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by

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COMPARISON OF TYMPANIC, ORAL, AND AXILLARY TEMPERATURES IN WOMEN DURING LABOR

Nancy Ann Dezell

ABSTRACT

The measurement of body temperature in women during labor is an essential aspect of care upon which many clinical decisions and interventions are based. Mouth breathing, sweating, and other physiological changes inherent in the labor process may affect the accuracy of temperature measurement. The purpose of this study was to compare tympanic, oral, and axillary temperatures in women during active labor to provide a baseline of information for temperature interpretation in the clinical setting. The convenience sample consisted of 30 afebrile women between the ages of 18 to 37 who had uncomplicated pregnancies and presented to this midwest military medical center in active labor. Tympanic, oral, and axillary temperatures were measured simultaneously five times during one hour of labor using a non-contact, infrared-sensing tympanic thermometer in the core mode and an electronic thermometer in the predictive mode. Tympanic temperatures averaged 1.04°F (±0.57°F) higher than oral temperatures and were 1.89°F (±0.75°F) higher than axillary temperature measurements. Oral and axillary temperatures differed by 0.85°F (±0.70°F). Tympanic temperature measurement variation was less over the five measurement times (0.48°F, ±0.26°F) than oral (0.75°F, ±0.4) and axillary (0.86°F, ±0.25). Correlations between paired methods were fair (tympanic-oral r=0.52; tympanic-axillary r=0.34; oral-axillary r=0.35) and the differences were significant for all pairs (p=.0001). Repeatability of the temperature measurements was evaluated between the first two measurements for each method as they were obtained within 60 seconds of each other. Correlations were strong for all three methods (r=0.84 to 0.97) and all tympanic temperature measurements were reproduced within ±0.3°F. Tympanic temperatures, calculated to oral equivalent values, averaged 0.24°F (±0.57) higher than oral readings. All temperatures were lower in women receiving oxygen by face mask, while oral and axillary temperatures were higher in women using mouth breathing during labor. Axillary temperatures were lower in women with epidural anesthesia. Overall, tympanic temperature measurement was less variable and highly repeatable in this sample of women in labor. Given the differences between the paired temperature methods, it may not be feasible to compare temperature measurements at different sites in women during labor due to the effects of conditions inherent in the labor process. Thus, the temperature differences noted in this study should be taken into consideration when measuring and evaluating body temperature in women during labor.

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to my father, Leonard Joseph Sulkowski.

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CHAPTER I

INTRODUCTION TO THE STUDY

Introduction to the Problem

Accurate measurement of body temperature in women during labor is an essential aspect of health care upon which many clinical decisions and interventions are based (Freeman & Polland, 1992; Nurses' Association of the American College of Obstetricians and Gynecologists, 1991). Presently, the most commonly used routes for measuring body temperature in obstetric settings are oral and axillary with a more recent impetus toward using the external ear canal, or "tympanic" site, for temperature measurement based on its reported comfort, speed, and accuracy in reflecting core temperature in other patient populations.

Numerous conditions inherent in the process of labor may affect the accuracy of temperature measurements and must be taken into consideration when making patient care decisions based on temperature alterations. Mouth breathing, hyperventilation, and oral intake of ice or fluids are reported to have an effect on oral temperatures (Dressler, Smejkal, & Ruffolo, 1983; Durham, Swanson, & Paulford, 1986; Goodlin & Chapin, 1982; Neff, Ayoub, Longman, & Noyes, 1989; Terndrup, Allegra, & Kealy, 1989), while excessive perspiration or changes in environmental temperature can affect axillary temperature readings (Giuffre, Heidenreich, Carney-Gerston, Dorsch, & Heidenreich, 1990; Mahan, 1991; Summers, 1991).

