Appl Psychophysiol Biofeedback
DOI 10.1007/s10484-013-9219-4

An Exploratory Analysis of the Utility of Adding Cardiorespiratory Biofeedback in the Standard Care of Pregnancy-Induced Hypertension

Sandy W. Cullins · Richard N. Gevirtz · Debra M. Poeltler · Larry M. Cousins · R. Edward Harpin · Frederick Muench

Abstract This study examined the efficacy of a cardiorespiratory biofeedback intervention compared to bed rest in the treatment of 47 women diagnosed with pregnancy-induced hypertension (PIH). The investigation consisted of a historical control group with 31 PIH subjects receiving treatment as usual (TAU), bed rest and antihypertensive medications, and an experimental group with 16 PIH subjects receiving TAU and instruction on using a portable respiratory sinus arrhythmia (RSA) biofeedback device once daily until delivery. Results indicated that systolic and diastolic blood pressure levels were unchanged for either group. Failing to find the intended main effects, a series of exploratory analyses were performed. Findings of associated hypotheses revealed that the RSA BF group had a 35 % higher birth weight than the TAU group. The gestational age at delivery was 10 % greater in the RSA BF group than in the TAU group. A significant relationship was found between the StressEraser Total and the 1-min Apgar score. Eighty-one percent of the subjects stated that the device was relaxing. Fifty percent of the subjects believed that the device helped them fall asleep. Overall, these results suggest that portable RSA biofeedback may be effective in reducing stress during pregnancy and improving perinatal outcomes.

Keywords Pregnancy-induced hypertension · Stress during pregnancy · Respiratory sinus arrhythmia · Cardiorespiratory biofeedback · Preeclampsia

S. W. Cullins (✉) · R. N. Gevirtz · R. Edward Harpin
Alliant International University, 10455 Pomerado Rd., San Diego, CA 92131, USA
e-mail: sandy.cullins@gmail.com

R. N. Gevirtz
e-mail: rgevirtz@alliant.edu

D. M. Poeltler
Sharp Mary Birch Hospital for Women, San Diego, CA, USA

L. M. Cousins
Maternal-Fetal Medicine Division, Children's Specialists of San Diego, San Diego, CA, USA

F. Muench
Columbia University College of Physicians and Surgeons, Manhattan, NY, USA

Introduction

Hypertensive disorders in pregnancy include: (1) chronic hypertension; (2) preeclampsia-eclampsia, a serious, systemic syndrome of elevated blood pressure, proteinuria and other findings; (3) chronic hypertension with superimposed preeclampsia; and (4) gestational hypertension, nonproteinuric hypertension of pregnancy, or pregnancy-induced hypertension (Zamorski and Green 2001). Pregnancy-induced hypertension (PIH) is the most prevalent medical disorder in pregnancy, affecting between 6 and 8 % of all pregnancies in the United States (Walling 2004; Zamorski and Green 2001)To date, the etiology and pathogenesis of gestational hypertension and preeclampsia are unknown (Sibai 2003). Preeclampsia-eclampsia has been documented to be an important cause of maternal mortality in the United States, Scandinavia, Iceland, Finland, and the United Kingdom (Roberts and Redman 1993). Between 1970 and 1990, preeclampsia was responsible for 18 % of maternal deaths in developed nations, including the United States (Contreras et al. 2003). In countries where prenatal care is inadequate, preelampsia-eclampsia accounts for 40–80 % of maternal deaths, an estimated 50,000 mortalities per year (Lain and Roberts 2002).

Published online: 24 April 2013

Pregnancy-induced hypertension can seriously threaten the health and life of both mother and infant. Women with severe gestational hypertension or severe preeclampsia have similar incidence of placental abruption, preterm delivery, and small for gestational age babies (Walling 2004). Infants of mothers with preeclampsia are five times more likely to die than infants of mothers without the disorder (Lain and Roberts 2002). Approximately 15 % of preterm births (before 37 weeks) in the United States (Lain and Roberts 2002) and 40 % of iatrogenic premature deliveries are a result of preeclampsia (Chappell et al. 1999). Preterm birth is often caused by high blood pressure and is the leading cause of early neonatal death and infant mortality, especially in developing countries (Atallah et al. 2002). Preterm survivors have a significant risk of developing chronic lung disease and long-term neurological diseases. In summary, hypertensive disorders in pregnancy are an important cause of maternal death in the United States and a major risk factor for maternal and fetal morbidity (Bucher et al. 1996).

Despite the high cost to families and health care services, there is no effective treatment for preeclampsia other than expectant management before delivery and no therapeutic intervention to prevent or delay the onset of preeclampsia (Chappell et al. 1999). Although mother and fetus should be carefully monitored, the optimal form of maternal and fetal surveillance has not been determined (Walling 2004). Prolonged bed rest or hospitalization is frequently recommended between 20 and 36 weeks gestation (Maloni et al. 1998), but no randomized controlled trials have validated these approaches (Walling 2004). Even though antihypertensive drugs may lower rates of progression to severe disease, they have not been found to improve outcomes for the mother or the fetus (Walling 2004). Aspirin, calcium supplementation, fish oils, vitamins C and E, zinc, and magnesium sulfate have been studied, but have not been proven to prevent this disorder (Walling 2004).

