learn</td>
<td>118 (39.8)</td>
</tr>
<tr>
<td>Happy (with group assignment, tub)</td>
<td>72 (24.3)</td>
</tr>
<tr>
<td>Easy/choice</td>
<td>61 (20.6)</td>
</tr>
<tr>
<td>Reflect</td>
<td>12 (4.1)</td>
</tr>
<tr>
<td>Suggest</td>
<td>10 (3.4)</td>
</tr>
<tr>
<td>Disappoint (would have preferred tub group)</td>
<td>11 (3.7)</td>
</tr>
<tr>
<td>Influenced</td>
<td>4 (1.3)</td>
</tr>
<tr>
<td>Unnecessary/no interest</td>
<td>8 (2.7)</td>
</tr>
</tbody>
</table>

Choices for future labours

The sections regarding taking a bath, experiencing epidural analgesia and being in the study contained a question about their choices for subsequent labours. In general, the majority of the women would choose a similar experience to their current one (Table 17). Overall, eighty-two percent of women who responded to the question would like to use a bath for future labours (356/435). Having experienced a bath in labour was associated with a higher likelihood for choosing the option in the future; not experiencing a bath in labour was associated with more women not considering it as a future option (2p = .00014). Epidural analgesia would be the choice for 77.8% (361/464) women. If asked to participate in a research study, 91.5% (517/573) would do so if they had it to do over again. There were no differences between the groups in these two latter questions.
Table 17: Choices in future labours

<table>
<thead>
<tr>
<th>QUESTION</th>
<th>TUB GROUP frequency (percent)</th>
<th>CONTROL GROUP frequency (percent)</th>
<th>2p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Choose Bath?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>210 (88.2)</td>
<td>146 (74.1)</td>
<td>.00014</td>
</tr>
<tr>
<td>No</td>
<td>28 (11.8)</td>
<td>51 (25.9)</td>
<td></td>
</tr>
<tr>
<td>Choose epidural analgesia?</td>
<td></td>
<td></td>
<td>.59</td>
</tr>
<tr>
<td>Yes</td>
<td>186 (78.8)</td>
<td>175 (76.8)</td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>50 (21.2)</td>
<td>53 (23.2)</td>
<td></td>
</tr>
<tr>
<td>Participate in Study again?</td>
<td></td>
<td></td>
<td>.84</td>
</tr>
<tr>
<td>Yes</td>
<td>240 (91.3)</td>
<td>233 (91.7)</td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>23 (8.7)</td>
<td>21 (8.3)</td>
<td></td>
</tr>
</tbody>
</table>

Secondary Research Question #2: Effects on Pain

Pain measures were obtained from 219 (83.9%) of the 261 women in the experimental group who took a bath. Regarding the intensity of pain, the pre-immersion mean score was 6.39 (SD = 1.93) and the post-immersion score was 5.59 (SD = 2.19). Paired t-test analysis identified a statistically significant difference ($p = <0.0005$). Similarly, there was a statistically significant difference between the group means from the faces (pain affect) scale (pre-immersion, .760, SD = .149; post-immersion, .682, SD = .202, $2p = <0.0005$) (Table 18).

Table 18: Measures of pain pre and post immersion in the bath (N = 219)

<table>
<thead>
<tr>
<th>MEASURE</th>
<th>Pre immersion</th>
<th>Post immersion</th>
<th>95% CI</th>
<th>2p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pain intensity*</td>
<td>6.39 ± 1.93</td>
<td>5.59 ± 2.19</td>
<td>-1.092, -.507</td>
<td>&lt;0.0005</td>
</tr>
<tr>
<td>Pain affect**</td>
<td>.760 ± .149</td>
<td>.682 ± .202</td>
<td>-.103, -.523</td>
<td>&lt;0.0005</td>
</tr>
</tbody>
</table>

* as measured by a vertical, colour analogue scale; ** as measured by the faces scale
Additional Analyses

Logistic Regression Analysis

Logistic regression analysis was undertaken to determine which variables were predictive of the use of epidural analgesia. Only those variables existing at the time of randomization were entered into this analysis. These were parity, site, group assignment (tub group or control group), maternal age, pre-labour rupture of the membranes, and attendant. Only nulliparity (2p < 0.0005) and hospital site (2p = 0.016) were statistically significant predictors of epidural analgesia. The overall epidural analgesia rate for nulliparas was 88.3%, versus 63.4% for multiparas (2p = <0.0005). At the two sites, the nulliparas’ epidural analgesia rates were 91.7% (site 1, Central West Ontario) and 84.7% (site 2, Central East Ontario, 2p = 0.045).

Interaction analysis was undertaken to explore whether the site influenced, or had an effect on nulliparas’ and multiparas’ use of epidural analgesia. Both sites had similar differences in the use of epidural analgesia between the nulliparas and multiparas despite the actual differences in proportions seen in the two sites (2p = 0.308). Epidural analgesia rates for multiparas at the two sites were also higher at the Central West site (Site 1) but the differences were not significantly different (Site 1, 66.4%; Site 2, 60.4%, p = 0.27)

Early tub use (n=242) vs. later tub use (n=71)

There has been interest in the timing of tub bathing and the effects on labour and birth outcomes. In order to provide information for future consideration, the data about tub use were grouped into the early users (cervix <5 centimeters) and those who had their bath at a later stage in their labour (at ≥5 centimeters). The early group experienced: higher augmentation rate (49% vs. 29%, 2p = .003); more epidural analgesia administration (80% vs. 53%, 2p = <.0005); fewer spontaneous births (60% vs. 70%, 2p = .039); were less likely to have no analgesia throughout
the course of labour (11.6% vs. 32.4%, 2p = <0.0005); were likely to have an “early” epidural (63% vs. 2%, 2p = 0.0005). Of note is that the early group had a lower mean cervical dilation at the time of hospital admission (2.4, SD 1.2, vs. 4.3, SD 1.8, 2p = <0.0005). The early group experienced a longer admission to delivery time (640 vs. 412 minutes, 2p = < 0.0005).
CHAPTER 4

DISCUSSION

The discussion will consider the limitations and the strengths of this randomized controlled trial. Each research question will be discussed individually and reviewed in light of the existing literature. Possible explanations about the early stage of labour at which women participated in the study, and the effects, will be put forward. This study identified a reduction in mean pain scores following immersion but this did not decrease the women's use of epidural analgesia or their overall evaluation of labour pain intensity or affect. The discussion relating to the measures of pain and the theoretical issues will focus on the possible reasons for the observations.

Limitations and strengths

There are potential sources of bias. Clearly, blinding of both the staff and the participants to the group allocation was not possible. Women, however, were not aware of the primary outcome of the study. The consent form noted that taking a bath in labour might help with pain relief and relaxation, but that research was needed about these and other effects during labour. An expectation bias may have been created. Staff nurses were aware of the study questions and outcomes for analysis but several educational sessions and discussions were undertaken to reinforce the role of the nurse in the project.

Both of the study sites had whirlpool baths in their labour and delivery units prior to the development of the project. Pre-study observations and discussions with staff nurses revealed that the actual use of the tub during labour was low for various reasons, including maternal or staff preference, maternal/fetal condition or bath tub availability. In a previous trial at Site 1
(Rush et al., 1996), approximately forty-five percent of the women in the experimental group did not actually take a bath during labour. The current project attempted to improve group compliance by providing better information to the eligible mothers about random allocation, assessment and excluding the women who had firm preferences for taking a bath or immediate epidural analgesia, and explaining that supportive activities would be afforded to all women regardless of their group. Additionally, the sample size was increased and the time-line extended to ensure that only those women who were open to and understood randomization were included. Because of these efforts, the crossover rate was decreased to 18% of the participants in both groups. The resulting reduction in power was 4%. Based on the number of women who stayed in their assigned group, the study had the power of .76 to detect a 10% reduction in the use of epidural analgesia. The small reduction in power does not affect the outcome conclusion of no difference between groups.

The study was a randomized controlled trial. There are many variables that could have accounted for differences in women’s choices for pain relief measures and their various outcomes and experiences during labour and birth. It was anticipated that randomization would distribute the variables equally between the two groups. Parity is one variable that could have dramatically altered the outcomes under study and stratification was a component of the computerized group allocation procedure. The procedure for randomization was pre-developed by a consultation service and centrally controlled. Phoning a remote site and interacting with only a computerized voice throughout the enrolment procedure prevented the nursing staff from learning the participant’s group until after enrolment was completed. At randomization, the two groups were comparable in terms of their eligibility criteria, parity, age and birth attendant.

To strengthen the generalizability of the findings, this study involved two urban obstetrical units in southern Ontario. The settings, approximately 120 kilometers apart, were comparable in
terms of their size, number of annual births, and general procedures for care. In order to define the overall population during the project, the usual obstetrical assessment/admission logbook was adapted to record the study eligibility of every woman, along with the reasons for inclusion and non-inclusion.

The development of data collection tools was an important feature of the planning. Creating forms for computer scanning was undertaken in an attempt to limit the number of data entry errors. Logic checks were done to detect illogical entries, for example, non-agreement between study and hospital identification numbers, if the admission time preceded labour onset, or if data were present for more than one type of delivery. A second logic check was completed following any changes.

Beyond the quantitative data, this study included a measure for childbirth satisfaction and a qualitative component in order to learn the women’s perspectives relative to the bath, epidural analgesia, and study participation. Comprehensive evaluation of satisfaction and maternal evaluations have not been a feature of other clinical trials about bathing in labour. The Danish (Lenstrup et al., 1987) and the Belgian (Cammu et al., 1994) studies obtained feedback from only those who took a bath. The Canadian study (Rush et al., 1996) surveyed a small subset of women (50 from each group, 100/785) to learn about labour pain management strategies, including the bath, and the women’s impressions.

Primary Research Question: The effects of the bath on the use of epidural analgesia

It was hypothesized that offering a bath in labour would influence the woman’s experience of pain such that her need for medication, specifically epidural analgesia, would decrease. In this study, there were no differences in the use of epidural analgesia between the two groups. This is consistent with comparative studies where no statistically significant differences in the use of analgesia between bath and control groups have been observed (Cammu et al., 1994; Shorn et al.,
1993; Benfield, 1993; Lenstrup et al., 1987; Rush et al., 1996). Interestingly, this study is inconsistent with the earlier one at Site 1 (Rush et al., 1996) where a clinically important reduction in the use of pharmacological interventions (epidural analgesia +/- IM opioid injections) in the experimental group was observed (59% versus 66%, 2p = 0.06). In fact, the use of epidural analgesia was higher than the overall population from the two sites (76.4% for the Tub Trial sample vs. 69.4% in the overall population).