Tympanic temperature measurement is reported to reflect core body temperature in pediatric, intensive care, and perioperative settings. Additionally, it is unaffected by conditions influencing oral and axillary routes, and has been noted to be a more expedient and comfortable method of temperature measurement (Benzinger, 1969; Cooper, Cranston, & Snell, 1964; Cork, Vaughan, & Humphrey, 1983; Erickson & Kirklin, 1993; Webb, 1973). A few studies have measured tympanic temperature in women during labor in relation to evaluating temperature change during uterine contractions or anesthesia administration (Camann, Hortvet, Hughes, Bader, & Datta, 1991; Kapusta, Confino, Ismajovich, Rosenblum, & David, 1985; Marx & Loew, 1972), however, no other studies comparing tympanic, oral, and axillary temperatures in women during labor were found. Considering the significance of accurate temperature monitoring and the potential inaccuracies of axillary and oral temperature measurements, it is important to evaluate these methods of measuring temperature in women during labor to provide a basis for interpretation and decision making.

Purpose of the Study

The purpose of this study was to compare tympanic, oral, and axillary temperature measurements obtained simultaneously from women during labor. This comparison established a baseline of clinical temperature information to facilitate evaluation and interpretation of tympanic, oral, and axillary temperatures measured in women during labor.

Significance

Nursing care of the laboring woman is directed toward securing a physically safe and emotionally satisfying labor and delivery experience for the mother, fetus, and family (NAACOG, 1986). This responsibility includes the early recognition and prompt treatment of any adverse conditions that may affect the mother and fetus, as well as assuring that routine nursing interventions, such as temperature measurement, do not interfere with the labor experience. Body temperature changes during labor may reflect normal physiological alterations resulting from increased muscular activity, dehydration, or prolonged physical exertion or may be indicative of more serious conditions, such as infection or hyperthermia, which pose significant maternal and fetal risk (Blackburn & Loper, 1992; Kaunitz, Hughes, Grimes, Smith, Rochet, & Kafrissen, 1985; Scherwen, Scoloveno, & Weingarten, 1991).

All methods used to measure body temperature are designed to estimate the temperature of the body "core", which is that of the cranial cavity, abdominal organs, and deep body tissues (Ganong, 1989; Marieb, 1989). To be clinically useful, a temperature measurement site should not only reflect core temperature changes accurately, but also be safe, easily accessible, and not influenced by local environmental changes (Clark & Edholm, 1985; Erickson & Yount, 1991; Holdcraft, 1980; Houdas & Ring, 1982). Esophageal, bladder, rectal, and pulmonary artery temperature measurements are considered to be the most accurate reflections of core temperature (Cork et al., 1983; Lilly, Boland, & Zekan, 1980; Moorthy, Winn, Jallard, Edwards, & Smith, 1985; Mravinac, Dracup, & Clochesy, 1989; Summers, 1991), however, these methods are invasive, costly, and are not practical for routine clinical use.

Currently, the two routes of body temperature measurement commonly used in obstetric settings are oral and axillary. Unfortunately, these sites can be significantly affected by conditions that frequently occur in the laboring woman such as mouth breathing (Neff et al., 1989) or increased perspiration (Summers, 1991). Tympanic temperature measurement, however, is unaffected by hyperventilation, oral intake, or perspiration (Erickson & Kirklin, 1992; Summers, 1991) and should theoretically reflect body core temperature due to the proximity of the ear canal to the hypothalamus, the thermoregulatory center of the human body (Benzinger, 1969). Many studies have supported the use of tympanic temperature assessment in pediatric, perioperative, and intensive care settings, yet it is not routinely used in most obstetric clinical areas. Therefore, since perinatal health care providers must make important patient care decisions based on body temperature measurements, reliable monitoring of temperature throughout the course of labor is imperative for early detection of complications and promotion of a healthy mother-baby outcome.

Review of Literature

Review of previous studies

Even though studies to determine specific mechanisms of thermoregulation have been conducted since 1885 (Benzinger, 1969), the exact mechanism of body heat regulation is complex and is still being investigated. Considerable research has focused on evaluating the accuracy of different routes of temperature measurement in estimating core body temperature in various patient populations as compared to esophageal, bladder, or pulmonary artery sites. Numerous studies have compared tympanic, oral, and axillary temperature sites in pediatric subjects (Chamberlin, Gardner, Rubinoff, Klein, Waisman, & Huey, 1991; Freed & Fraley, 1992; Kenney, Fortenberry , Surratt, Ribbeck, & Thomas, 1990; Talo, Mackin, VanderBrug, & Medendorp, 1991; Terndrup & Milewski, 1991), however, for the purposes of this study, only investigations involving adult patient populations are presented for review.