Behavioral interventions have been successfully employed in the treatment of essential hypertension in nonpregnant patients (Bae et al. 2006; Grossman et al. 2001; Schein et al. 2001). Relaxation training and biofeedback, the primary components of the psychological interventions, have been found to significantly reduce blood pressure (Linden and Moseley 2006). Recent trials with respiratory retraining using cardiorespiratory biofeedback have demonstrated consistent results in lowering blood pressure levels (Reineke 2007; Rosenthal et al. 2001). Previous research suggests that cardiorespiratory biofeedback may be an efficacious treatment in reducing blood pressure in hypertensive patients, especially in conditions partly caused by baroflex dysfunction (Lehrer et al. 2000). Cardiorespiratory biofeedback targets the baroreflexes, reduces sympathetic arousal, and increases parasympathetic activation (Elliot and Izzo 2006). Daily practice of this training is recommended in order to amplify baroreflex efficiency, which has been found to reduce blood pressure in hypertensive patients. Cardiorespiratory biofeedback is designed to strengthen baroreflex sensitivity by having individuals breathe at the optimal resonant frequency (around six breaths/min) (Lehrer et al. 2000). This technique has also been shown to raise baseline high frequency heart rate variability, suggesting increased vagal tone and decreased blood pressure. Studies (Little et al. 1984; Somers et al. 1989) have demonstrated that biofeedback is a beneficial technique for treating PIH. When biofeedback was applied as an adjunctive treatment to bed rest in the treatment of PIH, blood pressure levels in the treatment groups were maintained or decreased (Somers et al. 1989).

Despite medical advances, PIH continues to be a dangerous condition. Based on this literature review, it appears that the most frequently prescribed medical treatment of bed rest has not been shown to be an adequate and valid approach to treating PIH. In contrast, the results of former investigations suggest that the behavioral treatments may be an effective adjunct to bed rest in the treatment of mild preeclampsia (Little et al. 1984; Somers et al. 1989). Therefore, the objective of this study was to evaluate the efficacy of an RSA BF group treated with cardiorespiratory biofeedback, bed rest, and antihypertensive medications compared to a TAU historical control group prescribed with bed rest and antihypertensive medications. The behavioral intervention was designed to decrease the blood pressure of PIH patients and to sustain the reductions throughout their pregnancies.

Materials and Method

Subject recruitment took place at San Diego Perinatal Center and Sharp Mary Birch Hospital for Women (SMBHW) in San Diego, CA. The subjects of this study consisted of 47 women between 24 and 36 weeks gestation with evidence of pregnancy-induced hypertension. The inclusion criteria for this study were: repetitive diastolic blood pressure of 90 mm Hg or higher and/or a systolic blood pressure of 140 mm Hg or higher; gestational age between 24 and 36 weeks; a structured bed rest regimen; and delivery at SMBHW. The exclusion criteria for this investigation were: evidence of another medical disorder that could account for the high blood pressure (e.g. systemic lupus erythematosus, other collagen vascular diseases); severe preeclampsia; or triplets.

Subjects had their blood pressure levels evaluated by a trained health care professional at scheduled prenatal visits or during hospitalization. The blood pressure measurements

were used for diagnostic purposes and obtained from medical records. Adult women who were diagnosed with PIH and met the study requirements were invited to participate in the study. The investigator received approval for the study from the Institutional Review Board (IRB) at Alliant International University (AIU), the Sharp HealthCare IRB, and the Sharp Women's and Infants' Research Forum. The nature and purpose of the investigation were explained to the subjects, including information about the procedures involved and their potential benefits and risks. Subjects were given informed consent and the California experimental subject's bill of rights. Furthermore, they were provided with an opportunity to agree or not to agree to participate in the research without any undue influence, fraud, deceit, duress, force, or coercion.

Subjects were informed that their participation in the study could be terminated at any time, a decision to withdraw from the investigation would not affect their ability to receive medical care, and personal information would remain confidential and would not be released under any circumstances without their written permission. They were given ample opportunity to ask questions about any aspects of the investigation. Thus, subjects were assured that all of their information would be kept anonymous and confidential.

The outcome measures for this study were: diastolic blood pressure, systolic blood pressure, and mean arterial pressure (MAP). Surveillance of blood pressure and urine protein was accomplished through systematic measurements and protocols. The blood pressure was measured using one of the following blood pressure monitors: DINAMAP Procare 200, Datascope Accutorr Plus, or Corometrics 120 Series. Urine specimens were collected to assess for proteinuira. The quantitative urine protein method was employed for urine analysis.

A nurse was employed to assist with subject recruitment at SMBHW. The nurse approached eligible PIH patients to determine if they were interested in participating in the study. The investigator contacted those who were interested and agreed to be consented into the experiment. The study contained stratified samples that were equivalent on gestational age at intake, parity, and diagnosis. The investigator collected blood pressure measurements and pregnancy related data from medical records. Appropriate demographic data was obtained from the medical charts to determine if the treatment as usual (TAU) historical control group was equivalent to the respiratory sinus arrhythmia (RSA BF) experimental group.

Subjects in the TAU group received a prescription of bed rest, antihypertensive medications per policy, and were hospitalized or attended regular prenatal appointments. Subjects in the RSA BF group were invited to participate in the study. Those who consented to the study received a prescription of bed rest, antihypertensive medications per policy, and a cardiorespiratory biofeedback treatment until termination of pregnancy. These subjects practiced cardiorespiratory biofeedback with a RSA biofeedback device known as the StressEraser. The device is a non-invasive portable biofeedback device that the subjects used at home or in the hospital. It is a Food and Drug Administration (FDA) regulated Class II (510[k] premarket notification-exempt) medical device (Muench 2008; Zucker et al. 2009) designed to enhance heart rate variability (Heilman et al. 2008). The indicated use of the device is for relaxation, relaxation training, and stress reduction (Muench 2008; Zucker et al. 2009). Research studies have shown that the device significantly reduces symptoms of anxiety compared to control groups (Muench 2008; Sherlin et al. 2009).