The following are possible explanations. This sample of women was admitted early in their labour when time was available for explaining the study and implementing the experimental protocol. Figure 4 shows that up to one-half of the eligible women were not approached because the labour unit was too busy or the woman was too far along in her labour. Women who arrive at the hospital in latent or very early active labour and whose cervical dilation is small (< 3 centimeters) are not usually admitted to the labour unit. This sample may have included women experiencing a complicated early labour related to such factors as ineffective contraction patterns or malposition of the presenting part. This could cause enhanced pain and distress necessitating hospital care. Extreme anxiety, fear or distress, without a physical complication, could also have been an issue with the study sample. The Tub Trial may have over-represented this category of women. Data to establish the presence of active labour were not collected beyond the professional’s notation (on the study entry form) that the woman was “in labour.” Variations in nursing or medical staff decisions for hospital admission could have been an issue.

An early admission to the hospital may be a factor in early epidural analgesia administration. While some women may desire to avoid or delay pain medication in labour, the majority in both groups either requested or accepted medication in this study, many during latent or very early in the active phase of labour. The administration of epidural analgesia occurred at 0-2 centimeters for about 15%, and at 3-4 centimeters for 40% of the study participants.
Early admission to a labour and delivery unit may have influenced the women’s anticipation or anxiety. There may have been a desire on the parts of both the woman and the staff to initiate activities to advance the progress of labour. This could have accounted for the number of women who experienced artificial rupture of the membranes (364/635, 57.3%) and labour augmentation with an intravenous oxytocic agent (267/635, 42.1%). No data, however, were collected about the timing of artificial rupture of the membranes or augmentation during labour. Stimulating labour may have influenced the woman’s pain experience and the use or timing of pharmacologic pain relief measures.

The sites for this study had a higher use of epidural analgesia than the average hospitals in Ontario. In Ontario, the overall rate of epidural analgesia has been reported as 38% with the larger hospitals reporting rates in excess of 60% (Oyston, 1995). The use of epidural analgesia in large, urban hospitals may relate more to social pressure, anaesthetist availability, professional preference or influence, high intervention rates or consumer expectations, than on the women’s individual, subjective, experience of pain in labour.

Acceptance of epidural analgesia is high among the obstetricians and orders on the women’s charts routinely include “epidural upon request” or “epidural when ready.” At both sites, the Department of Anaesthesia provided a 24-hour service. It was not unusual for an anaesthetist to visit a woman directly to advise her about the availability and the pain relief effects of epidural analgesia.

Epidural analgesia is described to women during prenatal tours and in prenatal classes as available whenever they need or want it. In the context of this study, taking one bath in early labour may not have been able to compete with the many influences on the women’s use of epidural analgesia.
Secondary Research Question #1

Effects of the bath on labour and birth events

This study also compared the events of labour and birth between the groups. The experimental group was not different from the control group in: fetal presentation, experience of rupture of the membranes, febrile events, alterations in blood pressure, the number of other pain medications, the length of labour, augmentation rates, position for delivery, condition of the perineum, operative birth and maternal signs of infection during the hospital postpartum period.

These findings are consistent with other studies that found no differences in labour and birth events between bath and control groups (Lenstrup et al., 1987; Schorn et al., 1993; Cammu et al., 1994; Benfield, 1993). However, in one previous study (Rush et al., 1996), the rate of forceps and vacuum deliveries was lower in the experimental group ($2p = 0.05$), and an intact perineum was more likely ($2p = 0.019$). These differences were not found in the current study.

More women in the control group (53/316, 16.9%) used a shower than in the experimental group (12/319, 3.8%). The information flyers about the study advised women that showers were permitted if that was their wish. Another bath evaluation (Schorn et al., 1993) permitted other pain relief measures including showers but did not describe the proportion of women who used this form of hydrotherapy. The purpose of including showers as part of the data collection was to monitor the extent of use and, if feasible, to alter the study protocol to prevent the co-intervention of another hydrotherapy measure. At the beginning of the trial, there was an attempt on the part of staff nurses to prevent possible maternal disappointment by actively offering showers to women, primarily those allocated to the control group. In reinforcing the protocol, the nurses were advised to assist with a woman who requested a shower rather than actively suggesting a shower as a consolation or default activity. Following this, the number of women taking showers decreased.
Effects of the bath on fetal/neonatal morbidity

The issue of both benefit and harm relating to bathing during labour applies to the mother and the baby. While adverse newborn outcomes have not been reported in the literature, the perceived risk of infection (if the membranes are ruptured), fetal distress and alterations in thermoregulation from the effects of warm water immersion have been a source of controversy (Waldenstrom & Nilsson, 1992; Alderdice et al., 1995; Nikodem, 1999).

This study included women whose membranes had ruptured as did other published studies about bathing in labour (Rush et al., 1996; Schorn et al., 1993; Cammu et al., 1994; Lenstrup et al., 1987; Benfield, 1993). The similar outcomes between groups in this study are consistent with the other comparative trials. The outcomes assessed included Apgar scores, admissions to the Neonatal Intensive Care Unit, the newborn's first temperature and any chart notations of possible infectious morbidity. In healthy mothers and newborns, postpartum and newborn infection is usually a community, rather than an in-hospital, issue. The length of hospital obstetrical stay in this study was, on average, 1.5 days affording too little time to confirm overt infection in this sample of newborns.

Data were also collected on the observation of meconium-stained amniotic fluid. The statistically significant difference in the notations of meconium-stained amniotic fluid among the control group versus the experimental group (62/316, 19.7% vs. 43/319, 13.6%, 2p = .040) has not been reported in other bath studies. The passage of meconium-stained amniotic fluid during labour is an indication of fetal distress and carries with it associated risks of poor newborn outcome (Grant, 1989). The similarities in the low incidence of admissions to a Neonatal Intensive Care Unit and neonatal signs of morbidity suggest that the difference could have been a chance finding. In a study of newborn effects, Gradert and colleagues (1987) evaluated the presence of stress hormones in the cord blood of babies whose mothers had a bath (n = 13) and
compared the findings with control babies (n = 9). They did not detect significant differences in the two groups in plasma concentrations of the stress hormones studied (adrenaline, noradrenalin and Beta-endorphin-like immunoreactivity). The sample size may have limited their ability to find a true difference and further research is recommended.

Effects on childbirth experiences

Labour Support

Offering a bath is a tangible, instrumental means of support for a woman in labour (Hodnett, 1996). This study measured the women's recall of the amount of time nurses spent with them at the bedside offering continuous care. In addition, the women rated the frequency of activities that were offered by her nurse during labour. While there was no difference between the two groups in the estimates of the amount of time nurses spent at the bedside, the mean score of the number and frequency of supportive activities by nurses for the tub group was statistically significantly higher than the control group (2p = 0.005).

When a bath is taken, staff perform additional tasks such as preparing the bath, physically accompanying mother to the bath, offering drinks, auscultating the fetal heart rate, providing linen and settling the mother back to bed. The control group would not necessarily have had as many of these related tasks and the difference in mean scores seems logical. In her systematic review of the studies comparing the effectiveness of continuous, one-to-one support by a trained care giver during labour, Hodnett (1998) reported that support was directly associated with decreased rates of analgesia, operative birth, higher newborn Apgar scores and a positive maternal rating of their childbirth experience. Continuous, one-to-one support was not part of this study's protocol and not the experience of the study sample. The higher average mean scores about specific activities by the experimental group does not support a conclusion that more nursing presence existed.
Therefore, comparing the findings of this study with the trials of labour support would be misleading. Furthermore, a 2-point mean difference in labour support activities scores is statistically significant because of the large sample size and is of questionable clinical importance.

**Perceived Control**

The women rated their childbirth experience of control during labour in the ten-item Labour Agency Scale (Hodnett, 1983). As it measures aspects of control, it has been demonstrated that a high score on the scale is predictive of a high level of childbirth satisfaction. The women from the two groups did not differ in their average group scores which were, on overall average, 51.1 (SD 9.46) out of a possible score of 70. Women’s expressions about their satisfaction with the effects of epidural analgesia in providing pain relief and helping them maintain control or cope with labour may account for the similarities in the scores.

**Postpartum recall of labour pain**

This study used postpartum recall to measure the overall labour pain intensity and affect of both groups. The difference in the mean scores of 0.35 of a point on the 0-10 scale for labour intensity is not considered clinically important. The difference in the mean scores of the faces scale favoured the control group in the measurement of pain affect. This finding is inconsistent with the women’s comments about the pleasantness of their bath experiences. The pain affect scale was developed for and tested on children, ages 3-17 (McGrath, 1996). No reports regarding the testing of this scale for adults have been uncovered in the literature and future testing for the adult population, specifically women in labour, is warranted. The affect scale was not validated for this population, however, the data provide a base for future development of the scale.

According to the Gate Control Theory, the amount and quality of perceived pain are determined by many psychological variables in addition to the sensory input (Melzack & Wall,
1965). Intensity, affect and self-report measures, therefore, may be inconsistent. For women in the experimental group, there was additional emphasis placed on measuring pain and it may have been possible that this attention could have ascribed special meaning to their labour pain. This could have resulted in higher ranking on the postpartum pain measures when the sensory input may have been equivalent to their control counterparts. Recent thoughts about the Gate Control Theory by Wall (1996) suggest that a person reacts to noxious stimuli as a single unitary system that is modified by experience. This project did not evaluate the women’s overall, unitary expression regarding labour pain, her prior experience or conditioning, or the meaning and nature of her labour pain.

**Perspectives about taking a bath in labour**

Relaxation was the most prevalent theme from women who commented on their bath experience. Also included in this theme were the notions of distraction, soothing, calming and rest. Pain relief ranked second in women’s predominant comments. Relaxation appeared again in the third theme where their comments combined relief with relaxation. Cammu and colleagues (1994) also found that relaxation was a dominant theme, ranking ahead of pain relief. They postulated that pain reduction and stabilization is mediated through the relaxation effects of warm water immersion. Pain and anxiety have been conceptualized as interrelated (Lederman et al., 1978). A combination of additional factors beyond the physiologic effect of heat and immersion could have influenced a feeling of relaxation, such as the personal care and attention of a nurse, the familiarity with having a bath and the anticipation or expectation of relief from anxiety and pain. In her study, Benfield (1993) measured anxiety on a 10 cm. visual analogue scale, similar to pain intensity tools. The bathers’ anxiety scores were statistically significantly lower than the control group at 15 minutes post immersion.

Ten percent of the women expressed that taking a bath had a short-term pain relief effect.
It has been postulated that the spinal gating mechanism can habituate to stimuli (Bonica, 1990), which could explain the loss of response to the innocuous afferent stimulation of heat and tactile receptors during bathing. The study protocol allowed for unlimited baths but only 33/261 (12.6%) of the women took more than one bath. It may have been possible that labouring women and staff would not retry an intervention whose effects had "worn off" after the first experience. On the other hand, additional obstetrical interventions may have interfered with a plan for bathing later in labour.