Oral temperature. Numerous investigations support the oral route as an adequate reflection of core temperature. One study by Gerbrandy, Snell, and Cranston (1954) compared oral, esophageal, and rectal temperature measurements during a simulated onset of fever utilizing infusion of warm intravenous solution in nine subjects and immersion of a limb into a warm water bath by another 17 subjects. The authors concluded that oral temperatures were more highly correlated with esophageal temperatures than rectal, which actually lagged behind core temperature changes. However, the sample size was small (n = 26) and simulation of fever may not accurately reflect normal body temperature changes occurring during actual febrile episodes.

Cranston et al. (1954) found mean differences of 0.35°C (±0.01°F) between rectal and oral and 0.09°F (±0.015°F) between esophageal and oral temperatures in 40 subjects, however, data were collected over a single 10 minute period. Rectal and oral temperatures were compared by Royston and Abrams (1982) in 54 female subjects, noting a difference of 0.2°C. They concluded that either method was satisfactory for estimating basal body temperature. However, the women took their own temperatures and thus accuracy can not be presumed.

Laurent (1979) compared single measurements of oral and pulmonary artery temperatures in critically ill patients and found a correlation of r = 0.85 (p<.0001), while Raulerson

(1982) noted a moderate correlation between oral and pulmonary artery temperatures (r = 0.46, p<.02) in patients rewarming after cardiac surgery. Oral and pulmonary artery temperatures were also noted to be moderately well correlated (r = 0.55 to 0.98) by Audiss, Brengelmann, and Bond (1989) in six of nine patients rewarming after cardiac surgery. Temperatures were sampled every 15 to 60 seconds over a 40 minute period.

Several researchers suggest that oral temperature is affected by factors such as oral intake, oxygen administration, and mouth breathing. Tandberg and Sklar (1983) studied 310 adults seen in an emergency department to determine the effect of mouth breathing and tachypnea on oral and rectal temperature measurements. An electronic thermometer was used for rectal and oral measurements and patients receiving oxygen were excluded. A statistically significant difference between the group of patients with less than 20 respirations per minute and the group with more than 20 per minute was noted, p<.001. Despite the large sample size, only one oral and rectal measurement was taken from each subject, which does not allow for differences due to chance or other factors. A replication of the previous study by Durham, Swanson, and Paulford (1986) also found significant effects of tachypnea on oral temperatures in 53 patients in a medical intensive care unit with a correlation of r = 0.33 (p<.01). Subjects included patients receiving oxygen by mask or nasal cannula and through two-way analysis of variance, the authors also concluded that oxygen therapy does not affect oral temperature measurement, most likely due to the insulating effect of the tongue.

In support of the latter findings regarding oxygen administration, Hasler and Cohen (1982) studied 40 healthy adults and found no significant differences between pre- and post-treatment oral temperature measurements related to administration of oxygen via aerosol masks, ventimasks, or nasal prongs ($p<.05$). They concluded that oral temperature could be adequately measured despite oxygen therapy. A significant difference however, was noted by Dressler et al. (1983) between oral and rectal temperatures in 30 male cardiovascular surgical patients receiving oxygen by mask. Rectal temperatures were noted to be more stable than oral (r = 0.91 for rectal and r = 0.75 for oral) and analysis of variance between temperature measurements was insignificant. The study lacked a control group of patients not receiving oxygen for comparison.

Axillary temperature. The accuracy of the axillary site as an indicator of core body temperature was investigated by Giuffre et al. (1990). Simultaneous core and axillary temperatures were measured in 30 intensive care unit patients. Pulmonary artery catheter temperatures were utilized to reflect core temperature and bilateral axilla temperatures were measured concurrently with a mercury-in-glass and electronic thermometers. The mean difference between core and axillary temperatures measured with the mercury-in-glass and electronic thermometers was 0.19°C and 0.33°C respectively. A Pearson Product Moment Correlation showed a strong relationship between core and axillary temperatures (r = 0.90 mercury thermometer, r = 0.87 electronic), however, only a single set of temperature measurements was obtained on each subject.