The RSA biofeedback device measures real-time pulse-by-pulse activity via an infrared finger sensor (Heilman et al. 2008; StressEraser 2010). The finger sensor has a built-in pulse detector to immediately identify every pulse. Each time a new pulse occurs, the device calculates a new pulse rate based upon the amount of time that has elapsed between the last two pulses, creating a wave like pattern called Respiratory Sinus Arrhythmia (RSA) (Ebben et al. 2009; StressEraser 2010). The wave like fluctuation caused by heart rate has been found to be strongly associated with parasympathetic nerve activity (StressEraser 2010). The pulse rate waves are depicted in the instrument as two types of symbols: triangles, which are above the waves, and squares, which are beneath the waves The triangles guide the individual in finding the optimal time to exhale (Sherlin et al. 2009) and the square provides feedback on the effectiveness of breathing and the influence of the limbic activity on the parasympathetic nervous system (Ebben et al. 2009). Through proper respiration of 4.5–7 breaths per minute subjects maximized their parasympathetic activity (Muench 2008; Sherlin et al. 2009; StressEraser 2010).

Subjects in the RSA BF group were informed about proper breathing techniques prior to usage of the device. During a 45-min training session monitored by a health care professional, subjects were shown a training video, given a general information sheet on handling and operating the device, and assigned self-paced homework, consisting of 20 min of practice each day and a daily score of 100 points. Subjects were informed about the potential side effects (feeling sleepy, lightheaded, and/or having mild anxiety when learning to use the device) of using the device (Muench 2008), instructed to stop using the device if this occurs, not to drive or operate heavy machinery until the feeling passes, and encouraged to stop using the device if they experienced headaches, motion sickness, finger or hand numbness, or eyestrain. Furthermore, they were advised that there are no known long-term side effects from

using the device. The investigator answered any questions or concerns and addressed any obstacles that may prevent them from following these procedures. Subjects were informed that the investigator would contact them in 2 weeks to conduct a structured follow up interview designed to assess device usage and increase compliance with the protocol. They were offered the opportunity to receive a new device after completion of the study provided free of charge by makers of the device.

Results

One thousand nine hundred twenty-nine women were screened in the experimental group; 1,863 pregnancies were screen failure; and 66 patients were eligible for enrollment and participation in the study (Fig. 1). Fifty patients declined and 16 patients agreed to enroll in the RSA BF group (Fig. 1). In addition, two hundred nine patients were screened and 31 were enrolled in the TAU group (Fig. 1). As seen in Table 1, the study sample was diversely distributed. The subjects in this study ranged in age from 18 to 47, with a mean age of 31.6 years. The sample consisted of eight African Americans, 16 Caucasians, five Asians, three Native Hawaiian or Pacific Islanders, and 15 other race. Furthermore, 30 subjects were identified as Hispanic or Latino and 17 subjects were considered Not Hispanic or Latino. Thirty-three of the subjects were married and 14 of them were single. Overall, nineteen subjects were nulliparous and 28 subjects were multiparous. Twelve subjects were primigravidas, nine were gravida twos, and 26 were gravida three or more. The majority of the births in this study were singleton (42) rather than twins (5). With twin births, only the first baby was counted in the statistical analysis. Therefore, statistical procedures were only performed on the first baby. Because Sharp Mary Birch Hospital for Women does not universally assess for the level of education, this information was unavailable for the TAU group. The investigator, however, decided to collect this data from subjects in the RSA BF