Some women entered the bath at a very early point in their labour. A comparison of 242 women in the early group (<5 centimeters of cervical dilation) and the later group (≥5 centimeters) showed that the early group came into hospital earlier, had a longer labour recorded, had higher intervention rates, (augmentation and epidural analgesia) and fewer spontaneous births. Two other studies have explored the issue of the timing of the bath. A Swedish randomized controlled trial (Eriksson et al., 1997) used the <≥ 5 cm. parameter to define the early (n = 100) and late groups (n = 100). Lower rates of epidural analgesia (9% versus 27%, p = 0.0015) and oxytocin administration (30% versus 57%, p = 0.0002) favoured the late group. In their study, labour was defined by contraction frequency and women were admitted with a cervical dilation of less than 3 centimeters. A Toronto retrospective analysis of early (<5 centimeters dilation, n = 253) and late (n = 177) bath users (Little, 1998), showed similar results relative to higher oxytocin augmentation and epidural analgesia rates with the early cohort. In the Tub Trial and in the Little (1998) study, women were not randomized to early and late bath, and pre-existing factors predictive of different labour experiences may have led the early group to seek comfort in a tub at an earlier point in their labour. Whether the early bath interferes with labour progress or is a marker of a different labour cannot be determined from the available studies.
Perspectives about epidural analgesia

Most women (187/290, 64.5%) who had epidural analgesia and completed the postpartum survey were satisfied with the pain relief they experienced. About one-quarter of the women wrote about dissatisfaction or disappointment with the procedure. A pre-study audit at Site 1's preregistration clinic was conducted on a sample of pregnant women (n = 32) to learn about their pain medication preferences (Rush and Frisina, 1996). A seven-item listing of preferences adapted from Simkin (1989b) forced a response ranging from a desire to have immediate pain medication as soon as possible to a wish for absolutely no medication under any circumstance. Approximately 70% of the women preferred to delay or avoid pharmacologic analgesia for their labour and childbirth. Their hope was to achieve as unmedicated a childbirth as possible. The issue of women's preferences is important as expectation relates to satisfaction; however, the Tub Trial did not measure the mothers' pre-labour pain medication preferences.

The written comments from this current study reinforce the notion that "natural childbirth" is a vision for many mothers and disappointment may follow when it has not been achieved. The disappointment had no apparent effect on their sense of overall control as measured by the Labour Agency Scale. The proportion of women who expressed comments within the theme of dissatisfaction related this to the adverse effects during the procedure, the poor analgesic effects or problems with the fetus. Being disappointed and dissatisfied may require additional time or strength on the part of the mother to resolve her feelings at a time when celebrating her birth and beginning her new role and relationships should take precedence. The issues of early admission, amount of labour support and additional interventions in women experiencing epidural analgesia could all be factors in these postpartum feelings.

The dominant themes expressed by women who did not have epidural analgesia were those of personal plans or preferences, a fear of needles, the possibility of adverse effects on
themselves or the baby and a desire to cope without medication. Consistent with the literature, there was an overall impression that this subgroup of women placed value on natural childbirth and personal achievement.

**Perspectives about study participation**

Women were asked, “if you had it to do over again, would you have participated in this study?” A sense of personal gratification was found in the comments. Women appreciated that they did not have to do extra tasks, take unusual risks, or be pressured to undergo interventions that could interfere with their childbirth experiences. These issues are important in the development of promotional information about future studies involving women in labour. Some women used the comments space to reflect on their childbirth experience, make suggestions or provide feedback to the staff nurses about their care.

**Secondary Research Question #2: Bath use and measures of pain**

Three studies have evaluated the bath at a later stage of labour than the current trial. In her study, Benfield (1993) offered the bath when the mother had achieved 4 centimeters of cervical dilation. The Danish study (Lenstrup et al., 1987) allowed the bath at five centimeters or beyond, and Schorn’s group (1993) allowed bathing at cervical dilations between 4 and 7 centimeters.

The Tub Trial protocol did not guide the nursing staff as to the time for offering the bath. This was left up to the nurse and the labouring woman. Baths were administered to the majority of women during the early period of active labour and to some women, during the latent phase. The early administration of epidural analgesia would have limited additional, later bathing and the overall rates of artificial rupture of the membranes and oxytocin augmentation may also have contributed to early bathing. Data were not collected as to why women left the tub.
Most of the women in the Tub Trial used the bath only once and the average time in the bath was 51 minutes (SD = 37). The other studies of bathing in labour report similar time intervals (Cammu et al., 1994; Schorn et al., 1993; Lenstrup et al., 1987; Rush et al., 1996). Benfield (1993) reported that the women in her study (n = 9) remained in the bath for 60-120 minutes. Only Bastide's (1990) study protocol involved multiple bathing experiences.

This study was concerned with the pain experience of women who used the tub. The post-immersion scores from both measures of pain (intensity and affect) were statistically significantly lower than pre-immersion scores. Other studies found a decrease in labouring women's pain during their bath (Benfield, 1993; Cammu et al., 1994; Lenstrup et al., 1987). Benfield found a statistically significant difference between bather's and non-bather's pain intensity (visual analogue scale) scores at corresponding 15 and 90 minute measurement times post immersion. Eight of the nine women in the experimental group had their pain measured at the 15 minute post immersion period and the difference was 2.9/10 points less than the pre immersion score. At the 30 minute mark, 4 women in the bath group had pain intensity measures taken and their post immersion difference was 2.6/10. In their randomized controlled trial, Cammu and colleagues (1994) reported that there was a 0.1 reduction in pain intensity for bathers at the 25 minute mark post bathing (pre: 6.8 ± 1.7; 25 minutes post, 6.7 ± 1.7). The control group's pain intensity increased during the 25 minute period from 6.3 ± 1.8 to 7.3 ± 1.6. At the end of the bath protocol (after about one hour) the mean pain score for the experimental group was 1 point less than the control scores, and the authors concluded that the bathers experienced a temporary pain stabilizing effect, possibly facilitated by the relaxation effects of the bath. In the Danish study (Lenstrup et al., 1987), visual analogue scores were used before, during and after bath immersion and analyzed with control group scores at comparable time periods. Women scored their pain lower after 30 minutes in the bath (7.2 points lower on a 100mm scale).
In the Tub Trial, measures of pain were taken at about 20 minutes post immersion. As with other reports, pain intensity decreased ($2p = <0.0005$). The magnitude of the reduction (.80 of a point on the 0-10 scale) was greater than the Belgian study and about the same as the Danish study. The study also used a measure for pain affect (distress, unpleasantness), the scores of which were statistically significantly lower following bath immersion ($2p = <0.0005$).

The clinical importance of the .80 reduction in pain intensity and the .08 reduction in pain affect was considered. In examining the distribution of the scores, a secondary analysis was done to compare the women whose pain scores increased post immersion with those whose pain scores decreased. About one quarter of the women had higher pain intensity (59/227, 25.9%) and pain affect (53/227, 23.4%) scores. The results of the secondary analysis are contained in Appendix K. In general, the group of women who scored higher pain intensity and affect entered the study later in their labour, took a bath when their labour was more advanced, were more likely to be multiparous and experienced fewer interventions. Interestingly, the majority was pleased with the bath, would choose it again and would participate in a study such as this if they had it to do over again. The women’s comments from those in the higher scoring group were reviewed. The women wrote about how the bath relaxed them between contractions or at the beginning of a contraction (“I was so tense and it relaxed me”; “didn’t help the bad pain but relaxed me in between”; “took my mind off the pain and relaxed me”). Some felt it advanced their labour (“brought the contractions closer together”; “may have helped the labour along”; “helped between the increasingly painful contractions”; “brought on the birth instantly, I had no time for the epidural”).

Among the women whose pain increased post immersion, the magnitude of the mean score increase was 2 points on the intensity scale and .19 (a difference of about 2 “faces”) for pain affect. The pre and post immersion scores for the 75% of women who experienced pain intensity
and affect reductions showed similar differences (see Appendix K). The secondary analysis is helpful in understanding and interpreting the overall findings of the pain measures. Some women interpreted the increase in pain as a sign of progress in labour and viewed the bath as either helping them to cope with the increased pain and/or as facilitating labour progress. Those whose pain decreased post immersion also tended to have favourable views of the bath, because it relieved their pain or helped them to relax. It is also apparent that relaxation is a phenomenon that is important to women in labour and associated with comfort and pain relief. It should be a feature of future studies of pain relief measures.

**Theoretical issues**

Previous studies of bathing in labour stimulated interest in exploring an explanation of bathing’s specific analgesic effect. The current study was underpinned by the interrelated associations among the phenomena of labour and labour pain, the properties of warm water immersion and a theoretical framework, the Gate Control Theory (Melzak & Wall, 1965; Melzak & Casey, 1968; Melzak 1998; Wall, 1998). This study used a theoretical framework and multiple measures of pain in order to study pain as a complex, subjective, multidimensional phenomenon where experience, meaning and context are integral components. To isolate the specific effects of bathing, the use of epidural analgesia was selected as a surrogate measure of pain relief. This study also included measures of three dimensions of pain: the sensory dimension or pain intensity, the affective dimension or the distress and unpleasantness of pain and the evaluative dimension where expressions about using a bath and having epidural analgesia were explored. However, biochemical and hormonal markers of pain and stress, and other physiological signs that correspond to a pain experience were not obtained in this study. Behavioural indicators were not specifically assessed. Therefore, there remains much about the pain experience and bathing that is not well understood.
In this study, the majority of women who used the bath rated their pain intensity and affect as significantly reduced following immersion. Most of the written comments about using a bath related to the powerful relaxation and analgesic effects. Still, the use of analgesia was similar between the groups. Furthermore, women from the experimental group rated their recall of labour pain as more intense and unpleasant than the control group and the groups were similar in their use of epidural analgesia. The issues of the use of epidural analgesia and the meaning of pain for women in the experimental group have been discussed. A question, however, remains as to whether the pain intensity and affect reductions during immersion were specific analgesic effects, whether the effects were placebo in nature or a combination of both.

**Specific and placebo effects**

This section will consider whether the specific, analgesic effects that were observed in women who used the bath, are related to a placebo effect. The relevant components purported to contribute to a strong placebo response will be presented as they relate to the labouring woman.

The hypothesis in this study was that taking a bath in labour would decrease the mother’s use of epidural analgesia in the experimental group. This did not occur but a reduction in pain intensity and affect was shown during the bath experience itself and this is considered a specific analgesic effect. If the bath is a treatment with a specific action and the overall treatment effect is a function of the specific minus the non-specific effect (Gøtzsche, 1994; Shapiro, 1964; Clark and Leaverton, 1994), a question remains; what portion of the bath’s overall or total effects are purely placebo? Four components have been described as the major influences on a placebo effect.