In a similar study, Heidenreich and Giuffre (1990) noted high correlations between axillary, rectal, and pulmonary artery temperatures in 18 postoperative subjects using a glass-mercury thermometer (r = 0.96) and an electronic instrument (r = 0.92). Four hourly simultaneous axillary, rectal, and pulmonary artery temperatures were obtained in 16 intensive care patients by Fullbrook (1992). A mean difference of -0.19°F was noted between axillary and pulmonary artery, and a "strong, constant, linear relationship" was noted between all three temperature methods.

Cork et al. (1983) noted a significant difference between axillary and tympanic temperatures (p<.05) in 53 patients during noncardiac surgery, using tympanic temperature as the core reference. Erickson and Meyer (1994) agreed that the axillary site is easily accessible but highly influenced by environmental exposure. They noted a mean difference between axillary and pulmonary artery temperatures of -0.7°C with correlations between $\underline{r}$ = 0.80 and 0.82.

Axillary and pulmonary artery temperatures were compared by Heidenreich, Giuffre, and Doorley (1992) in 25 patients during rewarming after cardiac surgery. Regression coefficients were between 0.17 to 0.52 over a range of temperatures between 91.4 to 98.6°F. The authors concluded that a true difference exists between core and other more peripheral sites due to regional differences in blood perfusion.

Tympanic temperature. Since 1948, research studies have supported tympanic temperature measurement as reflective of core temperature based on the proximity and shared circulation of the tympanic membrane and the hypothalamus (Baker, Stocking, & Meehan, 1972; Benzinger, 1969; Benzinger & Benzinger, 1972; Benzinger & Taylor, 1963; Clemente, 1985; Gibbons, 1967; Nobel, 1992; Rawson & Hammel, 1963; Williams & Thompson, 1948). A thermistor device for obtaining a continuous recording of tympanic body temperature was described by Williams and Thompson (1948). It was applied close to the tympanic membrane of one male subject and continuous recordings were made over three nights. The tympanic measurements were noted to be 0.25°C lower than oral temperatures.

Baker et al. (1972) implanted thermocouples into the hypothalamus and tympanic membranes of two cats and a monkey and made multiple comparisons over a one month period. They noted a mean difference between the hypothalamus and tympanic membrane temperatures of only 0.10°F, concluding that tympanic thermometry is a good indicator of hypothalamic temperature. Webb (1973) reported a mean difference of 0.2°C between esophageal and tympanic temperatures obtained in 35 cardiopulmonary bypass patients using a thermocouple wire placed close to the tympanic membrane.

The previous studies used invasive instruments to directly measure temperature at the tympanic membrane which caused discomfort and presented a potential for injury (Benzinger, 1969). More recent studies have used newer non-contact infra-red heat sensing probes placed into the external auditory canal. Since the external auditory canal is lined with skin rather than mucus membrane, there is also a decreased risk of infection.

Summers (1991) compared tympanic and esophageal temperatures in a convenience sample of 96 postanesthesia patients between the ages of 18 to 89 years using a non-invasive tympanic thermometer. Analysis with paired t test indicated no significant difference between esophageal and tympanic temperatures (t = -0.67, p=.503) and the author concluded that tympanic thermometry is an accurate reflection of core temperature as well as expedient (i.e. registering in less than two seconds), noninvasive, convenient to use, and causing little disturbance to the patient.

Tympanic and pulmonary artery temperatures were noted to have a high correlation ($\underline{r}$ = 0.98) in postoperative cardiac patients undergoing rewarming procedures (Shinozaki, Deane, & Perkins, 1988) and a moderate correlation ($\underline{r}$ = 0.74) in nine intensive care patients examined by Milewski, Ferguson, and Terndrup (1991). Ferrara-Love (1991) found no significant difference between tympanic and pulmonary artery temperatures in 20 elderly postoperative subjects ($\underline{t}$ = -0.31, $\underline{p}$=.76).

