RASPBERRY LEAF IN PREGNANCY: ITS SAFETY AND EFFICACY IN LABOR

Michele Simpson, CNM*, DipRemedial Therapies, MHNA, Myra Parsons, CNM*, BHSc, MRCNA, MACMI, Jennifer Greenwood, CNM*, MEd, PhD, FRCNA, and Kenneth Wade, BSc, DipEd, PhD, MEdAdmin, MACE

ABSTRACT

Objective: Many women consume the raspberry leaf herb during their pregnancies in the belief that it shortens labor and makes labor "easier."

Methodology: Because of the paucity of research regarding this herb, particularly in relation to pregnancy and birth, the authors undertook a double-blind, randomized, placebo-controlled trial. The sample consisted of 192 low-risk, nulliparous women who birthed their babies between May 1999 and February 2000 at a large tertiary-level hospital in Sydney, Australia. The aim of the study was to identify the effect and safety of raspberry leaf tablets (2 × 1.2 g per day), consumed from 32 weeks' gestation until labor, on labor and birth outcomes.

Results: Raspberry leaf, consumed in tablet form, was found to cause no adverse effects for mother or baby, but contrary to popular belief, did not shorten the first stage of labor. The only clinically significant findings were a shortening of the second stage of labor (mean difference = 9.59 minutes) and a lower rate of forceps deliveries between the treatment group and the control group (19.3% vs. 30.4%). No significant relationship was found between tablet consumption and birth outcomes.

Conclusion: The lack of significant differences between the groups on measures expected to demonstrate the effect of raspberry leaf ingestion during pregnancy on labor prompted consideration of the issue of effectiveness of dosage level. Suggestions for further research are offered. J Midwifery Womens Health 2001;46:51–9 © 2001 by the American College of Nurse-Midwives.

INTRODUCTION

There is a belief that the raspberry leaf herb, taken in tablet, tea, or tincture form during pregnancy, shortens labor and makes labor "easier." Pregnant women consume raspberry leaf under the advice of book and magazine authors and advertisements, friends and relatives, health food store salespersons, naturopaths, herbalists, doctors, and midwives. To the investigators' knowledge, the effect of raspberry leaf during pregnancy on the labor, birth, and postpartum period has never been examined, except in laboratory studies (1,2). All information regarding the effect of raspberry leaf on parturient women had been anecdotal before a retrospective study performed by Parsons et al (3). The study reported herein was developed to examine the effectiveness of raspberry leaf tablets on birth outcomes and to determine side effects, if any, that may be attributed to the consumption of raspberry leaf tablets by low-risk, nulliparous women during pregnancy on their labor and birth outcomes.

Research questions explored included the following: Compared with a control group, does the regular intake of raspberry leaf tablets from 32 weeks' gestation by nulliparous women:

- have any adverse effects on the mother (eg, increase in blood pressure or an increase in blood loss at birth) and baby (eg, lower Apgar score at birth or birth weight)?
- affect the duration of pregnancy (eg, preterm or postterm onset of labor)?
- shorten the duration of labor?
- reduce the likelihood of medical interventions during labor and birth (eg, medical or surgical augmentation of labor, epidural anesthesia, or increased rate of forceps, ventouse or cesarean delivery)?

REVIEW OF THE LITERATURE

The raspberry leaf plant (Rubus idaeus Linn, Family: Rosacea) has been used medicinally for centuries—certainly as early as the sixth century (4). Burn and Withell (1) stated that the raspberry leaf herb is "the best known and oldest of all the herb infusions and [is] included as a proved aid in maternity in the most ancient of herbal books." They also found that an intravenous injection of raspberry leaf extract had a relaxant effect on the uterine muscle of cats (1) and discovered a by-product in raspberry leaf tea that not only reduced the strength and frequency of contractions but also caused tonically contracted muscles to relax. Whitehouse (2) also found that uterine contractions diminished in frequency and strength and secondary contractions were eliminated in those women given 20–40 g of raspberry leaf extract (fragarine) in the first few days after birth.

Address correspondence to Myra Parsons, CNM, BHSc, MRCNA, MACMI, 7 Jordana Place, Castle Hill, NSW 2154, Australia.

* Australian nurse and certified midwife.

1526-9523/01/$20.00 • PII S1526-9523(01)00095-2

The relaxant effect of raspberry leaf extract noted by Burn and Withell was later interpreted as "producing more coordinated uterine contractions" in labor by Bamford et al (1,5). As Bamford et al (5) explained, a major problem in obstetrics "is in coordination of uterine action, and it may be that raspberry leaf extract is able to modify the course of labor favorably to produce more coordinated uterine contractions." This is the expectation that underpins the research questions. The only side effect of raspberry leaf extract noted in earlier studies was an accompanying change in blood pressure, although results were contradictory (1,2). Burn and Withell noted a rise in blood pressure, whereas Whitehouse found instead a slight fall in systolic blood pressure (1,2).