1. **The nature of the disease/condition**

   The less specific the disease or condition, the greater a placebo’s effect (Wall, 1993, Clark and Leaverton, 1994; Ernst and Herxheimer, 1996). Labour provokes a state of distress and pain
at several levels, is multifaceted and, as such, may lend itself positively to placebo therapies. Various interventions considered complementary to conventional medical prescriptions, and that have been purported to influence the descending inhibitory pathways (Melzack & Wall, 1965; Simkin, 1989a), have had an effect on the labouring woman, physically and/or emotionally. Examples of complementary therapies include continuous care giver support, transcutaneous electronic nerve stimulation, acupuncture, massage, effleurage, aromatherapy, music therapy, yoga, hypnosis, imagery and distraction (Simkin, 1989a; Wall, 1993). Interventions which focus on outcomes such as the patient's view, quality of life or satisfaction seem to be more likely to respond to a non-specific, placebo therapy (Gotzsche, 1994). Childbirth satisfaction is reported frequently as an important outcome in obstetrics.

2. **Past experience relative to the condition or treatment**

   About one half of the women admitted to a maternity unit has had the experience of labour. It is possible that past knowledge of the severity of labour pain would cause a woman to doubt the effects of a bath, in which case a more negative response to bathing might have been observed in this study. On the other hand, some women who have had pain medication in previous labours regret their decision and wish and plan to avoid them in subsequent labours (Christensen-Szalanski, 1984; Rush and Friesen, 1998). Therefore, there may be enthusiasm for an intervention that may help a mother avoid or delay pain medication. Those without actual labour experience may have had times where abdominal or uterine cramping has responded to the effects of a bath or other non-pharmacological interventions. Memory of these experiences may have made stronger the acceptance and positive perception of the bath.

3. **Expectation of relief by the care giver**

   The relationship between the caregiver and the patient is considered an important influence on a positive placebo response (Pearce, 1995). Attributes of the care giver and
measures taken which comfort the patient, provide information, suggest relief with the treatment and convey genuine interest, caring and sensitivity have a profound additive and complementary effect. In hospitals, nurses provide routine care to labouring women. The nurse is in a central position of influence over the selection of pain management strategies. A woman in pain is likely to agree, not only to take a bath if offered by her nurse, but also more fully appreciate the effects if the nurse has been optimistic about the bath. This effect may, in fact, have been stronger within the context of the Tub Trial where labouring women were study subjects and could have felt, or have been treated, as special.

3. **Expectation of relief by the labouring women**

Wall (1993) asserts that the expectation of relief by the patient is crucial to a positive response to an intervention. If expectation is a learned state and learning of expected effects is dependent on culture, background, experience and personality, then it follows that a placebo response has a fit within the Gate Control Theory's central influencing systems. Experience with bathing is virtually universal, used for comfort, relaxation and tension release. Bathing is considered by many women to be a time of personal pleasure within an ambience of quiet, containment and protection. It is likely that a woman would not only have experience of bathing but also have a real expectation that it would confer more relief than distress.

4. **The presentation of the intervention**

The presentation of a treatment may enhance the placebo effect (Pearce, 1995; Ernst & Herxheimer, 1996). Up until the past 5 years, most maternity units did not have facilities for taking a bath in labour. With the philosophical concepts of Family Centred Maternity Care turning into tangible programs and facilities (Rush, 1997), staff and consumer's input to renovations has resulted in the installation of baths in many labour units. In a national survey, approximately 45% of hospitals reported that showers and baths were used for pain relief during
labour (Levitt et al., 1995). A survey question about showers and baths had not appeared in previous questionnaires. Some “bath rooms” resemble spas, are pleasantly decorated, smell sweetly and convey a soothing ambience where the woman may feel special. A placebo effect is further potentiated by the use of an apparatus (Pearce, 1995; Ernst and Herxheimer, 1996). The bath is a familiar item; however, its placement in the labour and delivery unit, and more recently in the form of a whirlpool tub, is novel. The therapeutic relationship of the professional nurse with the labouring woman probably contributes the greatest to the strength of the placebo effect. The added measures of supportive presence, nurturing, care and providing encouragement in combination with the bath may increase the magnitude of both the specific and placebo effects (Weiner & Weiner, 1996). Simply telling a woman to take a bath during labour (alone, without the supportive, therapeutic relationship activities) may be less effective.

Based on the above, it is possible that the non-specific, placebo effect may be more powerful than the specific effect of the bath. The two, however, complement each other as specific and non-specific effects operate in tandem (Wall, 1993). The Tub Trial did not set out to measure the relative proportion of specific to non-specific effects of taking a bath in labour. It has been suggested that it is the magnitude of the outcome, rather than the relative proportion of specific to non-specific effects that is important (Gøtzsche, 1995). The reduction in pain intensity and affect, the women’s’ positive comments and their intention to use the bath as a pain relief option in future labours are considered important, overall outcomes of the Tub Trial. Beyond the properties of heat and hydrotherapy, taking a bath in labour also involves the contributions of experience, meaning and expectation but also the addition of continuous support.

No single factor confers an independent influence on the multidimensional phenomenon of
labour pain and opportunities for complementary, multi-modal interventions abound (Lowe, 1996). Measurement of the combined and independent influences influencing the effects of the bath and other complementary therapies will challenge future research.
CHAPTER 5

SUMMARY, IMPLICATIONS AND CONCLUSIONS

Summary of the project

Using a bath has become an increasingly popular option for labouring women. Baths have been hypothesized to influence pain, anxiety, the length of labour and childbirth satisfaction, however, the scientific evidence regarding effectiveness has been inconclusive.

The purpose of this study was to evaluate the effects of a policy of facilitating a bath in labour on the use of epidural analgesia, labour and birth events, fetal/newborn health, mothers' perceptions of their childbirth experience and, in the experimental group, pain measures pre and post bath immersion. A reduction in the use of epidural analgesia, as a surrogate measure for labour pain relief, was selected as the primary outcome.

In this two-site study, 635 healthy, labouring, women at term were randomly allocated to an experimental group (n = 319) for whom baths were encouraged, and a control group (n = 316) who experienced conventional care without the offer of a bath. The randomization procedure included stratification for parity and site. An intent-to-treat method of analysis was employed and a crossover rate of 18% resulted for each group.

Groups were similar at randomization. There was no difference between groups in the use of epidural analgesia administration (experimental group, 245/319, 76.8%; control group, 240/316, 75.9%, 1p = .90). Labour and birth events were similar with the exception that the control group was more likely to experience meconium stained amniotic fluid during labour (62/316, 19.7%) than the experimental group (43/319, 13.6%, 2p = .04). Newborn outcomes
between the groups, however, were not significantly different. A bath in labour did not appear to
be harmful for the woman, the fetus or the newborn.

Women's scores regarding their control during labour and the amount of continuous
nursing presence they received were similar. The experimental group had higher mean scores on
a scale that measured the frequency of selected supportive, nursing activities (experimental group,
47.04 ± 7.6; control group, 43.20 ± 7.3, 2p = .005).

The most prevalent theme about bathing, from the qualitative analysis of the women's
comments, was relaxation, followed by pain relief. The majority of the women (81.8%) would
request to use the bath in future labours.

In this study, the Gate Control Theory of pain (Melzack and Wall, 1965; Melzack and
Casey, 1968; Melzack, 1996; Wall, 1996) served as a framework to explain the possible benefits
of warm water immersion on the pain of labour. Measures of the intensity and affective
dimensions of pain were taken pre and post bathing. Following bath immersion, the measure for
pain intensity showed a statistically significant reduction (pre, 6.39 ±1.93; post, 5.59 ± 2.19, 2p =
<0.0005) as was the measure for pain affect (pre 76.04, ±14.19; post, 68.26, ± 20.28, 2p =
<0.0005).

Of those who used a bath, 77.3% (242/313) did so between 0-4 centimetres of cervical
dilation. Labour and birth events for this early group of bath users were compared to those who
had a bath at ≥ 5 centimetres of cervical dilation. The early group experienced a higher use of
augmentation (2p = .003), epidural analgesia (2p = <.00005) and had fewer spontaneous births
(2p = .039).

Epidural analgesia administration occurred during this earlier time period for 56.7%
(275/485) of the women in the Tub Trial. The early group experienced, greater use of augmentation (2p = <.0005), had fewer spontaneous births (2p = <0.0005), had less likelihood of an intact perineum (2p = .02) and had a higher cesarean section rate (2p = .0002). The
associations between earlier bath and early epidural analgesia administration with increased interventions and adverse labour and birth outcomes provoke new questions regarding early labour support and management of latent labour.

The majority of women (62.9%) noted that they were pleased with having experienced epidural analgesia. However, 30% reported dissatisfaction and disappointment with having epidural analgesia. Exploring women’s preferences and expectations about labour pain management, their knowledge of the effects of the procedure and personal and professional influences during labour are considered for practice and future research.

To isolate the specific, analgesic, properties of the bath, future research should include measures related to the influence of bathing on physical, biochemical, hormonal, behavioural and evaluative responses to the pain of labour. Measuring the effect of the bath on relaxation and anxiety is recommended given the written comments by bath users about their experience of the bath.
Implications for Practice

Given the absence of evidence of harm, the reduction of pain intensity and affect immediately following immersion and the participants’ favourable evaluations of their bath experiences, baths should be available for those labouring women who wish to use them.

From the written comments and suggestions by the participants, the following specifications about the bath should be considered:

- women prefer the bath to be located within or adjacent to the labour room;
- if a communal room for bathing is available, it should be large enough for the presence of the nurse and the woman’s companion(s);
- some women prefer to move about in the bath and to vary their positions (back or side lying, sitting up, squatting or an all-fours posture) and the bathtub should be large enough to accommodate this;
- the depth of the water should allow coverage of the abdomen (some women noted that they added water to the bath for greater comfort);
- whirlpool jets were noted as comforting by some women and used by the majority; the option of whirlpool jets is recommended. Women suggested that the jets should be positioned for the option of direct flow to the lumbar area and the hips.

In this study, baths were offered and taken predominantly during the period of early labour (cervical dilation 0-4 centimetres) and, for the majority, taken only once. Encouraging additional baths is suggested for labouring women. Taking a bath (or additional baths) during the later period of active labour may provide added reprieve from the stress of labour.
**Implications for research**

Rather than discouraging or restricting baths in the early labour period or setting arbitrary limits for the timing of bathing, evaluating the effects of early versus late and/or later additional baths would be useful in developing protocols for care.

While this study included pain measures for intensity, affect and some self-report responses (women's comments about the effects of the bath and epidural analgesia), little is known about the effects of the bath on other measures of pain. Further research is recommended that extends the measurement to include physical, biochemical, hormonal responses. The Tub Trial provides preliminary data about the use of the faces scale for measuring pain affect in an adult population. Future research is necessary to refine the scoring system, the validity and reliability. Fetal and neonatal responses to their mothers' bath experience are not understood beyond the generally accepted measures of distress and health. Cord blood, neonatal serum hormonal and biochemical stress measures and neonatal behavioural outcomes could be considered in future studies.