Nierman (1991) compared tympanic, bladder, and pulmonary artery temperatures measured simultaneously every four hours in 15 patients receiving care in a medical intensive care unit. Tympanic and pulmonary artery temperatures differed by a mean of -0.38°C and tympanic and bladder temperatures varied by -0.34°C. Erickson and Kirklin (1993) obtained tympanic, bladder, oral, and axillary temperatures every 20 minutes for three hours in 38 adults in a cardiac care unit. Mean offsets from the pulmonary artery catheter reference were 0.07°C for tympanic, 0.03°C for bladder temperatures, 0.05°C for oral, and -0.68°C for axillary temperatures. The researchers concluded that tympanic temperature provided a relatively close estimate of pulmonary artery core temperature, but had significant variability between subjects. In another study, Erickson and Meyer (1994) reported that tympanic or "ear-based" temperatures correlated well with pulmonary artery temperature (*r* = 0.87 to 0.91) in 50 ICU patients, but also had high variability between subjects (±0.05°C). The authors also evaluated the use of an ear tug versus no tug for obtaining tympanic temperatures with no significant difference noted.

Tympanic and oral temperatures were compared for equivalence and stability in 60 adults undergoing major abdominal surgery (Erickson & Yount, 1991). Oral and tympanic temperatures were measured four times during the perioperative period. A repeated measures analysis of variance indicated that temperature changed significantly over time at both sites (tympanic, F = 118.41, p<.0001; oral, F = 120.62, p<.0001) and that tympanic temperatures were more stable over time.

Temperature in labor. Few studies have investigated temperature measurement on women during labor and most reflect temperature changes related to anesthesia or analgesia rather than the accuracy of any specific method of temperature measurement. Most recently, Camann et al. (1991) studied the effect of analgesia and anesthesia on oral and tympanic temperature progression in 53 women during labor. Women who were less than 37 weeks gestation, with evidence of infection, or febrile were excluded. Temperatures were measured hourly with an electronic oral thermometer and a tympanic thermometer in three randomized groups of women, two of which received extradural anesthesia and the control group received intravenous analgesia. A significant correlation between oral and tympanic temperature measurements was noted using simple linear regression ($r = 0.62$, $p < .001$) and analysis of variance with a small but consistent increase in maternal temperature noted with administration of extradural anesthesia.

Tympanic temperature was measured by Marx and Loew (1975) during the labor and delivery of 11 women to determine central temperature changes in women throughout labor, delivery, and early postpartum. Tympanic thermometry was utilized and rectal temperatures were attempted in two subjects but were discontinued as they were affected by amniotic fluid leakage, internal examinations, and pushing efforts. Increases in maternal tympanic temperature of 0.03°C to 0.2°C were noted with every uterine contraction as well as progressively throughout labor. The authors attributed these increases to metabolic expenditures associated with contraction of uterine and skeletal muscles; rectal temperatures did not reflect changes during uterine contractions. Unfortunately, a small sample size ($n = 11$), incomplete description of methodology, and no discussion of statistical analysis limit the significance of the results.

Overall, review of the literature supports tympanic temperature measurement as an accurate reflection of core body temperature as compared with esophageal, bladder, and pulmonary artery temperatures in perioperative and intensive care adult populations. No other research studies comparing the use of tympanic, oral, and axillary temperature measurement in the labor and delivery setting were located, thus supporting the need for research in this area.

Theoretical Rationale

Normal Thermoregulation

An understanding of human thermoregulation as well as the physiological thermoregulatory differences inherent in pregnancy is essential when evaluating temperature measurement in women during labor. Body temperature reflects the balance of heat production and heat loss within the human body and is regulated by feedback mechanisms operating through the temperature regulatory center located in the anterior and posterior portions of the hypothalamus (Blackburn & Loper, 1992; Clark & Edholm, 1985; Ganong, 1989; Marieb, 1989). The posterior hypothalamus receives input from peripheral thermoreceptors located in the skin and from core thermoreceptors positioned in the spinal cord, abdominal viscera, and the great veins, and responds by initiating appropriate heat-promoting or heat-loss reflex mechanisms (Guyton, 1991; Marieb, 1989). Heat is generated by metabolic processes as well as by heat production mechanisms involving cutaneous vasoconstriction, shivering, and voluntary skeletal muscle activity. Body heat is dissipated to the periphery by activation of sweat glands with increased evaporative loss, through peripheral vasodilation, and through respiration (Blackburn & Loper, 1992; Guyton, 1991).