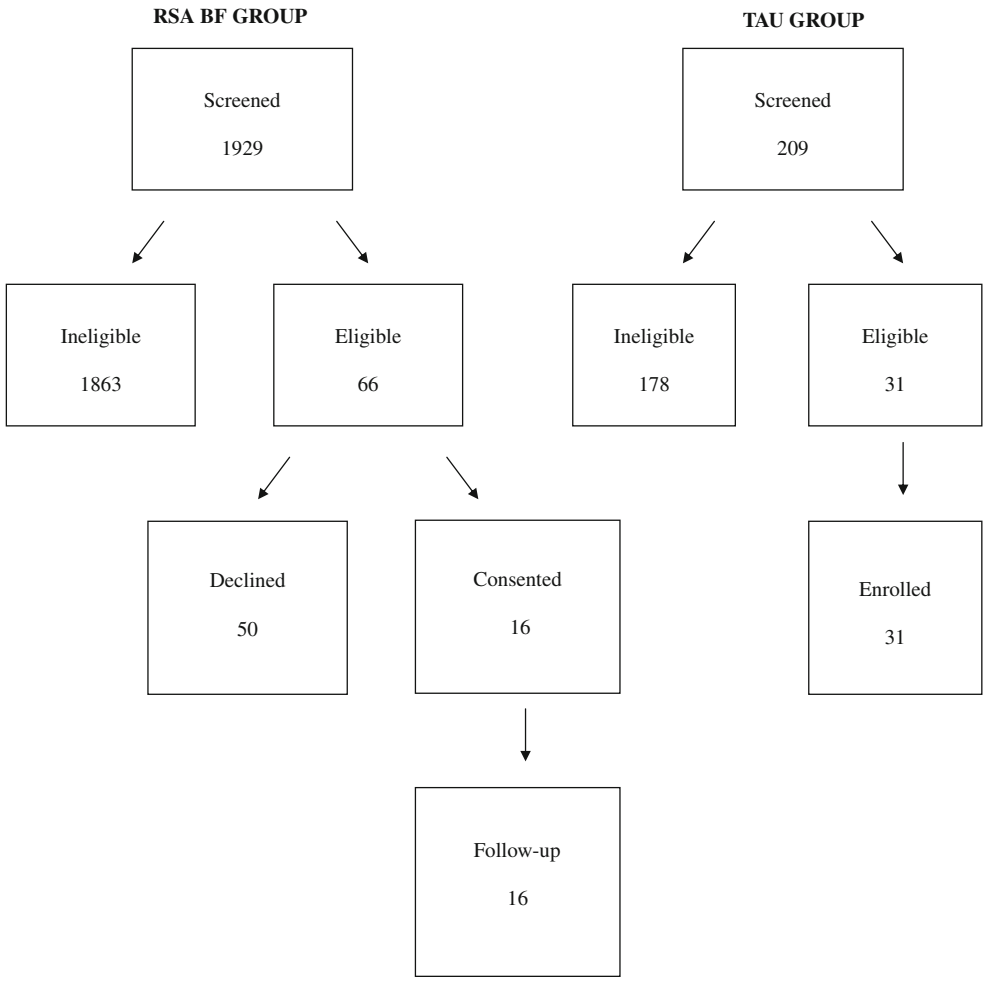

Fig. 1 Screening process

Table 1 Descriptive statistics for entire sample (N = 47)

Characteristic	n	%
Age		
18–30	19	40.0
31–40	22	47.0
41–50	6	13.0
Race		
Black or African American	8	17.0
White/Caucasian	16	34.0
Asian	5	11.0
Native Hawaiian or Pacific Islander	3	6.0
Other race	15	32.0
Ethnicity		
Hispanic	30	64.0
Not hispanic	17	36.0
Marital status		
Single	14	30.0
Married	33	70.0
Gravidity		
Primigravida	12	26.0
Gravida two	9	19.0
Gravida three or more	26	55.0
Parity		
Nulliparous	19	40.0
Multiparous	28	60.0
Births		
Singleton	42	89.0
Twins	5	11.0

Table 2 Chi squares used to assess group equivalency

Characteristic	χ^2	df	*p*
Race	.46	4	n.s.
Ethnicity	.02	1	n.s.
Marital status	.27	1	n.s.
Parity	4.19	6	n.s.
Gravidity	4.21	7	n.s.

group. As a result, subjects in the RSA BF group were ranked based on the highest level of education achieved from eighth grade to graduate school. Twelve of the participants in the RSA BF group were college educated.

Comparative analyses of demographic variables were performed using SPSS 16.0 statistical software to ensure that there were no significant differences found between the groups. An alpha level of .05 was used for all statistical tests. The results of a Chi square analysis in Table 2 showed that the groups did not differ on race, ethnicity, marital status, parity, or gravidity. Based on the findings of a *t* test in Table 3, the groups were equivalent in maternal

Table 3 *t* Tests used to assess group equivalence

Characteristic	T	df	*p*
Maternal age	−.99	45	n.s.
Maternal height	.009	45	n.s.
Systolic blood pressure intake	−1.40	45	n.s.
Diastolic blood pressure intake	−1.01	45	n.s.
Mean arterial pressure intake	−1.24	45	n.s.
Gestational age intake	.44	45	n.s
Body mass index	2.05	45	.046

Table 4 Group means and standard deviations for body mass index

Measure	Diagnostic group	
	TAU group M (SD)	RSA BF group M (SD)
Body mass index	33.15 (5.95)	36.81 (5.45)

age, maternal height, systolic blood pressure at intake, diastolic blood pressure at intake, mean arterial pressure at intake, and gestational age at intake. However, a significant difference was observed in the body mass index. Group means and standard deviations for body mass index are depicted in Table 4. To analyze this initial difference in outcome, body mass index was correlated with systolic blood pressure at intake, diastolic blood pressure at intake, mean arterial pressure at intake, gestational age at delivery, maternal age, and infant birth weight. Because the correlations were not significant, group equivalence was assumed.

Main Hypothesis

The results of a two-way analysis of variance with one repeated measure (ANOVA) indicated that the systolic and diastolic blood pressure levels were unchanged for either group (Table 5). No significant main effects or interactions were found and no simple effects were used. Hence, contrary to the original hypothesis, final results of the study revealed that the blood pressure levels of the RSA BF group did not differ significantly from the blood pressure measurements of the TAU group. Group means and standard deviations for blood pressure measurements are provided in Table 6.