Measures of the concepts of relaxation, anxiety and/or stress should be included in further explorations of the effects of the bath given the expressions of the women who provided written comments about their responses to taking a bath.

Wider evaluation of the effects of the properties of hydrotherapy on the labouring woman is suggested to understand the specific effects on fluid volume, core temperature and the responses of skin, muscle and collagen.

This study included both nulliparous and multiparous women. It is well accepted that the
labour and birth events of a first-time labouring woman are different from those who have prior experience. A focus on the distinct effects of the bath in labour on nulliparas and multiparas may be of value in future studies.

Both study sites had policies which state that a women would be admitted to the labour ward once she was in the active phase of labour. As evidenced by the data regarding the low cervical dilation on admission (mean = 2.99, SD 1.63), the women in this study were admitted during latent or the very early active phase of labour, not according to the policy of the units. This may have been a determinant in the extent to which epidural administration occurred during this early period. Over one-half (56.7%) of the epidural analgesia users in this study experienced an early administration of the bath. They experienced additional interventions and more adverse outcomes than those who received later epidural analgesia. A reevaluation of labour assessment criteria and admission procedures may be warranted.

Women who present to hospital assessment units at very early stages of labour may be less tolerant of the stress of labour, or may be having more difficult labours, and require additional, supportive approaches. Management of their care within the milieu of an active labour and delivery unit could inspire further anxiety and, by extension, additional interventions. Evaluating an alternative to direct admission to a labour and delivery unit for anxious, early labouring women in pain, may be one way to test the outcomes of early care in a different setting versus the conventional custom of direct admission or sending the woman home. An alternative setting could be adjacent to the labour unit, home-like in its climate and supportive in approach. Home assessment, as done by Midwives, is another strategy for consideration. An array of supportive activities should be available including nursing presence, information, ongoing assessment, helping
others to help the woman and non-pharmacologic pain relief options.

As a surrogate measure of pain relief, epidural analgesia was chosen as the primary outcome for this study. The association of epidural analgesia with pain relief as well as longer labours, operative birth and maternal dissatisfaction was the basis for the selection. Encouraging a bath was thought to be one way of reducing the incidence of epidural analgesia. Women in the Tub Trial were open to the concept of delaying or avoiding pharmacologic pain relief measures. The study did not set out to encourage a delay of epidural analgesia through the use of the bath.

Front-line staff play an important role in the administration of epidural analgesia. The influence of staff nurses and physicians on epidural analgesia administration may be a stronger determinant or motivator in epidural analgesia administration than the woman’s preferences or her ability to cope.

Research regarding staff "rates" of epidural analgesia is suggested. Furthermore, research is recommended that considers a protocol to test the effects of suggesting that staff members try to delay epidural analgesia versus usual labour care management. The bath, then would be one of the various ways women would be supported in the experimental arm of the study. The effects of staff influence on maternal outcomes would be the focus of a study that would evaluate the effects on labour and birth events as well as staff responses.

The decision for epidural analgesia administration may be fraught with competing values. A woman in unbearable pain may be urged by a staff member to accept the medication. Conversely, the woman who originally wished a natural childbirth may have changed her mind and wish medication to take the pain away (Christensen-Szalanski, 1984). The staff (nursing, anaesthesia and medical) may not know that an epidural analgesia may fuel eventual dissatisfaction, or, on the other hand, that helping women achieve their wishes for an unmedicated
birth may enhance satisfaction. Most staff nurses are educated and socialized to provide pharmacological methods for pain relief, and may not realize the negative long-term emotional sequelae of the epidural analgesia administration for some women. The epidural analgesia procedure is invasive and requires the woman’s written consent prior to administration. Consent is usually obtained during labour. It is questionable whether the woman is fully informed about effects of the procedure beyond pain relief (Swan & Borshoff, 1994). An exploration of a woman’s (and those who may influence the intervention) knowledge about the benefits and risks of epidural analgesia would provide important information for the timing and nature of educational information.

The design of this study was a randomized controlled trial. Many women did not agree to participate owing to their firm preference for using a bath or having immediate epidural analgesia. As such, some who would have participated in a study that compared bathing against not bathing in labour were not included in the evaluation. The design of a preference trial (Jadad, 1998) would allow for the evaluation of women who did not wish to be randomized along with those who were randomized. Four groups would comprise the study sample: randomized to being encouraged to use a bath; randomized to not being offered a bath; non-randomized women who chose to use a bath and non-randomized women who did not use a bath. This may isolate the effects of one component of placebo effect (expectation of relief by the labouring woman) in the non-randomized bathing group.
Conclusion

Taking a bath is one of many non-pharmacologic, complementary care strategies becoming increasingly popular and used for supporting the labouring women. The existing evidence suggests that taking a bath during labour is not a harmful intervention to the pregnant woman, the fetus or the newborn. In this study, taking a bath in labour significantly reduced pain intensity and affect immediately following immersion. The women reported that the bath also had an effect on improving relaxation. From the responses of the participants in this study, a bath would be used in future labour experiences. Further research is required to support evidence-based care protocols, specifically regarding the measurement of labour pain, the bath’s effects on wider measures of pain relief, relaxation and the effects of the timing of immersion and/or multiple baths. Encouraging a bath is an intervention that nurses can safely offer as a comfort measure for the woman in labour.
REFERENCES


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Sharma, S..K., Sidawa, J.E., Ramin, S.M., Lucas, M. J., Leveno, K.J. &


APPENDIX A

CONSENT FORM
STUDY CONSENT FORM

Title of the Project: "The Tub Trial"
The effects of the bath in labour on epidural analgesia, operative births, pain intensity and maternal coping and satisfaction: a randomized controlled trial.

Investigators:

* Director of Nursing Research. St. Joseph's Hospital. Hamilton. Ontario. (905) 522-1155. ext 3316

Under the supervision of:
Dr. E. Hodnett. Department of Nursing Science. University of Toronto

Nurses, doctors and midwives use many different methods to promote comfort for women in labour. The methods include pain medication like needles or the "epidural" and other ways like walking, coaching and massage. Some women like to try many different alternatives for relief of labour pain.

At St. Joseph's Hospital (Hamilton) and at North York General Hospital (Willowdale), a research study being conducted about the effects of a taking bath on a woman's comfort during labour. A bath in labour may help with relaxation and pain control but research is needed about these and other effects during labour. It is planned that 640 women will be involved in this study.

I understand that:

♦ two groups of women will be studied. one group will be offered a tub bath during labour and the other group will have the usual care (care just as if I wasn't in the study). without the offer of a bath.

♦ by a random numbering system, like flipping a coin, my chances are equal that I will be selected for either one group or the other.

♦ women can be part of the study if they are healthy, in labour, have a full-term pregnancy and if they are willing to consent to participate.
having a bath in labour may be of benefit in terms of my comfort or decreasing my need for an epidural;

if I am in the bath group, the water temperature is fixed so as not to be too hot. There are no known risks to myself or my baby if the bath temperature is fixed but, as a precaution, my temperature will be taken every four hours. There are no proven risks of infection if a bath is taken in labour even if the membranes are ruptured. The labour will be closely observed so the baby will not be born in the tub;

if I am in the bath group, I will be asked about my pain before and after taking a bath. To do this, the nurse will use a simple numbering scales with me;

If I am in the control group, I will not have a bath offered to me but I will have every other comfort measure which is available should I wish. I still may take a shower if I am in the control group;

I will be asked to fill in questionnaires on the day after my baby's birth about my childbirth experience and my recollection about my nursing care during labour.

information will be collected about me from my hospital record (like my age, the progress of my labour and the details about the birth) but the research forms will be coded with a number and my name will never appear.

I am free to stop being a part of the study at any time. I can change my mind at any time about my pain medication wishes or requests. Being in the study means that I may still have a shower or have an epidural if this is my wish (or if it is ordered by my doctor)

If I have any questions about my involvement in the study, I can call Janet Rush, the Principal Investigator at 1-905-522-1155, ext.3316 (I may call "collect").

I agree to participate in the study

________________________________________
Signature of Participant

________________________________________
Signature of Witness

________________________________________
Date

Study # □□□□□□
APPENDIX B

COLOUR ANALOGUE SCALE: PAIN INTENSITY

2nd International Paediatric Pain Symposium
McGill, 1991

Compliments of
CHILDREN'S
TYLENOL

1-800-365-7323
* Tylenol

MOS T PA I N

NO PA I N
APPENDIX C

FACES SCALE: PAIN AFFECT


PAIN ASSESSMENT SCALE

Compliments of CHILDREN'S TYLENOL®
1-800-265-7323
APPENDIX D

DATA COLLECTION PACKAGE
THE TUB TRIAL

STUDY DOCUMENTS

- ENTRY FORM
  - staff to fill in at the time of consent
  - has the phone # to call for group allocation

- POOLSIDE PROTOCOL
  - use this form for the Tub Users
  - staff to fill in info re. tub use and pain measurement

- DATA COLLECTION SHEETS
  - for the chart data
  - filled in by the study worker

- POSTPARTUM QUESTIONNAIRE PACKAGE
  - all moms to complete pre discharge
  - distribute and pick up the Questionnaire Package on the postpartum unit

Make sure that the STUDY # and the mom's hospital ID # are on each form

All study forms to be kept with the chart until discharge then, when completed, put in the Nurse Manager's mailbox/office (St. Joe's) or the Program Director's office (North York)...to be picked up by Janet Rush
THE TUB TRIAL
Entry Form

ASSESSMENT FOR ELIGIBILITY
(NOTE: Please use a black felt-tipped pen)

1. Is the mother's temperature normal (≤ 37.5°)?
   - No
   - Yes

2. Is the mother in labour?
   - No
   - Yes

3. Is the mother at term (≥ 37 weeks)?
   - No
   - Yes

4. Is the mother medically appropriate for this study (i.e., no orders for continuous EFM or stat epidural)?
   - No
   - Yes

5. Has the mother consented, in writing, to participate?
   - No
   - Yes

(The patient is ineligible if any of the above questions is filled "No". DO NOT PROCEED)

ADDITIONAL QUESTION

6. When does the mother believe her "true" labour started?
   
   Date: [ ] [ ] [ ] [ ]
   Time: [ ] : [ ]

   Date and Time of Randomization: [ ] [ ] [ ] [ ] [ ] [ ] [ ]

RANDORIZATION PROCEDURE

STEP 1. Complete the above questions.

STEP 2. Follow the instructions for making the telephone call:
   - North York: Call 351-3788 (dia direct)
   - St. Joseph's: Call 9-0-416-351-3788. After the message dial 416-351-3788-3175 (this is the calling card #).
   