The pre-optic area of the anterior hypothalamus controls the setpoint or threshold temperature of the body. This "setpoint" maintains the core temperature within a narrow range for optimal body functioning (Blackburn & Loper, 1992; Ganong, 1989; Guyton, 1991). The "core" temperature is that of the blood in the cranial cavity, abdominal organs, and deep tissues and remains constant within the range of 36.1° to 37.8°C or 97° to 99.5°F despite external temperature or amount of heat production by the body. It is considered higher than skin or surface temperatures due to the thermal gradient created as heat is dissipated peripherally (Ganong, 1989; Marieb, 1989; Schoenbaum & Lomax, 1990). There is an elevation in body temperature of 1°F (0.56°C) for every seven percent increase in metabolism, and with strenuous exercise, more than three-quarters of the increased metabolism resulting from muscular activity appears as heat within the body (Porth, 1990).

<u>Thermoregulation in Pregnancy</u>

During pregnancy, the amount of heat produced by the body increases by 30 to 35 percent due to the thermogenic effects of progesterone, alterations in maternal metabolism, and increase in large muscle mass (Blackburn & Loper, 1992). The fetus is also dependent on the mother for thermoregulation and thus heat generated by fetal metabolism is eliminated through the amniotic fluid or via the maternal-placental circulation (Blackburn & Loper, 1992). This additional heat is dissipated by peripheral vasodilation with a significant increase in blood flow and pronounced activity of the sweat glands; thus maternal temperature is usually increased by 0.5°C (0.3°F) with an additional elevation of 0.5 to 1°C (1 to 2°F) during labor due to an increase in metabolic and overall physical activity (Knor, 1987). Consequently, an elevated temperature related to illness, infection, or exercise may reduce maternal heat dissipating capacity, especially of the placental circulation, resulting in an increase in fetal temperature and a potential for fetal distress (Blackburn & Loper, 1992; Mittelmark, Wiswell, & Drinkwater, 1991).

Overall, it is clear that alterations in maternal temperature during labor may be indicative of normal physiologic and metabolic processes or may reflect serious alterations in homeostasis such as infection or illness that affect both the mother and fetus. Therefore accurate and reliable temperature measurement and interpretation is essential for promoting a safe outcome for both mother and baby.

Statement of the Problem

This study was designed to investigate the relationship between tympanic, oral, and axillary temperatures in women during labor, in order to provide a basis of temperature information for perinatal health care providers to facilitate interpretation of temperature data during labor.

Research Question

The research question addressed in this investigation was, "What is the relationship between tympanic, oral, and axillary temperatures measured in women during labor?" More specifically, the study examined the variability within each method of measurement as well as the relationship between paired measurements of tympanic-oral, tympanic-axillary, and oral-axillary temperature measurements.

Conceptual and Operational Definitions

Tympanic temperature

Conceptually, tympanic temperature is defined as the amount of heat emitted from the tympanic membrane and aural canal, reflecting the core temperature of the hypothalamus (Benzinger, 1969). In this study, tympanic temperature referred to the number of degrees in Fahrenheit registered digitally on a FirstTemp Genius® tympanic thermometer (Model 3000A, Intelligent Medical Systems, Carlsbad, CA) after placement of the temperature probe in the external auditory canal.

<u>Oral temperature</u>

Oral temperature is defined as the amount of heat emitted from the sublingual artery in the posterior sublingual pocket under the base of the tongue (Clemente, 1985). In this study, oral temperature referred to the number of degrees in Fahrenheit registered digitally on a Dinamapp™ Portable Vital Signs Monitor (Model 8100T, Critikon, Tampa, FL) after placement of the temperature probe in the posterior sublingual pocket under the base of the tongue of women during labor.

<u>Axillary temperature</u>

Conceptually, axillary temperature is the amount of heat present in the skin and tissues under the arm, high in the axillary area (Clemente, 1985; Kozier & Erb, 1989). Axillary temperature is defined in this study as the number of degrees in Fahrenheit registered digitally on a Dinamapp™ Portable Vital Signs Monitor (Model 8100T, Critikon, Tampa, FL) after placement of the temperature probe high in the axilla of women during labor.

<u>Labor</u>

Labor is conceptually defined as the dynamic process of physiological changes encompassing childbirth, including regular myometrial activity, progressive cervical effacement and dilatation, and expulsion of a baby (Blackburn & Loper; Mattson & Smith, 1993). In this study, labor is defined as the period identified by the registered nurse or attending physician as "active labor", characterized by cervical dilatation between 4 to 10 centimeters with uterine contractions occurring approximately every 2 to 5 minutes, lasting more than 45 seconds, and of moderate to strong intensity.