Associated Hypotheses

Labor and delivery complications were analyzed to determine if these outcomes varied as a function of the treatment condition. The following variables associated with labor and delivery complications were assessed: emergency cesarean

Table 5 Analysis of variance for blood pressure measurements

Measure	Pre-treatment			Post-treatment		
	F	df	*p*	F	df	*p*
Systolic blood pressure	.132	44	n.s.	.19	44	n.s.
Diastolic blood pressure	.56	44	n.s.	.41	44	n.s.
Mean arterial pressure	.37	44	n.s.	.71	44	n.s.

delivery, intrauterine growth restriction, oligohydramnios, and poor tone and cry. A composite score of labor and delivery complications was computed for each subject. To contrast how groups differed on this composite score, a Chi square analysis was calculated. A statistically significant difference was found between groups, $\chi^2 = 8.52$ (1), $p = .004$. Therefore, labor and delivery complications were higher in the TAU group (56 %) than in the RSA BF group (15 %). The method of delivery was measured and analyzed in this study. Results for this evaluation showed that 84 % of infants in the historical control group and 69 % of infants in the experimental group were delivered via cesarean birth. A trend toward significant differences between groups was found for the method of delivery ($p < .10$).

In an effort to determine how groups differed in infant birth weight, a one-way analysis of covariance was utilized. On average infants in the RSA BF group had a 35 % higher birth weight than those in the TAU group. The mean birth weight for the RSA BF group and the TAU group were 2,156 and 1,410 g, respectively. After important confounds were controlled for, including gestational age at intake, body mass index, and maternal age, a statistically significant difference was found between groups, $F(1, 42) = 8.30$, $p = .006$. The relative magnitude of the treatment effect of the group differences in infant birth weight was determined by using Omega Squared, $\omega^2 = .13$, which is considered a moderate effect size (Keppel 1991).

A one-way analysis of covariance was performed to decide whether groups differed in regard to the gestational age at delivery. The average gestational age at delivery was 10 % greater in the RSA BF group than in the TAU group. On average, infants in the RSA BF group were born at 34.00 weeks while those in the TAU group were delivered at 30.43 weeks. This difference was statistically significant even with the covariates of body mass index, systolic blood pressure at intake, gestational age at intake, and maternal age, $F(1, 41). = 11.49$, $p = .002$. The relative magnitude of the treatment effect of the group differences in gestational age at delivery was determined by calculating Omega Squared, $\omega^2 = .18$, which is regarded as a large effect size (Keppel 1991).

A significant correlation was found between gestational age at intake and gestational age at delivery, $r = .74$, $p < .01$. Thus, the proportion of variance accounted for by this relationship was 55 %. After controlling for gestational age at intake in a one-way analysis of covariance, a statistically significant difference was found between groups on gestational age at delivery, $F(1, 44) = 18.82$, $p < .001$. However, the interaction between gestational age at intake and group was also statistically significant, indicating that we have violated the assumption of homogeneity of regression. As a result, we reset our p value for this analysis to .01 to correct for this violation and to ensure a confidence level of 99 %. The moderating effect of the biobehavioral treatment on the relationship between gestational age at intake and gestational age at delivery is illustrated in Figs. 2 and 3.

The Apgar test was applied during labor and delivery to decide if an infant was at a higher risk for requiring pediatric intervention. Results from an ANOVA analysis revealed that no group differences existed on the 1- or 5-min Apgar tests. Information on device usage was recorded on the device and evaluated at the end of the study. In each session, the data contained the number of points achieved by each user and the amount of time spent using the device. Furthermore, during data analysis, the total number of points was divided by the total amount of time to calculate a variable called the StressEraser Total (SE Total). The SE Total is an estimate of how efficiently each subject used her device.

Table 7 provides results of the Pearson product-moment correlations that were computed between SE Total and infant birth weight, gestational age at delivery, the 1-min Apgar score, and the 5-min Apgar score. A significant correlation was found between SE Total and the 1-min Apgar score, $r = .63$, $p = .02$. Therefore, the proportion of variance accounted for by this relationship was 40 %. No other significant correlations were found between SE Total and the outcome measurements noted above. A general trend was found between SE Total and the aforementioned birth outcome measures.

Despite the fact that there were no significant differences in blood pressure levels, we hypothesized that a longer gestational age at delivery should lead to higher blood pressure readings, if the intervention had no effect. Therefore, we adjusted diastolic blood pressure, systolic blood pressure, and mean arterial pressure for gestational age at delivery, and compared all blood pressure levels with the revised estimates. Our results were in the predicted direction, but no significant differences were found between groups.

Although there was no relationship between gestational age at delivery and blood pressure measurements in the historical control group, we found a negative relationship between gestational age at delivery and blood pressure levels in the experimental group. If the historical control

Table 6 Group means and standard deviations for blood pressure measurements

Measure	Diagnostic group			
	TAU group M (SD)		RSA BF group M (SD)	
	Pre	Post	Pre	Post
Systolic blood pressure	146.19 (14.06)	142.58 (12.56)	140.56 (10.82)	142.81 (9.60)
Diastolic blood pressure	83.65 (8.57)	82.94 (9.77)	80.88 (9.52)	83.06 (6.95)
Mean arterial pressure	104.61 (9.31)	102.77 (9.81)	101.06 (9.21)	102.94 (6.49)