It is believed that the uterus is strengthened and toned by the regular ingestion of raspberry leaf throughout pregnancy and labor, assisting contractions and checking any hemorrhage during labor (6,7). It is of interest that medical opinions are often opposed to the use of raspberry leaf, believing it may cause or augment a miscarriage or premature labor, although only one reference can be found in the literature to support this view (5). This study, performed in 1970, found that contractions were initiated in strips of human uteri injected with raspberry leaf extract between 10 and 16 weeks of pregnancy.

Although much is written about raspberry leaf, especially for pregnancy and childbirth (6–10), there is a paucity of empirical research; the only experimental studies are now dated (1941, 1954, 1970). Two studies were specific to animals (1,4), one involved postpartum women (2), and the third experimented on first trimester uteri after removal from the body (5). A retrospective observational study conducted at a large tertiary-level hospital in Sydney, Australia, in 1998 by the authors demonstrated the safety of the raspberry leaf herb for women and their babies when consumed during pregnancy (3). A sample size of 109 postnatal women (day 1–4), primiparous and multiparous, were interviewed. Fifty-eight women consumed raspberry leaf tea in some form (tea, tablet, or tincture), at various dosages, commencing consumption as early as 8 weeks' gestation to as late as 39 weeks' gestation. A control group of 51 postnatal women who had taken no raspberry leaf products during their pregnancy were used as a comparison. The average length of the first stage of labor for women who ingested raspberry leaf was found to be shorter than for women who did not ingest raspberry leaf, whereas the average lengths of the second and third stages of labor were similar in both groups. There was one preterm labor and birth in the control group compared with none in the treatment group. The percentage of normal births in the raspberry leaf group (77.2%) was slightly larger than the percentage in the control group (66.7%). As a retrospective study, there was no control of the level of ingestion by mothers in the raspberry leaf group, and other somewhat confounding variables also impacted on the findings.

Michele Simpson is an Australian nurse and certified midwife currently employed by a major tertiary-level hospital in Sydney where she manages a midwifery-led prenatal clinic. She holds a diploma in massage and remedial therapies and is a founding member of the Holistic Nurses Association in the State of New South Wales.

Myra Parsons is an Australian certified midwife practicing in hospital and home settings. She holds a degree in nursing and a Graduate Certificate in Research from the University of Western Sydney. Ms. Parsons is currently enrolled in a Master's (Honors) program at the University of Western Sydney, Nepean, and is a member of the Royal College of Nursing, Australia, and the Australian College of Midwifery.

Jennifer Greenwood is a clinical professor of nursing, jointly appointed by Western Sydney Area Health Service and the University of Western Sydney. Greenwood holds a Master's of Education from Exeter University, UK, and a PhD in Education from the University of Leeds, UK. She is a Fellow of the Royal College of Nursing, Australia.

Kenneth Wade is a policy and systems coordinator at the University of Western Sydney, and formerly a senior lecturer in research methods and statistics at Cumberland College of Health Sciences in Sydney. Dr. Wade holds a Bachelor of Science degree from the University of New South Wales, Australia; a Diploma in Education, a PhD in Mathematical Psychology from the University of Sydney, Australia; and a Master's of Educational Administration from the University of New England, Australia. He is a Member of the Australian College of Education.

METHODOLOGY

Study Design and Setting

This was a double-blind, randomized, placebo-controlled trial to explore the effect of the raspberry leaf herb, consumed in tablet form by nulliparous women from 32 weeks' gestation until the commencement of labor, on labor and birth outcomes. The study was undertaken at a major tertiary referral hospital in Sydney, Australia, in which annual births number approximately 4,200. Recruitment for the study took place in the hospital's antenatal clinic.

Sample Size

Because this was an exploratory study, the aim was to estimate the relative effectiveness of the treatment compared with the control. The major dependent variable for the study was the length of nulliparous labor, an interval estimate of the difference between the average lengths of labor of the treatment and control groups. This interval estimate was based on the t-test distribution, the accuracy of which improves with an increase in the number of subjects in each group. To estimate a reasonable sample size for the study, the magnitude of the difference between the mean lengths of labor had to be hypothesized. It was assumed that:

- the average length of nulliparous labor is 12 hours
- the standard deviation of the lenght of labor is 5 hours
- the treatment reduction in the length of labor will be on average, at least 2 hours.

Thus, with a significance level set at .05 and power set at .80, the required sample size would be 100. If the standard deviation was found to be less than 5, maintaining the proposed sample size would increase the power if a hypothesis test were conducted. The sample size of 100 per group was logistically feasible and forms the only constraint in the accuracy of the interval estimate to be calculated.