CHAPTER II

METHODOLOGY

Design of Study

Type of Study

A prospective, descriptive, correlational design was used to compare tympanic, oral, and axillary temperature measurements in women during labor. An experimental design was not appropriate for practical and ethical reasons, as measurement of temperature is a required standard of practice in the assessment of laboring women and should not be withheld or otherwise manipulated.

Tympanic, oral, and axillary temperatures were measured simultaneously on each subject at 15 minute intervals for a total of five measurements during approximately one hour of labor. Five measurements of each method were obtained to enhance the precision of statistical analysis as well as to serve as a control for internal validity (Cohen, 1988; Gravetter & Wallnau, 1992; Polit & Hungler, 1991).

Setting

The setting for the study was a five bed Labor and Delivery Unit located in a military medical facility in the midwest. This facility serves a military population of over 30,000 and has approximately 100 births per month.

Subjects

Criteria for inclusion and exclusion. The population of subjects for this study consisted of low-risk pregnant women between the ages of 18 to 37 who were eligible for medical care in this military facility as either a military member or as a dependent of a military member. To establish a baseline comparison of temperature measurements in low-risk pregnant women during labor, specific exclusion criteria included women with pre-existing medical problems or maternal or fetal complications such as multiple gestation (i.e. twins, triplets), preterm labor (i.e. prior to 37 weeks gestation), placental abnormalities (i.e. placenta previa or abruptio placenta), malpresentation (i.e. breech or non-vertex presentation), infection of the uterus or amniotic sac, or evidence of fetal stress. These exclusions also prevented any potential interference with medical care that might be necessitated with complicated pregnancies. In addition, women presenting with a history of ear trauma or injury, signs of ear infection, or with an admission temperature greater than 100.5°F were excluded from this study to avoid the potential risk of complications.

Thirty-two subjects were enrolled in this study, but two subjects were dropped immediately after completion of their data collection when complications were noted that had not been known prior to participation in the study. One subject had a normal admission temperature but elevated temperatures were noted during data collection with subsequent diagnosis of chorioamnitis. The other subject had a fetus with intrauterine growth retardation that was not in distress but had a potential risk for complications.

Sample. The convenience sample consisted of 30 women admitted to the Labor and Delivery Unit in active labor who met the inclusion criteria and consented to participate in the study.

Protection of Subjects. Temperature measurement is a routine procedure performed on women during labor that involves minimal risk of injury. The overall benefit from this study is derived by health care providers who now have additional knowledge related to tympanic, oral, and axillary temperature measurements in women during labor.

Confidentiality of the subjects was maintained through the use of subject code numbers assigned to each set of data. Register numbers and social security numbers were recorded by the researcher on a separate log and will not appear in any publication or release of data.

Although temperature monitoring during labor is a routine procedure in women during labor, the simultaneous measurement of three temperature sites during this study posed a minimal risk of discomfort to the subject and the potential for injury to either the mouth, axilla, or auditory canal. Therefore, the attending physician or resident was notified for approval of the woman's participation in the study and a written informed consent was required of each individual prior to enrollment.

Prior to enrollment in the study, the researcher informed the woman and her significant other(s) about the purpose, methods, benefits, and risks involved in participating in the study as outlined in the prepared informed consent (Appendix A). In addition, the woman was informed of her right to refuse to participate in this investigation or to withdraw at any time without any change in the medical care provided.

Instruments

The instruments used in this study were the Dinamapp™ Vital Signs Monitor (Model 8100T, Critikon, Tampa, FL) and the FirstTemp Genius® tympanic thermometer (Model 3000A, Intelligent Medical Systems, Carlsbad, CA). These instruments were selected as they were the temperature monitoring instruments presently available at the medical center. The FirstTemp Genius® tympanic thermometer used in this study was supplied by the manufacturer, Intelligent Medical Systems, Carlsbad, CA.