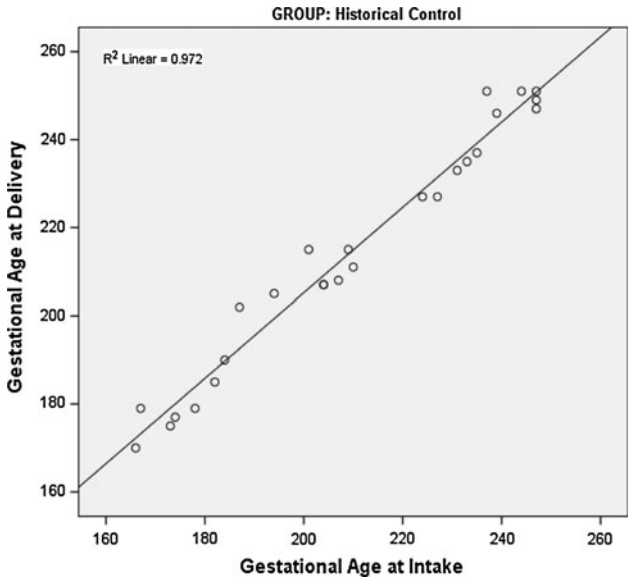

Fig. 2 Moderating effect on TAU historical control group

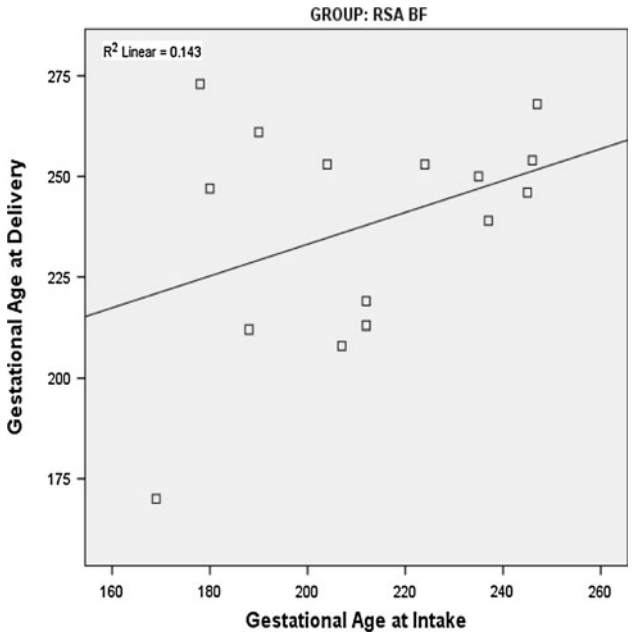

Fig. 3 Moderating effect on RSA BF group

Table 7 Correlations for SE Total and birth outcomes

Measure	r	*p*
SE Total and infant birth weight	.42	n.s.
SE Total and gestational age at delivery	.34	n.s.
SE Total and 1-min apgar	.63	.02
SE Total and 5-min apgar	−.01	n.s.

group delivered at 34 weeks, their final blood pressure levels would have increased by 4.5 mmHG. Based on this information, the mean systolic blood pressure levels at delivery for the historical control group would have been 147 mmHg. The differences between the changes in blood pressure readings approached statistical significance, $t_{(45)} = 1.93$, $p = .06$. If RSA biofeedback device does in fact prolong gestational age, we should have experienced increases in blood pressure levels at termination of pregnancy. Instead, blood pressure measurements were unchanged for both groups.

The possibility of two different groups was assessed to determine if our results would vary based on the presence or absence of proteinuria. A two-way analysis of variance with no repeated measure was applied. The results of the statistical analyses indicated that no statistical differences were found between groups, $F(1, 46) = .17$, $p = .684$, and no significant main effects and interactions were observed. Because gestational age at delivery and birth weight did not correlate well, we used each of these variables as a covariate in a one-way analysis of covariance. The statistically significant results that were obtained earlier in our analysis on gestational age at delivery and birth weight were eliminated when we used gestational age at delivery as a covariate, $F(1, 44) = .35$, $p = .555$, and infant birth weight as a covariate, $F(1, 44) = .51$, $p = .480$.

Subjects in the RSA BF group were interviewed at follow up. Eighty-eight percent of the subjects had favorable reviews about the device. Subjects reported that their devices were used an average of 4.4 days per week. In addition, these women achieved a mean of 49.1 points per day. Eighty-one percent of the subjects found the device

relaxing. Fifty percent of the subjects believed the device helped them fall asleep. Eighty-five percent of the subjects requested a new device sent to their home upon completion of the study.

Discussion

The objective of this study was to evaluate the effectiveness of a cardiorespiratory biofeedback intervention compared to bed rest in the management of PIH. It was hypothesized that subjects in the RSA BF group treated with cardiorespiratory biofeedback would maintain their systolic and diastolic blood pressure measurements at significantly lower levels than subjects in the TAU historical control group. Hence, this study was not a randomized controlled trial. The results of the study did not support the original hypothesis. Instead, the outcomes showed that the blood pressure levels did not differ significantly between groups. Because both groups maintained their blood pressure measurements, the effect of ambulatory RSA biofeedback on increasing baroreflex efficiency was inconclusive. Decreases in blood pressure levels were not experienced in either group because the modern medical treatment utilized in this study, including antihypertensive medications, effectively maintained blood pressure measurements. In summary, the findings from this study revealed that practice with the RSA device was unrelated to changes in blood pressure levels. The results of this investigation did not support the findings of two previous studies that successfully applied behavioral methods to subjects with mild PIH (Little et al. 1984; Somers et al. 1989). It appears that differences in group characteristics, treatment settings, and blood pressure assessments may account for some of the inconsistencies found between the present investigation and two former studies.