Sample and Sampling

Participants in this study ($n = 192$) were women booked to birth their first baby at the participating hospital between May 1999 and February 2000. Criteria for selection in the study included being nulliparous with a low-risk, healthy pregnancy, fluent in reading and writing English, and having a doctor's approval for participation. All women meeting the criteria were invited to participate. The convenience sample of women, who consented to participate, were randomly allocated to either the treatment ($n = 96$) or placebo ($n = 96$) group.

Instruments

Data were collected from the hospital obstetric database and medical records of subjects, and included the length of the three stages of labor, mode of birth, parity, gestation at birth, age, blood loss, medical or surgical augmentation, meperidine (pethidine) and epidural anesthesia use, newborn Apgar score at 5 minutes and birth weight, the presence of meconium liquor [fluid], incidence of admission to neonatal intensive care facilities within the first 24 hours after birth, maternal weight and blood pressure at the first antenatal visit and at 32 weeks' gestation, and the last prelabor blood pressure. Information regarding tablet consumption compliance was documented and held by the subjects until the birth of their baby, when the documentation was given to their midwife. Side effects experienced by the subjects during the study period were recorded on a separate form at each antenatal visit by the caregiver and held in the subject's medical record.

The raspberry leaf and the placebo tablets in this study were contained in individual, dark-brown, sealed bottles and were identical in appearance. The constituents of both types of tablets (raspberry leaf and placebo) were calcium phosphate, cellulose microcrystalline, magnesium stearate, and soy polysaccharide. The only difference was the addition of .4 g (3:1 = 1.2-g extract) of raspberry leaf to the raspberry leaf tablets. Because this was the first study of its kind, a conservative dose (2.4 g per day) was chosen on the basis of the dosage recommended by the Pharmaceutical Society of Great Britain (4–8 g per day) and the dosage recommended by manufacturers (personal correspondence with Blackmores Naturopathics) of raspberry leaf tablets supplied in health food stores in Australia (1.8–3 g per day) (11). Tablets, rather than tea, were selected for investigation for two reasons. First, the dosage is more accurate when using tablets, and second, compliance with tea was thought to be better than tincture because reportedly many women do not like their taste.

Procedure

Approval was obtained from the participating institution's Human Subject Ethics Committee. Nulliparous women who met the inclusion criteria were approached by one of the first two authors (MS or MP) or a clinic midwife regarding the study during their regular 26–30-week gestation antenatal checkup. The randomized bottles of tablets, raspberry leaf and placebo, were given in numerical, sequential order (1–240) to the women after informed and written consent. Commencement of the 32 weeks' gestation tablets was determined according to the most accurate estimate of the date of confinement (EDC), the woman's stated last menstrual period (LMP), and/or earliest ultrasound result. Each woman was directed to take two tablets per day, one tablet with breakfast and one with their evening meal until commencement of established labor (regular contractions). Each raspberry leaf tablet contained 1.2 g (400 mg of 3:1 extract) of raspberry leaf extract. Because anecdotal and scientific data have suggested that a related species of raspberry leaf may have a hypoglycemic action (12), the women were asked to ingest the tablets with food and were requested not to take any other additional form of raspberry leaf while participating in the study.

Data Analysis

In February 2000 all data were analyzed by using the Statistical Package for the Social Sciences (SPSS) software package (PC Version). Descriptive and inferential statistics appropriate to each variable and to address the research questions were calculated and examined.

Missing Data

- There was one recording of a postpartum blood pressure that was not found in the participant's record.
- Four tablet consumption cards were not collected. The participants had changed their address and were not able to be contacted.
- Forty-four participants experienced cesarean birth, and

TABLE 1
Characteristics of the Raspberry Leaf Treatment and Placebo Control Groups

	Raspberry Leaf Group (n = 96)	*Control Group (n = 96)*
Maternal age in years (range and mean)	19–43 (28.5)	18–41 (26.8)
Maternal weight in kg at booking [first] visit (mean range ± SD)	39.5 (± 104.6) to 66.3 (± 14.8)	38 (± 121) to 66.6 (± 14.8)
Ethnicity (n, %)		
Caucasian	81 (84.4)	79 (82.3)
Asian	12 (12.5)	15 (15.6)
South Pacific Islander	3 (3.1)	2 (2.1)
Private patients (n, %)	11 (11.5)	5 (5.2)
Public patients (n, %)	85 (88.5)	91 (94.8)
Doctors clinic	35 (36.4)	45 (46.9)
Midwives clinic	34 (35.4)	29 (30.2)
Team midwifery care	14 (14.6)	14 (14.6)
GP shared care*	2 (2.1)	3 (3.1)

* Local family doctors (GPs) provide most of the antenatal care; the remainder of the antenatal and all of the intrapartum and postpartum care are provided by the hospital doctors' clinic.

thus data collected for the length of each stage of labor and blood loss were excluded from the analysis.