   You will then be connected to the Randomization Service!

STEP 3. Follow the instructions given over the phone to enter the answers to questions #7-10 below. All answers must be followed by the number sign (#) on the telephone key pad, as directed on the questions below. At the end of each question, your response will be repeated back to you for confirmation. If you wish to make changes, wait for the question to begin again before re-entering your answer. After confirming your answer to the "parity" question no further changes can be made as the group (Tub or Control) has been assigned.

STEP 4. Mark the study group assigned by the Randomization Service under question #11 below.

If there are any problems with the randomization service, call the Randomization HELP line at 416-351-3799. St. Joseph's staff are to use credit card # 416-351-3799-3003 to pay for the call for HELP and follow instructions on the answering machine to reach a member of the HELP staff. Assistance about the Tub Trial may be obtained by contacting Janet Rush, Sue Kwolek, Sue Burlock or Eileen Bain — or refer to the Bulletin Board.

7. The TUB TRIAL'S "Study Identifying Code":
   - 003 #

8. Patient Study Number (from top of this form):
   - #

9. Mother's Hospital ID Number (from top of this form):
   - #

10. Parity (# previous births > 20 weeks)
    [Enter "00" if primip]
    - #

11. Study Group Allocation [Fill in circle as per the telephone message]
    - 1. Tub Group
    - 2. Control Group

Entry Form
## THE TUB TRIAL
### Poolside Protocol

<table>
<thead>
<tr>
<th>FOR TUB USERS ONLY</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Duration in the Tub:</td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
</tbody>
</table>

Note: It is not necessary to check the cervix prior to tub — note dilation from the last time the mother was checked.

2. Was mother in the tub >4 times?  
   - [ ] No  
   - [ ] Yes → Total # of times: [ ]

3. Were the whirlpool jets used (beyond just to try them)?  
   - [ ] No  
   - [ ] Yes →  
     - [ ] Continuously  
     - [ ] Intermittently

---

A Pain Scoring Tool is at each bedside. Extras are at the Nursing Station.

4. Pain intensity score PRE TUB ENTRY (First time in tub only, describing PEAK of last contraction)  
   [ ]  

5. Faces of Pain score PRE TUB ENTRY (First time in tub only, describing PEAK of last contraction)  
   [ ]

6. Pain intensity score POST TUB ENTRY (Ten minutes after first immersion, describing PEAK of last contraction)  
   [ ]

7. Faces of Pain score POST TUB ENTRY (Ten minutes after first immersion, describing PEAK of last contraction)  
   [ ]

8. If mother was randomized to the TUB group and did not use tub, provide reason(s) below: (Fill in all that apply)  
   - [ ] Refused  
   - [ ] Epidural given before tub used  
   - [ ] Delivered too soon  
   - [ ] Other (please specify)  
   - [ ] Tub Not Available

---

Page 1
# THE TUB TRIAL

## Data Collection Sheets

### LABOUR

**Mother's Date of Birth:**

<table>
<thead>
<tr>
<th>Y</th>
<th>Y</th>
<th>Y</th>
<th>M</th>
<th>M</th>
<th>D</th>
<th>D</th>
</tr>
</thead>
</table>

**Date and Time of Admission:**

<table>
<thead>
<tr>
<th>Y</th>
<th>Y</th>
<th>Y</th>
<th>M</th>
<th>M</th>
<th>D</th>
<th>D</th>
</tr>
</thead>
</table>

(24-hour clock)

<table>
<thead>
<tr>
<th>H</th>
<th>H</th>
</tr>
</thead>
</table>

**Gestational Age at Admission:**

| weeks | days |

**Rupture of Membranes:**

- Prelabour SROM
- SROM during labour
- Artificial ROM

**VBAC?**

- No  
- Yes

**Presentation:**

- Vertex
- Face
- Breech
- Brow
- Trans
- Oblique

**Augmented during labour?**

- No  
- Yes

**Epidural?**

- No
- Yes → Started:

<table>
<thead>
<tr>
<th>Y</th>
<th>Y</th>
<th>Y</th>
<th>M</th>
<th>M</th>
<th>D</th>
<th>D</th>
</tr>
</thead>
</table>

(24-hour clock)

<table>
<thead>
<tr>
<th>H</th>
<th>H</th>
</tr>
</thead>
</table>

**Fully dilated at:**

<table>
<thead>
<tr>
<th>Y</th>
<th>Y</th>
<th>Y</th>
<th>M</th>
<th>M</th>
<th>D</th>
<th>D</th>
</tr>
</thead>
</table>

**Delivered at:**

<table>
<thead>
<tr>
<th>Y</th>
<th>Y</th>
<th>Y</th>
<th>M</th>
<th>M</th>
<th>D</th>
<th>D</th>
</tr>
</thead>
</table>

**Placenta delivered at:**

<table>
<thead>
<tr>
<th>Y</th>
<th>Y</th>
<th>Y</th>
<th>M</th>
<th>M</th>
<th>D</th>
<th>D</th>
</tr>
</thead>
</table>

**Analgesia/Anaesthesia:**

1. None
2. Epidural (anaesthetic agent only)
3. Epidural (spinal epidural, opioid & anaesthetic agent)
4. Narcotic IM
5. Pudendal/Local
6. Nitrous Oxide
7. General
8. TENS
9. Other (please specify):

<table>
<thead>
<tr>
<th>Y</th>
<th>Y</th>
<th>Y</th>
<th>M</th>
<th>M</th>
<th>D</th>
<th>D</th>
</tr>
</thead>
</table>

**Was a shower used in labour?**

- No  
- Yes

**Maternal B/P normal during labour?**

- No  
- Yes

**Meconium noted during labour?**

- No  
- Yes

**Maternal temperature normal during labour?**

- No  
- Yes

**Balanced maternal intake and output?**

- No  
- Yes  
- Unknown

**Maternal ketones detected in urine during labour?**

- No  
- Yes  
- Not tested
THE TUB TRIAL
Data Collection Sheets

DEPARTMENT

Study No: [ ] [ ] [ ]
Mother’s Hospital No: [ ] [ ] [ ]

DELIVERY

Place:  O LDR  O OR  O Bath

Type of Delivery:
O Spontaneous
O Forceps
O Vacuum
O C-Section
O Other (please specify)

Position:
O Back/Semi-fowler’s
O Side
O Squat
O Kneel
O Other (please specify)

Condition of the Perineum:
O Intact
O Episiotomy
O 1° Laceration
O 2° Laceration
O 3° Laceration
O 4° Laceration
O Episiotomy + laceration

Primary attendant for pregnancy & birth:
O GP
O OB
O GP-OB
O Midwife
O Other (please specify)

POSTPARTUM

Maternal infection?  O No  O Yes → Code: [ ] [ ]

Breastfeeding?  O No  O Yes

Twins? O No → Birthweight: [ ] [ ] [ ] grams

Apgar 1: [ ]  Apgar 5: [ ]

Infection?  O No  O Yes → Code: [ ] [ ]

NICU?  O No  O Yes → Reason: ________________________________

Code: [ ] [ ]

O Yes → TWIN #1:

Birthweight: [ ] [ ] [ ] grams

Apgar 1: [ ]  Apgar 5: [ ]

Infection?  O No  O Yes → Code: [ ] [ ]

NICU?  O No  O Yes → Reason: ________________________________

Code: [ ] [ ]

TWIN #2:

Birthweight: [ ] [ ] [ ] grams

Apgar 1: [ ]  Apgar 5: [ ]

Infection?  O No  O Yes → Code: [ ] [ ]

NICU?  O No  O Yes → Reason: ________________________________

Code: [ ] [ ]
APPENDIX E

POSTPARTUM QUESTIONNAIRE PACKAGE
THE TUB TRIAL

POSTPARTUM QUESTIONNAIRE PACKAGE

Please complete the attached forms. Instructions are provided inside.

Give them to your nurse or leave them on your bedside table for the nurse or project worker to pick up.

Your answers and written comments are very important to us.

Thank you very much for taking the time to complete all the forms.

Please keep all the forms stapled together!
THE TUB TRIAL
Childbirth Experience

In the Childbirth Experience Form we would like you to share your feelings about your Childbirth Experiences. Instructions on how to complete the attached forms are provided below.

When you have completed all forms, please give them to your nurse or leave them on your beside table for the nurse or project worker to pickup. Please keep all forms stapled together.

Your answers and written comments are very important to us. We will learn more about how you felt during labour and how you felt about being part of this study.

Thank you very much for taking the time to complete all the forms.

HOW TO USE THIS SCALE:
For each statement, fill in the one circle that best describes what labour was like for you. There are no "right" or "wrong" answers.

This question is used as an example.

I felt confident

If you felt confident almost all of the time

If you felt confident a lot of the time but not always

If you felt confident a little more than half the time

If you felt confident about half the time

If you felt confident slightly less than half the time

If you sometimes felt confident

If you never or almost never felt confident

Almost Always 〇 〇 〇 〇 〇 〇 Rare

fill in this position

Almost Always 〇〇〇〇〇〇〇〇〇 Rare

fill in this position

Almost Always 〇〇〇〇〇〇〇〇〇 Rare

fill in this position

Almost Always 〇〇〇〇〇〇〇〇〇 Rare

fill in this position

Almost Always 〇〇〇〇〇〇〇〇〇 Rare

fill in this position

Almost Always 〇〇〇〇〇〇〇〇〇 Rare

fill in this position

Patient
Just as no two women are exactly alike, no two women have exactly the same experiences during childbirth. Please try to recall your labour and your baby's birth as vividly as you can. Think about your feelings during labour and birth. Of course, you probably had many different feelings, but try to remember what it was generally like for you during this time. (Please see the previous page for instructions)

Fill in only one circle for each item.

1. I felt tense
2. I felt important
3. I felt confident
4. I was in control
5. I felt fearful
6. I felt relaxed
7. I felt good about my behaviour
8. I felt helpless (powerless)
9. I felt I was with people who cared about me
10. I felt like a failure

Almost Always
Almost Always
Almost Always
Almost Always
Almost Always
Almost Always
Almost Always
Almost Always
Almost Always
Almost Always

Rarely
Rarely
Rarely
Rarely
Rarely
Rarely
Rarely
Rarely
Rarely
Rarely

Patient - Page 1
Some mothers have thoughts and feelings about the events during labour and about being in a study. For this study, we are especially interested in your thoughts about the epidural, the bath and your labour pain. Please mark your answers by filling in the circles and then write your extra comments, feelings and thoughts in the spaces. You may use the back of the form if you need extra room for writing your comments.