Tests of associated hypotheses found that infants in the RSA BF group had a significantly higher birth weight than those in TAU group. Further evaluation of associated hypotheses revealed that the gestational age at delivery was greater in the experimental group than in the historical control group. If this information was replicated in a random control trial and if in fact it was responsible for the changes, it would suggest that the biobehavioral intervention in this study represented an increase in infant birth weight and gestational age at delivery. In the analysis on labor and delivery complications, a statistically significant difference was observed between groups. If this finding was replicated in the results of future random control studies, it would allow for the inference that subjects in the TAU historical control group were at greater risks for the development of labor and delivery complications than subjects in the RSA BF group.

This investigation adds to the body of research on nonpharmacologic approaches for stress among pregnant women (Beddoe and Lee 2008). Studies on prenatal stress and anxiety have demonstrated the deleterious effects of stress on pregnant women and their infants (Beddoe and Lee 2008). Research suggests that stress during pregnancy affects birth outcomes (Beddoe and Lee 2008). Mind–body interventions have been found to lower stress, improve sleep, and diminish pain in healthy women (Beddoe and Lee 2008). Clinical evidence for the efficacy of mind–body treatments during pregnancy suggests that relaxation techniques, such as breath retraining, may be an efficacious modality in decreasing prenatal stress and pregnancy complications. Because the RSA device is an inexpensive portable biofeedback device, it may represent not only a reduction of fetal health risk, but perhaps a reduction of health care costs as well, including the cost of neonatal intensive care for a preterm infant. During a follow-up interview in which subjects were questioned about their use of the device, the majority of the subjects stated that the device helped them fall asleep, calm down, and relax. Most women requested a new device upon completion of the study, highlighting the acceptability and interest in continuing the practice.

This study had several limitations. Without a randomized controlled trial, it was difficult to ensure that confounding factors were evenly distributed between groups and to control for the possibility of unknown confounding factors. There are several noteworthy issues with the study design. Retrieval of the study devices was a dilemma. Even after several attempts to contact the subjects, two of the study devices were never returned. Several subjects had trouble operating their devices at the beginning, but with practice were able to use their devices regularly. It appears that those who set aside a time each day to practice their instruments were able to practice RSA biofeedback more frequently.

Subject recruitment was a limitation of the study. PIH patients were identified through nurses who had access to the hospital staffing sheets. The nurses received permission from the PIH patients for the investigator to approach them about the study. Many of the patients on the staffing sheet were diagnosed with preterm labor, which disqualified them from the study. The investigator also found that some women were ineligible for the study because they were scheduled for a cesarean delivery the next day. Future studies should attempt to approach a PIH patient as close as possible to her hospital admittance date. Generally, the women that refused or declined to participate in the study were influenced by their partner or family members, disinterested in the study, overwhelmed with their medical condition, coping with family issues, moving to another hospital, and/or scheduled to deliver in the near future.

Due to subject recruitment issues, a historical control group was implemented in the present study. This problem can be remedied in future studies by recruiting subjects from multiple hospitals and randomly assigning them into a control or treatment group. In order to eliminate the possibility of a placebo effect, in the future the control group could be offered a RSA device with feedback representing a non-critical physiological parameter. Although similar in design to the actual RSA device, the control version does not measure the user's beat-to-beat heart rate. Another limitation of this study was we were unable to measure the subjects' pre and post treatment heart rate variability parameter. This could be resolved in future research by implementing more sophisticated biofeedback devices. In addition, the routine collection of blood pressure measurements by varying health care professionals with three different types of blood pressure monitors served as another limitation of this study. Future research may benefit from using 24-h monitors, which are considered the gold standard in research on blood pressure. Finally, the experiment contained a small sample of 47 subjects who were hospitalized. Thus, the generalizability of these results was limited by the restricted nature of the sample to hospitalized PIH patients. Most patients in the hospital had moderate to severe PIH rather than mild PIH as originally hypothesized.

Overall, the results of this investigation suggest that RSA biofeedback may be effective in reducing stress during pregnancy and maximizing healthy birth outcomes. In this study, the cardiorespiratory biofeedback program was a statistically significant method to increasing gestational age and infant birth weight in moderate to severe hospitalized PIH patients. Furthermore, the manner in which it helped was safe and cost effective. In order to add to the growing number of research in this area, a reprisal of this study within a non-hospitalized and non-pharmacologically treated mild PIH population is recommended. Future studies with larger control trials may be able to discern if the differences between groups on the method of delivery are statistically significant, determine if higher SE Totals are correlated with better birth outcomes, and compare the differences between blood pressure levels and gestational age at delivery. It should be noted that any type of breath retraining at approximately six breaths per minute might result in similar outcomes. Patients should be encouraged to practice the type of therapeutic breathing they find most accessible and helpful.

Acknowledgments This research was supported through the generosity of a grant from Helicor, Inc., the makers of the StressEraser portable biofeedback device used in this study, and a scholarship from the Ferne Miller Memorial Research Fund. Frederick Muench is the former Director of Clinical Research at Helicor. Investigators have no other financial conflicts of interest with the sponsor. The authors would like to thank Marna Morimoto for her assistance with subject recruitment and follow up interviews.

References

Atallah, A. N., Hofmeyr, G. J., & Duley, L. (2002). Calcium supplementation during pregnancy for preventing hypertensive disorders and related problems. *Cochrane Database of Systematic Reviews, 1*(CD001059).

Bae, J. H., Kim, J. H., Choe, K. H., Hong, S. P., Kim, K. S., Kim, C. H., et al. (2006). Blood pressure change following 8-week, 15-minute daily treatment with paced breathing guided by a device: A Korean multi-center study. *Journal of Clinical Hypertension, 8*(5), A43.