RESULTS

Withdrawal of Subjects

The number of subjects who originally commenced the study was 240. Withdrawal during the course of the study ($n = 48$) was either by the woman's choice or the investigators' advice. Six women reported experiencing nausea while taking the tablets (three women were taking raspberry leaf, and three were taking the placebo). Two women complained of diarrhea and preferred to withdraw from the study; both were in the placebo group. One woman withdrew due to constipation; others gave nonspecific reasons (eg, lost the bottle, car stolen with bottle inside, difficulty in swallowing tablets, transferring to another hospital). A percentage of women were withdrawn for medical reasons (eg, developed hypertension, polyhydramnios, late identification of twin pregnancy). These women were evenly distributed between the two groups. Despite the large number of women who withdrew from the study, the sample size of 192 remained adequate to ensure the validity of the research.

Demographic Comparison

The total sample size was 192, which consisted of 96 women in the group who ingested raspberry leaf tablets (RL) and 96 in the placebo group (P). All women birthed between May 1999 and February 2000. Data analysis included a comparison of the two groups. The demographic characteristics of the sample are displayed in Table 1.

The sample consisted of a majority of Caucasian women. The average age was 28.5 years in the raspberry leaf group and 26.8 years in the placebo group. The average weight of the mothers in the raspberry leaf group was 66.3 kg (SD = 14.812) and 66.6 kg (SD = 14.848) for mothers in the placebo group. There was no difference between the two groups for age [$t(190) = .65$, $p = .52$] and weight [$t(190) = .13$, $p = .90$]. The only notable difference between the two groups was that there were more women in the raspberry leaf group who chose to receive their care from a private obstetrician (11/11.5%) compared with the control group (5/5.2%). All other women received their antenatal care from midwives working in either the Team Midwifery Program or Midwives Clinic or doctors in the antenatal clinic at the participating hospital. Any demographic differences between the two groups were considered to have occurred by chance and attributed to the randomization process.

Safety Comparison

The following variables were analyzed to assess the safety aspect of raspberry leaf consumption in pregnancy.

- Maternal blood loss at birth (estimated visually)
- Maternal diastolic blood pressures at first antenatal clinic presentation in early pregnancy, at 32 weeks, and prebirth and postbirth
- Presence of meconium-stained fluid
- Newborn Apgar score at 5 minutes
- Newborn birth weight
- Newborn admission to neonatal intensive care and special care facilities after birth
- The occurrence of participant-reported side effects

Maternal blood loss was measured on 148 women (44 were excluded for this variable because of cesarean

TABLE 2
Reasons for Admissions to the Neonatal Intensive Care Unit (NICU) and Special Care Nurseries (SCN) for the Raspberry Leaf Treatment Group and Placebo Control Group Newborns

	Raspberry Leaf Group		*Placebo Group*	
Reasons	*Admissions to NICU (*n)	*Apgar at 5 minutes*	*Admissions to NICU or SCN (*n)	*Apgar at 5 minutes*
Total Admissions	10		7	
Respiratory distress after vaginal breech delivery	1	8	0	—
Observation 2° meconium	2	6,4	3	6,8,9
Respiratory distress after instrumental delivery	3	8,8,9	1	7
Respiratory distress	4	8,8,9,9	0	0
Prematurity	0	0	1	9
Respiratory distress after shoulder dystocia	0	0	1	7
Low birth weight	0	0	1	9

births). There were 21 incidences of blood loss greater than 600 mL, 6.1% ($n = 9$) in the raspberry leaf group compared to 8.1% ($n = 12$) in the placebo group, and no significant difference between the groups was demonstrated [$M_{RL} = 345.5$ mL, $M_P = 357.2$ mL, $t(147) = .18$, $p = .86$].

The raspberry leaf group demonstrated a slightly higher diastolic blood pressure (BP) value, on average, in early pregnancy (M = 64.4 mmHg) and 32 weeks (before tablet consumption) (M = 71.7 mmHG), compared with the placebo group (M = 64.0, M = 69.0). The measures of BP at 32 weeks were used as a covariate in the comparison of the two groups on prelabor BP and postlabor BP. No difference was found between the two groups in this analysis of covariance. Of the 240 women initially recruited, 10 (4.2%) from the raspberry leaf group and 5 (2.1%) from the placebo group developed pregnancy-induced hypertension/preeclampsia. Of these, four from the raspberry leaf group and two from the placebo group chose to remain on the study and were not withdrawn by their caregiver.