Did you have an epidural?
○ No
→ If "No", how did you feel about not having had an epidural?
  ○ Pleased
  ○ Neutral
  ○ Disappointed

Please explain:
________________________________________________________________________
________________________________________________________________________
________________________________________________________________________
________________________________________________________________________

Office Code □□

If you have another baby, would you choose to have an epidural?  ○ No  ○ Yes

Did you take a bath during labour?
○ No
→ If "No", how did you feel about not taking a bath during labour?
  ○ Pleased
  ○ Neutral
  ○ Disappointed

Please explain:
________________________________________________________________________
________________________________________________________________________
________________________________________________________________________
________________________________________________________________________

Office Code □□

If you have another baby, would you choose to take a bath during labour?  ○ No  ○ Yes
The TUB Trial
Childbirth Experience

Study No: [ ] [ ] [ ] [ ]  Mother's Hospital No: [ ] [ ] [ ] [ ] [ ] [ ]

Please recall your overall experience of pain in labour. Using the line scale below, put an "X" on the line at the spot that best describes the intensity or strength of your pain.

| no pain | worst pain imaginable |

Look at the faces and mark an "x" under the face which best describes how you felt about the unpleasantness of your overall pain in labour: (Choose only one)

[ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ]

Happiest Feeling Possible

[ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ]

Saddest Feeling Possible

If you had it to do over again, would you have participated in this study?  ○ No  ○ Yes

Please explain:

__________________________________________________________________________

__________________________________________________________________________

__________________________________________________________________________

__________________________________________________________________________
NURSING SUPPORT IN LABOUR

Section 1: Amount of Nursing

Nurses spend varying amounts of time with women during labour, depending upon the women's needs and other factors.

About how much time did a nurse spend with you during your labour, from the time you came to the hospital until you gave birth? (fill in only one circle)

- A nurse was with me all of the time or nearly all (90%) of the time
- A nurse was with me most of the time, about 75% of the time
- A nurse was with me for about half the time
- A nurse was with me for about 1/4 of the time
- A nurse was with me for small amounts of time, a few minutes every half hour or so

Section 2: Type of Nursing Support

"Nursing support" is a term used to describe things that nurses can do to help women to cope with labour, including reassurance, comfort, and advice. On the next page is a list of types of nursing support during labour, but "support" refers to ways in which they offer comfort, reassurance, and advice. Your nurse(s) probably did some, but not all, of these things for you. But this questionnaire only concerns the amount and types of support you received from nurses, not the total amounts and types of support you received from everyone during your labour.

Here is how to complete the Type of Nursing Support questions:

Look at each activity on the list. How often did a nurse do it for you - never, occasionally, or often?

"Occasionally" means one or more times, but not often.
"Often" means several times, frequently, repeatedly.

Consider each activity separately and fill in the appropriate circle beside the activity.

For example, the first item on the list is "gave me cool cloths or warm compresses." Your husband or partner may have done this for you, but if a nurse never did this for you, fill in the circle under "Never". If a nurse occasionally did this for you, fill in the circle under "occasionally". If a nurse often did this for you, fill in the circle under "often".
## NURSING SUPPORT IN LABOUR

**How often did a nurse do this for you?**

<table>
<thead>
<tr>
<th>Number</th>
<th>Description</th>
<th>Never</th>
<th>Occasionally</th>
<th>Often</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Gave me cool cloths or warm compresses</td>
<td>o</td>
<td>o</td>
<td>o</td>
</tr>
<tr>
<td>2.</td>
<td>Helped me with my breathing</td>
<td>o</td>
<td>o</td>
<td>o</td>
</tr>
<tr>
<td>3.</td>
<td>Touched me lightly, in a comforting way: held my hand, stroked my skin</td>
<td>o</td>
<td>o</td>
<td>o</td>
</tr>
<tr>
<td>4.</td>
<td>Offered me ice chips or fluids or food</td>
<td>o</td>
<td>o</td>
<td>o</td>
</tr>
<tr>
<td>5.</td>
<td>Reassured me</td>
<td>o</td>
<td>o</td>
<td>o</td>
</tr>
<tr>
<td>6.</td>
<td>Gave me information about my progress in</td>
<td>o</td>
<td>o</td>
<td>o</td>
</tr>
<tr>
<td>7.</td>
<td>Helped me to calm down, by focusing my attention</td>
<td>o</td>
<td>o</td>
<td>o</td>
</tr>
<tr>
<td>8.</td>
<td>Stayed with me to keep me company</td>
<td>o</td>
<td>o</td>
<td>o</td>
</tr>
<tr>
<td>9.</td>
<td>Explained what was happening</td>
<td>o</td>
<td>o</td>
<td>o</td>
</tr>
<tr>
<td>10.</td>
<td>Supported my decisions</td>
<td>o</td>
<td>o</td>
<td>o</td>
</tr>
<tr>
<td>11.</td>
<td>Massaged my back or other parts of my body</td>
<td>o</td>
<td>o</td>
<td>o</td>
</tr>
<tr>
<td>12.</td>
<td>Encouraged me</td>
<td>o</td>
<td>o</td>
<td>o</td>
</tr>
<tr>
<td>13.</td>
<td>Helped me to walk around</td>
<td>o</td>
<td>o</td>
<td>o</td>
</tr>
<tr>
<td>14.</td>
<td>Told other staff members what I needed</td>
<td>o</td>
<td>o</td>
<td>o</td>
</tr>
<tr>
<td>15.</td>
<td>Changed my underpad, sheets, nightgown</td>
<td>o</td>
<td>o</td>
<td>o</td>
</tr>
<tr>
<td>16.</td>
<td>Helped me to the toilet</td>
<td>o</td>
<td>o</td>
<td>o</td>
</tr>
<tr>
<td>17.</td>
<td>Helped to distract me from the pain or from other problems</td>
<td>o</td>
<td>o</td>
<td>o</td>
</tr>
<tr>
<td>18.</td>
<td>Helped me find a comfortable position</td>
<td>o</td>
<td>o</td>
<td>o</td>
</tr>
<tr>
<td>19.</td>
<td>Helped me to use a tub bath or shower or Jacuzzi as a way to relieve pain or relax</td>
<td>o</td>
<td>o</td>
<td>o</td>
</tr>
<tr>
<td>20.</td>
<td>Gave me a sponge bath</td>
<td>o</td>
<td>o</td>
<td>o</td>
</tr>
<tr>
<td>21.</td>
<td>Helped others (like my husband/partner/relative/friend) to help me, by demonstrating how or suggesting techniques</td>
<td>o</td>
<td>o</td>
<td>o</td>
</tr>
</tbody>
</table>
Appendix F
Women’s Comments: Bath Taken

Bath Taken: Theme #1: Relax

- the water was soothing, it relaxed me and helped me through my contractions;
- instantly relaxed my body and made my contractions a little easier to deal with and also since my body was relaxed more, I was more in control of my breathing;
- enjoyed the change of pace, whirlpool between contractions was soothing;
- was very relaxing! After each contraction I was able to just put my head back until the next one, so much that I could take naps in between!
- it relaxed me and I think it made things happen faster;
- it gave me temporary relief. It helped me through 1-2 hours of labour. I opted for the epidural at the end. You have a better sense of control over the pain. The shower and the tub shifted my focus from the pain for a little while at a time enabling me to put off using pain medication for as long as possible which I feel is better for me and the baby and the labour over all;

Bath Taken: Theme #2: Pain Relief

- reduced labour pain dramatically, I felt more in control;
- I don’t believe I could have done it without any pain medication without taking a bath. It greatly reduced the back labour;
- took all the pain away;

Bath Taken: Theme #3: Relax and Pain Relief

- I was pleased because the bath seemed to relax me to a point where the pain disappeared;
- I believe that taking a tub bath during labour is very helpful and an alternative to taking an epidural. I didn’t have an epidural so taking a bath in the tub really helped me feel relaxed and more confident that I could get through the labour. In a warm tub you almost don’t feel any pressure. I think my baby was happy too in the tub.
Appendix G
Women’s Comments: Bath Not Taken

Bath not taken: Theme #1: Disclaim

- The bath probably would not have helped in my case;
- I was in the control group;
- I knew the epidural would provide relief for me;
- I went so fast, I would have had no time for the tub anyway.

Bath not taken: Theme #2: Regret

- It may have helped make my labour easier;
- I would have liked to try it out;
- I was disappointed when I realized I was in the control group but after the epidural it was impossible;
- I felt it would have helped my back labour;
- I would have love to see how much the bath might have helped;
- I felt the distraction of the moving water would have been a positive intervention;
- I was looking forward to the experience but did not want to pass up the anesthetists availability.
Appendix H

Women's Comments: Epidural Analgesia Taken

Epidural taken: Theme #1: Satisfied
- made the entire experience more enjoyable;
- why would women not have an epidural and choose to avoid the pain?
- it totally relieved my pain;
- it took away the pain - long labour so it permitted rest;
- I was very tense and couldn't handle the pain at all before I took the epidural After I took it I relaxed and felt one hundred percent better;
- I was very pleased it didn't make me feel pain or anything the relief was incredible - I could have named the baby after the anaesthetist...;
- I wanted to go without but realized I couldn't and was very pleased with the results. I think epidural is a miracle and cannot imagine how could I handle the labour without;

Epidural Taken: Theme #2: Dissatisfied
- the shaking made me feeling not so comfortable;
- I didn't want to feel the pain, but it only took on 1/2 of my body so I still had pain;
- I was afraid;
- the doctor had trouble giving me the epidural, after several attempts, he got it right. It was very unpleasant even though I felt no pain. He gave me too much of a dose and delivery was delayed;
- the epidural although administered properly was not a great success since someone turned it off and I ran out of medication during labour. Later, the actual syringe ran out and there was only one anaesthetist in the hospital - unavailable at the time;
- nervous about the side effects, fear of the unknown;
- did not effectively block all nerves;
- I was not frozen for the stitches;
- it only worked for the first hour then I felt everything;
- did not relieve the pain;

Epidural Taken: Theme #3: Disappointed
- unexpected side effects (shaking) caused the baby's heart beat to fall below normal;
- took 3 times to get the needle in my hank and two times to insert the epidural which didn't ease major pain. I wanted to go natural;
- made me feel like a failure, and also happy to feel the pain go away;
- I really didn't want to have to take it. I thought I could go natural;
- I thought I was stronger and could take the pain better. I was also too tired;
- I was hoping to endure the whole process on my own without the assistance of the epidural;
- painful enough for an epidural although I didn't think I'd need one;

Epidural Taken: Theme #3: Cope
- after 10 hours the pain became too much. The epidural gave me the control I needed and the time to rest up;
- epidural did help me to be more relaxed, however the procedure scares me greatly - allowed me to handle the experience better;
- I was pain free and able to rest for the last phase of labour;
- I was really doing well before with the tub without epidural but after my water broke, my cervix thickened again, I had no more energy to go through more contractions;
- The pain just became too much to go on;
- the back labour was too intense to go on without the epidural;
- I felt I was weak and unable to cope with the pain;
- I came in to the hospital with an open mind but would have preferred to go without an epidural. However, looking back, I'm very happy I did get one because my labour was so long and I was extremely tired;
- I was in so much pain I couldn't bear it;
- due to the use of pitocin IV I was unable to manage painful contractions.
Appendix I
Women's comments: Epidural Analgesia Not Taken

Epidural not taken: Theme #1: Planned/Preferred
- had natural delivery before and preferred to feel my labour completely;
- glad not to have to resort to drugs to get me through;
- I preferred to most natural was to labour, I tried my best to suffer the pain;
- giving birth is a natural thing to do;
- I had an epidural with my first child. I could feel the lower back pain even several months after the birth. Also I had shivers every time I thought about the epidural;
- felt awake and happy;
- wanted and planned for a natural childbirth;
- I don't like them.