Beddoe, A. E., & Lee, K. A. (2008). Mind-body interventions during pregnancy. *Journal of Obstetrics, Gynecologic, & Neonatal Nursing, 37*(2), 165–175.

Bucher, H. C., Guyatt, G. H., Cook, R. J., Hatala, R., Cook, D., Lang, J. D., et al. (1996). Effect of calcium supplementation on pregnancy-induced hypertension and preeclampsia. *Journal of American Medical Association, 275*(14), 1113–1117.

Chappell, L. C., Seed, P. T., Briley, A. L., Kelly, F. J., Lee, R., Hunt, B. J., et al. (1999). Effect of antioxidants on the occurrence of pre-eclampsia in women at increased risk: A randomised trial. *The Lancet, 354*, 810–815.

Contreras, F., Fouillioux, C., Bolivar, A., Betancourt, M. C., Colmenares, Y., Rivero, M., et al. (2003). Endothelium and hypertensive disorders in pregnancy. *American Journal of Therapeutics, 10*(6), 415–422.

Ebben, M. R., Kurbatov, V., & Pollak, C. P. (2009). Moderating laboratory adaptation with the use of heart-rate variability biofeedback device (StressEraser). *Applied Psychophysiology and Biofeedback, 34*(4), 245–249.

Elliot, W., & Izzo, J. (2006). Device-guided breathing to lower blood pressure: Case report and clinical overview. *Medscape General Medicine, 8*(3), 23.

Grossman, E., Grossman, A., Schein, M. H., Zimlichman, R., & Gavish, B. (2001). Breathing-control lowers blood pressure. *Journal of Human Hypertension, 15*(4), 263–269.

Heilman, K. J., Handelman, M., Lewis, G., & Porges, S. W. (2008). Accuracy of the StressEraser in the detection of cardiac rhythms. *Applied Psychophysiology and Biofeedback, 33*(2), 83–89.

Keppel, G. (1991). *Design and analysis: A researcher's handbook* (3rd ed.). Upper Saddle River, NJ: Prentice-Hall Inc.

Lain, K. Y., & Roberts, J. M. (2002). Contemporary concepts of the pathogenesis and management of preeclampsia. *The Journal of the American Medical Association, 287*(24), 3183–3186.

Lehrer, P. M., Vaschillo, E., & Vaschillo, B. (2000). Resonant frequency biofeedback training to increase cardiac variability: Rationale and manual for training. *Applied Psychophysiology and Biofeedback, 25*(3), 177–191.

Linden, W., & Moseley, J. V. (2006). The efficacy of behavioral treatments for hypertension. *Applied Psychophysiology and Biofeedback, 31*(1), 51–63.

Little, B. C., Hayworth, J., Benson, P., Hall, F., Beard, R. W., Dewhurst, J., et al. (1984). Treatment of hypertension in pregnancy by relaxation and biofeedback. *The Lancet, 1*(8382), 865–867.

Maloni, J. A., Cohen, A. W., & Kane, J. H. (1998). Prescription of activity restriction to treat high-risk pregnancies. *Journal of Women's Health, 7*(3), 351–358.

Muench, F. (2008). The portable StressEraser heart rate variability biofeedback device: Background and research. *Biofeedback, 36*(1), 35–39.

Reineke, A. (2007). *The effects of heart rate variability biofeedback in reducing blood pressure for the treatment of essential hypertension*. San Diego: Alliant International University.

Roberts, J. M., & Redman, C. W. G. (1993). Pre-eclampsia: More than pregnancy-induced hypertension. *The Lancet, 341*(8858), 1447.

Rosenthal, T., Alter, A., Peleg, E., & Gavish, B. (2001). Device-guided breathing exercises reduce blood pressure: Ambulatory and home measurements. *American Journal of Hypertension, 14*(1), 74–76.

Schein, M. H., Gavish, B., Herz, M., Rosner-Kahana, D., Naveh, P., Knishkowy, B., et al. (2001). Treating hypertension with a device that slows and regularizes breathing: A randomised, double-blind controlled study. *Journal of Human Hypertension, 15*(4), 271–278.

Sherlin, L., Gevirtz, R., & Muench, F. (2009). The effects of brief respiratory sinus arrhythmia training on anxiety and heart rate. *International Journal of Stress Management, 16*(3), 233–248.

Sibai, B. M. (2003). Diagnosis and management of gestational hypertension and preeclampsia. *Obstetrics and Gynecology, 102*(1), 181–192.

Somers, P. J., Gevirtz, R. N., Jasin, S. E., & Chin, H. G. (1989). The efficacy of biobehavioral and compliance interventions in the adjunctive treatment of mild pregnancy-induced hypertension. *Biofeedback and Self-Regulation, 14*(4), 309–318.

StressEraser. (2010). Retrieved July 20, 2010.

Walling, A. D. (2004). Management of gestational hypertension-preeclampsia. *American Family Physician, 69*(4), 979–980.

Zamorski, M. A., & Green, L. A. (2001). NHBPEP report on high blood pressure in pregnancy: A summary for family physicians. *American Family Physician, 64*(2), 263–270, 216.

Zucker, T. L., Samuelson, K. W., Muench, F., Greenberg, M. A., & Gevirtz, R. N. (2009). The effects of respiratory Sinua arrhythmia biofeedback on heart rate variability and posttraumatic stress disorder symptoms: a pilot study. *Applied Psychophysiology and Biofeedback, 34*(2), 135–143.