Analysis of birth weight also showed no significant difference between the two groups [$M_{RL} = 3456.15$ g, $M_P = 3{,}500.42$ g, $t(190) = .74$, $p = .46$]. The newborns in the placebo group tended to have a higher average Apgar score at 5 minutes with a narrower spread of measures [$M_{RL} = 8.81$, $S_{RL} = .74$, $M_P = 8.95$, $S_P = .48$, $t(190) = 1.61$, $p = .108$]. No difference was found between the two groups in the occurrence of meconium stained amniotic fluid. There were a total of 17 (8.9%) admissions to the Neonatal Intensive Care Unit ($n = 14$) and the Special Care Nursery ($n = 3$) in the first 24 hours after birth (Table 2). Of these admissions, 10 babies (5.2%) were from the raspberry leaf group and seven (3.7%) were from the placebo group. Table 2 displays the reasons for these admissions.

Side Effects

All 192 forms used to assess side effects were received. Women with incomplete forms were contacted personally or by telephone, and all missing information was obtained. Reported discomforts experienced by women in the study seemed to be equally distributed between the groups. Most discomforts were pregnancy-related with more reports of nausea in the placebo group. Table 3 shows the discomforts/side effects women experienced during the study period. The figures in Table 3 do not include subjects who withdrew from the study.

Outcomes

The possible effects of raspberry leaf consumption were examined by comparing the raspberry leaf (RL) and placebo (P) groups for differences in:

TABLE 3
Tablet Side Effects Reported by the Raspberry Leaf Treatment and Placebo Control Groups

Side Effects	*Raspberry Leaf Group (n, %)*	*Placebo Group (n, %)*
Total reports of side effects	31 (32.3)	24 (25.0)
Diarrhea	9 (9.4)	8 (8.3)
Constipation	4 (4.2)	0
Nausea	8 (8.3)	11 (11.4)
Vomiting	4 (4.2)	2 (2.1)
Headaches	1 (1.0)	1 (1.0)
Heartburn	1 (1.0)	0
Strong uterine tightening	2 (2.1)	0
Dizziness	1 (1.0)	0
Bloating	1 (1.0)	0
Rash	0	1 (1.0)

TABLE 4
Length of Labor in Raspberry Leaf Treatment and Placebo Control Groups

	*Raspberry Leaf Group (n = 76) (mean, SD)**	*Placebo Group (n = 72) (mean, SD)**	t	df	p
Length of 1st stage	428.2 ± 227.7*	427.4 ± 209.5	0.02	140	0.98
Length of 2nd stage	71.2 ± 48.9	80.8 ± 59.0	1.08	146	0.28
Length of 3rd stage	7.0 ± 9.7	6.5 ± 8.6	0.36	146	0.72

* Mean (in minutes) ± standard deviation (SD).

- Length of gestation
- Incidence of induction of labor by syntocinon infusion and artificial rupture of membrane
- Incidence of medical augmentation of slow labor with syntocinon
- Incidence of artificial rupture of membranes
- Use of patient-requested pethidine and/or epidural block
- Length of the stages of labor: first, second, and third stage
- Mode of birth.

On average, the length of gestation in days for each group was the same [M_{RL} = 279.69 and M_P = 280.47, t(190) =.66, p = .51]. Gestations ranged from 36+3 weeks to 41+6 weeks for the raspberry leaf group and 34+5 weeks to 42+2 weeks in the placebo group. Of the 93 women in the raspberry leaf group who labored, 45 (48.4%) went into spontaneous labor, 29 (31.2%) were medically augmented, and 19 (20.4%) required induction either with oxytocin or prostaglandin. Of the 89 women in the placebo group who labored, 45 (50.6%) experienced spontaneous labor, 25 (28.1%) were medically augmented, and 19 (21.4%) required induction of labor. There was no difference between the two groups on the likelihood of medical augmentation of labor [$\chi^2(2)$ = .18, p = .91]. No difference was found between the two groups in the need for pethidine (meperidine) or epidural block for pain relief during labor. There was a tendency, however, for the placebo group to require more intervention in the form of artificial rupture of membranes (AROM). Of the 58 participants who required AROM, 54% were in the placebo group [χ^2 (1) = .87, p = .35].

The analysis of time in first, second, and third stages of labor excluded participants who gave birth by cesarean. No difference in first stage (determined by period between cervical dilatation of 3 cm accompanied by regular contractions to full dilatation) and third stage (time between birth of baby and birth of the placenta) was found between the two groups (Table 4). The mean difference between the groups for the period of second stage (period between full dilatation of the cervix and birth of the baby) of labor was 9.6 minutes (the raspberry leaf group was 12% shorter in time on average than the placebo group), [t(146) = 1.08, p = .28].