Epidural not taken: Theme #2: Fear
- I didn’t like the idea of having a needle in my back or the idea of possible prolonging labour by having the epidural. Mostly I didn’t want the baby to have drugs;
- afraid of side effects;
- I’m glad I didn’t have an epidural because there are lots of risks;
- do not like needles...

Epidural not taken: Theme #3: Cope/control
- doctor and myself want to be able to feel contractions and to push;
- pleased to be able to control pain by myself and be able and walking and fit for my son;
- I wanted to be in control of my body, to be able to walk and experience childbirth to the best of my ability;
- lots of pain but satisfying in the end;
- I felt more confident having the baby naturally;
- I was more alert and ready to enjoy my baby after I had her - which was not the case with my first;

Epidural not taken: Theme #4: Fast
- scared at first because there was no time and there was a line up for it [epidural] but it felt great knowing that I had experienced pushing him our and feeling him.
Appendix J
Women’s Comments: Participation in the Study

**Study Participation: Theme #1 Help/learn**
- I think such studies are important and useful for both patients and staff/hospital resource allocations
- I think the study would help other women to feel more confident about the labour;
- I think finding ways to make labour more comfortable is important and if this helps, I’ll participate;
- I like to help! The staff is incredible!
- I feel every mother should experience different opportunities - only a study can help with that;
- I think that it is a good thing to be able to help in studies like this especially if it benefits the hospital in the long run;
- I believe everyone should try to help find answers to help make others more comfortable or a situation more understood;
- to help in any way possible to help further the knowledge of childbirth and pain relief, the study wasn’t an inconvenience in any way;
- research is the key to understanding better concepts;

**Study Participation: Theme #2: Happy**
- I truly believe the jacuzzi helped me;
- being in the tub group was exceptional in helping me cope with contractions and feel better in control;
- it was worth it to get a birthing room;
- I wanted the tub and it was great;
- Glad to have the bath experience and glad to help out;
- I was luck enough to get the tub.

**Study Participation: Theme #3: Easy/choice**
- I think the bath was a great option for relaxation and pain relief. No harm in entering a study from which I can withdraw at any time;
- I didn’t feel participating in the study was difficult - it was straight forward and non-intrusive to my labour;
- it was helpful to know that I could have had excellent care whether I participated or not;
- things are best learned and understood by the experience of individuals - also the study always gave us the chance of backing out if our situation was no longer appropriate;

**Study Participation: Theme #4 Reflect**
- It did not alter my labour experience at all to participate in the study other than giving me the opportunity to reflect on how I feel about the labour;
- it can show what is important to moms during labour and how their care can be individualized to create a positive birth experience;
- If my thoughts and descriptions help staff deal with and work together with women in labour then any study is worth that. You need all the support, encouragement and compassion during labour and delivery;
- it helps me to try and explain my feelings at the time;
- it’s my way to tell other people of my feelings during labour
### APPENDIX K

Pre and post immersion mean scores: Secondary analysis, separating women who had higher post immersion scores from those who had lower post immersion scores.

<table>
<thead>
<tr>
<th>MEASURE</th>
<th>N*</th>
<th>Pre immersion</th>
<th>Post immersion</th>
<th>95% CI</th>
<th>2p</th>
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<tbody>
<tr>
<td>Pain intensity</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lower</td>
<td>152</td>
<td>6.37 ± 1.8</td>
<td>4.74 ± 1.7</td>
<td>-2.2, -1.7</td>
<td>&lt;0.0005</td>
</tr>
<tr>
<td>Higher</td>
<td>59</td>
<td>5.61 ± 2.2</td>
<td>7.62 ± 1.8</td>
<td>1.6, 2.4</td>
<td>&lt;0.0005</td>
</tr>
<tr>
<td>Pain affect</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lower</td>
<td>132</td>
<td>.783 ± .12</td>
<td>.592 ± .20</td>
<td>-22.4, -16.13</td>
<td>&lt;0.0005</td>
</tr>
<tr>
<td>Higher</td>
<td>53</td>
<td>.701 ± .19</td>
<td>.834 ± .12</td>
<td>9.91, 16.69</td>
<td>&lt;0.0005</td>
</tr>
</tbody>
</table>

* there were 8 women from the control group (crossovers) who had pain measures taken and their scores are included in this sub analysis. Sixteen women had the same pain intensity score pre and post immersion and the pain affect scores were the same for 42 women. Forty-one women had higher post immersion scores for both measures.
APPENDIX K (continued)

Secondary Analysis: A comparison of outcomes among women who had higher post immersion scores, lower post immersion scores and women from the total study sample

<table>
<thead>
<tr>
<th>MEASURE</th>
<th>Pain intensity higher</th>
<th>Pain intensity Lower</th>
<th>Pain affect higher</th>
<th>Pain affect lower</th>
<th>Total study sample</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>N = 59</td>
<td>N = 152</td>
<td>N = 53</td>
<td>N = 132</td>
<td>N = 635</td>
</tr>
<tr>
<td>Frequency(%)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nullipara</td>
<td>24 (40.7)</td>
<td>87 (57.2)</td>
<td>21 (39.6)</td>
<td>73 (55.3)</td>
<td>332 (52.3)</td>
</tr>
<tr>
<td>Multipara</td>
<td>35 (59.3)</td>
<td>65 (42.8)</td>
<td>32 (60.4)</td>
<td>59 (44.7)</td>
<td>303 (47.7)</td>
</tr>
<tr>
<td>PROM</td>
<td>11 (18.6)</td>
<td>40 (26.3)</td>
<td>7 (13.2)</td>
<td>32 (24.2)</td>
<td>139 (21.8)</td>
</tr>
<tr>
<td>SROM</td>
<td>11 (18.6)</td>
<td>31 (20.0)</td>
<td>13 (24.5)</td>
<td>26 (19.7)</td>
<td>124 (19.5)</td>
</tr>
<tr>
<td>AROM</td>
<td>36 (61.0)</td>
<td>79 (52.0)</td>
<td>32 (60.4)</td>
<td>72 (54.5)</td>
<td>364 (57.3)</td>
</tr>
<tr>
<td>Bath @ Cx:</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>0-2 cm.</td>
<td>12 (20.3)</td>
<td>62 (40.8)</td>
<td>12 (22.6)</td>
<td>52 (39.4)</td>
<td>99 (15.6)</td>
</tr>
<tr>
<td>3-4 cm.</td>
<td>31 (52.5)</td>
<td>61 (40.1)</td>
<td>27 (50.9)</td>
<td>57 (43.2)</td>
<td>143 (45.7)</td>
</tr>
<tr>
<td>5-6 cm.</td>
<td>13 (22.0)</td>
<td>23 (15.1)</td>
<td>13 (24.5)</td>
<td>16 (3.8)</td>
<td>59 (18.8)</td>
</tr>
<tr>
<td>7-10 cm.</td>
<td>2 (3.4)</td>
<td>4 (2.6)</td>
<td>1 (1.9)</td>
<td>2 (1.5)</td>
<td>12 (3.8)</td>
</tr>
<tr>
<td>Augmentation</td>
<td>19 (32.2)</td>
<td>72 (47.4)</td>
<td>20 (37.7)</td>
<td>60 (45.5)</td>
<td>267 (43.0)</td>
</tr>
<tr>
<td>Epidural analgesia</td>
<td>42 (71.2)</td>
<td>114 (75.0)</td>
<td>34 (64.2)</td>
<td>101 (76.5)</td>
<td>485 (76.4)</td>
</tr>
<tr>
<td>Epidural analgesia @ Cx &lt;5cm</td>
<td>20 (30.9)</td>
<td>72 (47.4)</td>
<td>13 (24.5)</td>
<td>63 (47.7)</td>
<td>355 (56.0)</td>
</tr>
<tr>
<td>Spontaneous delivery</td>
<td>43 (72.9)</td>
<td>83 (54.6)</td>
<td>40 (75.5)</td>
<td>71 (53.8)</td>
<td>393 (61.9)</td>
</tr>
<tr>
<td>Cesarean section</td>
<td>3 (5.1)</td>
<td>23 (15.1)</td>
<td>1 (1.9)</td>
<td>18 (13.6)</td>
<td>84 (13.2)</td>
</tr>
<tr>
<td>Intact perineum</td>
<td>20 (33.9)</td>
<td>48 (31.6)</td>
<td>16 (30.2)</td>
<td>38 (28.8)</td>
<td>189 (29.8)</td>
</tr>
<tr>
<td>Postpartum survey:</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bath taken</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pleased</td>
<td>34 (66.6)</td>
<td>101 (81.5)</td>
<td>31 (63.5)</td>
<td>84 (80.0)</td>
<td>214 (74.3)</td>
</tr>
<tr>
<td>Neutral</td>
<td>9 (17.6)</td>
<td>18 (11.8)</td>
<td>9 (18.5)</td>
<td>16 (15.23)</td>
<td>51 (17.7)</td>
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<tr>
<td>Disappointed</td>
<td>8 (15.6)</td>
<td>5 (3.3)</td>
<td>9 (18.5)</td>
<td>5 (3.8)</td>
<td>23 (8.0)</td>
</tr>
<tr>
<td>Future labours:</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bath (yes)</td>
<td>37 (80.4)</td>
<td>112 (95.7)</td>
<td>35 (66.0)</td>
<td>94 (71.2)</td>
<td>356 (81.5)</td>
</tr>
<tr>
<td>Participate in future studies (yes)</td>
<td>46 (92.0)</td>
<td>125 (94.6)</td>
<td>42 (89.5)</td>
<td>105 (95.9)</td>
<td>473 (91.5)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Mean ± SD</th>
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</thead>
<tbody>
<tr>
<td>Maternal age</td>
</tr>
<tr>
<td>Admission to epidural analgesia (min)</td>
</tr>
<tr>
<td>Admission to delivery (min)</td>
</tr>
<tr>
<td>Admission Cx distlation</td>
</tr>
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* missing data will account for some frequencies not equal to total N and some percentages < 100%