After exclusion of mothers who experienced an elective cesarean, the two groups were compared on type of birth. There was some difference in mode of birth between groups, with slightly more women in the raspberry leaf group having normal vaginal births [n_{RL} = 58 (62.4%), n_P = 45 (50.6%)] and more women in the placebo group having forceps or vacuum-assisted births than would be expected by chance, although not statistically significant [$\chi^2(2)$ = 3.35, p = .19]. The emergency cesarean section rate, however, was equal in both groups. Analysis of the data relating to mode of birth (Table 5) showed some difference between the groups [$\chi^2(2)$ = 3.35, p = .18]. Reasons for birth by cesarean section can be found in Table 6.

Analysis of Tablet Consumption

One hundred eighty-eight of the 192 tablet consumption cards were available and analyzed. Four participants were unable to be contacted to complete data. Tablet compliance was calculated by using actual tablet consumption in comparison with what the participant was expected to consume (expressed as a percentage). The average compliance rate was 89.4% (ie, 89% of tablets were consumed per woman). The relationship between consumption compliance for the raspberry leaf group and outcomes was analyzed using the following dependent variables:

TABLE 5
Mode of Birth for Treatment and Control Groups

	Raspberry Leaf Group (Total births = 93) (n, %)	*Placebo Group (Total births = 89) (n, %)*
Vaginal delivery		
Cephalic	53 (57)	44 (49.4)
Breech	5 (5.4)	1 (1.1)
Forceps/vacuum extraction	18 (19.3)	27 (30.4)
Cesarean section		
Emergency	17 (18.3)	17 (19.1)
Elective*	3	7

* Not included in analysis.

TABLE 6
Reasons for Births by Cesarean Section (C/S) in Raspberry Leaf Treatment and Placebo Control Groups

	Raspberry Leaf Group (n)	*Placebo Group (n)*
Total cesarean births	20	24
Emergency C/S	17	17
Failure to progress-first stage	6	8
Abnormal fetal heart rate	7	7
Failed forceps	1	1
Breech complication	3	0
Pregnancy-induced hypertension	0	1
Elective C/S	3	7
Pregnancy-induced hypertension	1	1
Genital herpes	1	0
Breech presentation	0	4
Abnormal fetal heart rate	1	1
Cephalopelvic disproportion	0	1

- Prelabor BP
- Blood loss
- Gestation
- Length of first, second, and third stages of labor.

No significant relationship was found between the amount of raspberry leaf tablets consumed and the outcome of any of the above variables, nor were any differences found between the two groups when the above variables were controlled for level of tablet consumption and weight of the mothers at 32 weeks.

DISCUSSION

To date, only one study has specifically investigated the relative effectiveness of the raspberry leaf herb ingested during pregnancy on the labor and birth process or the possible side effects ingestion may have for women and their babies (3). The current study found that raspberry leaf tablets not only seems to be safe, they may be of some benefit for women and their babies during the labor and birth process.

The treatment and control groups were very similar in the distribution of maternal weight, age, and ethnicity. The variables measured to ascertain safety of the raspberry leaf herb were found to be similar between groups. Maternal blood pressure and incidence of pregnancy-induced hypertension were similar in the raspberry leaf group as compared to the placebo group. This does not support the observations by Whitehouse (2) or Burn and Withell (1) who suggested that raspberry leaf influences blood pressure. There was little difference in maternal blood loss at birth between groups with postpartum hemorrhage (ie, greater than 600 mL) being statistically similar in both groups ($n_{RL} = 9$, $n_P = 12$). An overall lower newborn Apgar score in the raspberry leaf group was affected by five vaginal breech births compared to only one in the placebo group. Twelve babies in the raspberry leaf group received an Apgar score of 8 compared to only four in the placebo group. Of these, five were related to vaginal breech births. The relationship between vaginal breech births and low Apgar scores has been documented (13,14). Breech and forceps deliveries have a higher rate of respiratory distress (13–15), which, in this study, accounted for four admissions to the Neonatal Intensive Care Nursery from the raspberry leaf group. Two more admissions for meconium aspiration from the raspberry leaf group occurred in babies of mothers with pregnancy-induced hypertension who would normally have been withdrawn from the study but were allowed by their providers to remain. Although there was a larger frequency of admissions to the Neonatal Intensive Care Nursery from the raspberry leaf group, the frequency remained below the average admission rate for term babies born at the participating hospital at the time of the study (5.8%) (11).

One concern of the medical profession has been that raspberry leaf may cause or facilitate preterm labor and birth. The average length of gestation in the two groups were quite similar. The shortest gestation in the raspberry leaf group was 36+3 weeks compared to 34+5 weeks for the placebo group. If raspberry leaf were to produce more coordinated contractions, as hypothesized by Bamford and associates (5), the expectation would be that there would be shorter labors and less need for augmentation. This was not the case in this study; a slightly higher incidence of medical augmentation of labor among the raspberry leaf group was found. The average length of first and third stages of labor in the raspberry leaf group was similar to that of the placebo group. Only the second stage of labor was found to be shorter in the raspberry leaf group (M = 9.6 minutes) and coincided with an accompanying decrease in instrumental deliveries.

Other than the method of membrane rupture during labor and the mode of birth, variables to measure the incidence of medical intervention required to initiate or augment the labor process revealed no differences between the groups. The analyses suggested that women in the raspberry leaf group were more likely to give birth to their baby vaginally and unassisted and less likely to require a forceps delivery compared with the control group. Although not statistically significant, this result is considered to be clinically significant and may be associated with the reduction in the length of the second stage of labor. More mothers in the raspberry leaf group experienced spontaneous rupture of membranes and,

therefore, were less likely to receive an artificial rupture of membranes to either initiate or accelerate labor. The reason for this is not understood, but the reduced incidence of this intervention decreases the risks and discomforts that are inherent with the AROM procedure (16,17).

Among the participants who remained in the study there were no side effects from the tablets that could be attributed to the raspberry leaf herb. Common complaints of nausea, vomiting, and diarrhea were equally distributed between the two groups and were most likely pregnancy-related. Constipation, of which there were four cases, was the only complaint exclusive to the raspberry leaf group. This could be attributed to the speculated astringent action of raspberry leaf (15) or to its being a common pregnancy complaint (16,17).

The subjects, on average, showed an impressive study compliance rate of 91.4%, and it can be assumed that because the subject tablet consumption rate was high (89.4%), the maximum effect of the herb should have been evident. Apart from a shorter second stage and reduced incidence of instrumental deliveries, however, the effect anticipated (ie, a shorter first stage of labor and generally less intervention) was not found. Little difference was found between women who consumed only a small percentage of tablets and women who were 100% compliant, nor was there any relationship between the weight of the women and the dose effectiveness. These findings do, however, raise a clinical question regarding the dosage used in the study because previous studies of the herb have observed dose-related effects (1,2,5,18). It seems that a daily intake of 2.4 g of raspberry leaf in tablet form (as was used for this study) was enough to produce some positive effects (ie, shortening of the second stage of labor, reduction in forceps deliveries, and reduction in the incidence of AROM) while maintaining safety for mother and baby. The question now remains whether a higher dosage or commencement of the tablets at an earlier gestational age would contribute to a more clinically significant outcome.

LIMITATIONS

Because tablet consumption was self-reported by participants, it can only be assumed that the information provided to the authors was accurate. It was stressed to each woman at the time of recruitment that documenting omitted tablets was as important as documenting consumed tablets. The authors followed up the information provided by the participants on the "Tablet Consumption Cards" during the participants' antenatal visits throughout the study period and again after birth to increase the accuracy of the information. Because of the randomization process, however, over- and/or underreporting of tablet consumption should be equal between groups.

CONCLUSION

This study has provided a baseline for further research using the raspberry leaf herb in pregnancy. The dosage used in this study, while maintaining safety for both mother and baby, has been shown to possibly reduce the length of second stage of labor and the need for artificial rupture of membranes during labor or forceps to assist the birth. This outcome has clinical significance for mothers, their babies, and their birth attendants. Less intervention means a reduction in midwifery and medical time in labor and an increase in maternal satisfaction, which has been suggested to ease women's transition into motherhood (19). Further research is required to investigate the actions of the raspberry leaf herb on pregnancy and birth and to find an optimal dosage that will maintain safety while producing more profound and beneficial effects.

The authors gratefully acknowledge the support and advice provided by Dr. Andrew Pesce, MBBS, FRANZCOG, and the midwives at the participating hospital for their help and support in the recruitment and data collection phases of the study. This research was partially funded by the New South Wales Nurses Registration Board Scholarship. Tablets were supplied by Blackmores Naturopathics.

REFERENCES

1. Burn JH, Withell ER. A principle in raspberry leaves which relaxes uterine muscle. Lancet 1941;July 5:1–3.

2. Whitehouse B. Fragarine: an inhibitor of uterine action. BMJ 1941; Sept 13:370–1.

3. Parsons M, Simpson M, Ponton T. Raspberry leaf and its effect on labour: safety and efficacy. Aust Coll Midwives J 1999;12:20–5.

4. Beckett AH, Belthle FW, Fell KR, Lockett MF. Active constituents of raspberry leaves. J Pharm Pharmacol 1954;6:785–96.

5. Bamford DS, Percival RC, Tothill AU. Raspberry leaf tea: a new concept to an old problem. Proceedings of the British Pharmacological Society, 8th–10th July. Br J Pharmacol 1970;40:161–2.

6. Hoffman D. The new holistic herbal. Dorset: Element, 1990.

7. Mills S. The a–z of modern herbalism. London: Thorsons, 1989.

8. McFarlin BL, Gibson MH, O'Rear J, Harman P. A national survey of herbal preparation use by nurse-midwives for labor stimulation: review of the literature and recommendations for practice. J Nurse-Midwifery 1999; 44:205–16.

9. Belew C. Herbs and the childbearing woman: guidelines for midwives. J Nurse-Midwifery 1999;44:231–52.

10. Lee L. Introducing herbal medicine into conventional health care settings. J Nurse-Midwifery 1999;44:253–66.

11. Westmead Hospital Midwives Data Collection. March 2000.

12. Alonso RA. Preliminary study of hypoglycaemic activity "rubus fructicosus." Planta Medica 1980;40:102–6.

13. Kovavisarach E, Juntasom C. Risk factors of delivery of low Apgar

score newborn below 7 at 1 minute: a case-control study. J Med Assoc Thai 1999;82:660–5.

14. Towner D, Castro MA, Eby-Wilkens E, Gilbert WM. Effect of mode of delivery in nulliparous women on neonatal intracranial injury. N Engl J Med 1999;341:1709–14.

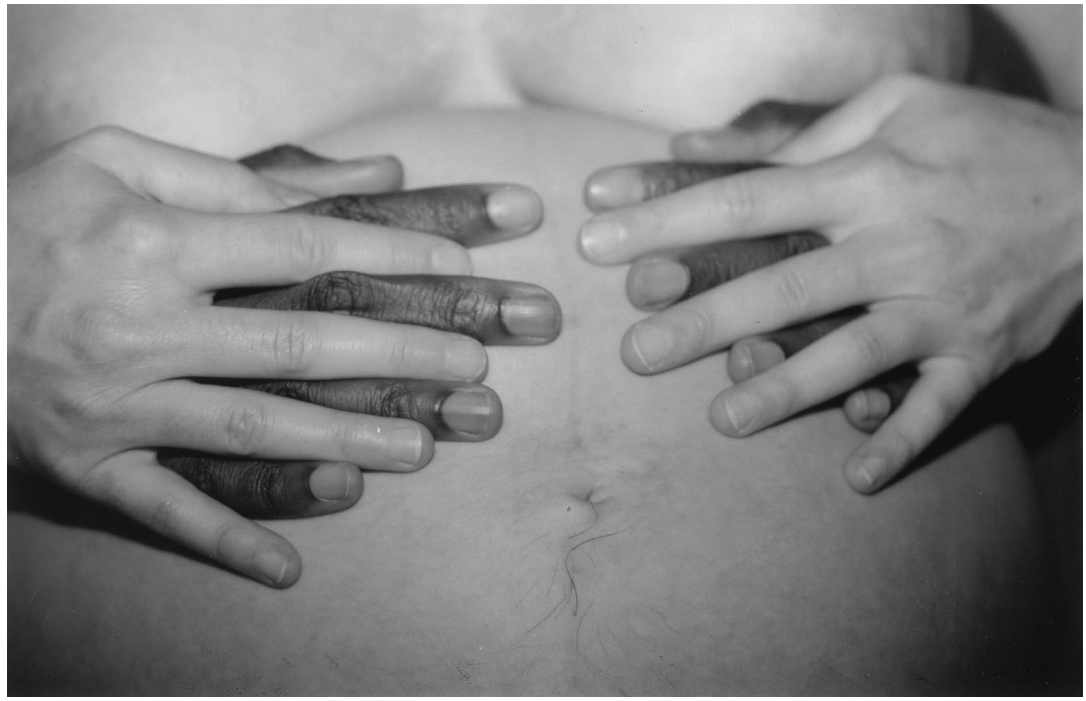
15. Dierker LJ, Rosen MG, Thompson K, Debanne S, Linn P. The midforceps: maternal and neonatal outcomes. Am J Obstet Gynecol 1985; 152:176–83.

16. Bennett VR, Brown LK, editors. Myles textbook for midwives. Edinburgh: Churchill Livingstone, 1996.

17. Beischer NA, Mackay EV. Obstetrics and the newborn: for midwives and medical students. Sydney: WB Saunders, 1976.

18. Pharmaceutical Society of Great Britain. Herbal medicines: a guide for healthcare professionals. London: The Pharmaceutical Press, 1996.

19. James J. Clinical: the role of childbirth as preparation for looking after a small baby. Br J Midwifery 1998;6:271–5.



Hands. Photo credits to Donna Weber, 2000.