Dinamapp™ Vital Signs Monitor

Although the glass-mercury thermometer has been considered the "gold standard" of temperature measurement in many clinical areas (Erickson, 1980; Kozier & Erb, 1989; Luckmann & Sorenson, 1992), electronic thermometry has been in use for over 20 years and has been demonstrated to accurately reflect oral and axillary temperatures (Closs, 1987; Erickson & Yount, 1991; Erickson & Kirklin, 1993;

Giuffre et al., 1990; Summers, 1991). An important consideration in measuring axillary and oral temperatures is that actual tissue temperature is not measured, but rather the temperature of the instrument probe after a period of contact with the target tissue (Nobel, 1992). The glass-mercury thermometer must reach equilibrium with the tissue, requiring from 5 to 12 minutes, while electronic thermometers use an algorithm to analyze the trend for a few periods of temperature change and then "predict" what equilibrium temperature would be, producing a result within 30 seconds (Nobel, 1992). The metal probes and disposable probe covers significantly decrease the potential risks of injury and cross-contamination inherent with the glass-mercury thermometer (Closs, 1987; Critikon, 1988; Erickson, 1980).

The temperature probes of electronic thermometers measure temperature by way of a thermistor, a sensor based on a metallic oxide sensing element that produces differences in electrical resistance as temperature varies (Critikon, 1988; Holtzclaw, 1993). This resistance is converted to a frequency which is transmitted digitally and then optically coupled to a microprocessor for determination and display (Critikon, 1988). Essentially, predictive thermometers compute the rate of temperature rise and anticipate what the final reading will be, rather than reaching thermoequilibrium with the surrounding tissue.

The Dinamapp™ Vital Signs Monitor (Model 8100T, Critikon, Tampa, FL) is a battery- or AC-powered, microprocessor controlled, portable monitor designed to measure blood pressure, pulse rates, and body temperature for neonatal, pediatric, or adult patient populations. The unit measures temperature in two modes, a NORMAL or predictive mode and a MONITOR or non-predictive mode. In the NORMAL mode, temperature is determined based on a predictive algorithm, a point at which the probe temperature should stabilize. In the MONITOR mode, the device continuously displays actual measured probes temperature, with display updates every 1.5 seconds (Critikon, 1988). predictive mode. The temperature range in the NORMAL predictive mode is between 88 to 108°F and in the MONITOR mode is between 85 to 108°F. The unit provides audible and visual alarms if the temperature falls outside of user selected limits in the MONITOR mode and the temperature component of the unit contains a dedicated power supply for patient safety and suppression of interference. The microcomputer automatically verifies the calibration of temperature circuits and temperature accuracy meets the American Society of Testing and Materials (ASTM, E1112-86) "Standard Specifications for Electronic Thermometer for Intermittent Determination of Patient Temperature".

FirstTemp Genius® Tympanic Thermometer

The ear, like all objects, emits electromagnetic radiation in proportion to its temperature in a gradient from warmest at the tympanic membrane to coolest at the outer opening (Product Comparison Systems, 1992; Schuman, 1990). The tympanic membrane emits heat from the blood vessels behind it into the auricular canal. The infra-red energy emitted has a longer wave length than those of visible light and requires a special sensor for measurement (IMS, 1992).

Tympanic thermometers were developed to detect the infra-red energy emitted by the tympanic membrane and ear canal and have been in use since the late 1960's (Benzinger, 1969). Earlier models used probes that were applied directly to the tympanic membrane with great risk of discomfort and injury to the patient. Most modern tympanic thermometers use thermopiles which put out a voltage level that changes proportionally to the intensity of the infrared emissions striking the thermopile window (IMS, 1992). Because infra-red thermometers determine the temperature of infrared energy emitted by a source rather than absorbing the heat from the object and coming to thermal equilibrium with it, the temperature is usually displayed in a only few seconds (Product Comparison Systems, 1992). Numerous studies have established the reliability and validity of the tympanic thermometer in reflecting core temperature as compared to other core body temperature sites, including pulmonary artery, esophageal, nasopharynx, and bladder (Benzinger, 1969; Cork et al., 1983; Ferrara-Love, 1991; Shinozaki et al., 1988; Webb, 1973).

The FirstTemp Genius® tympanic thermometer (Model 3000A, IMS, Carlsbad, CA) is a portable, battery-operated, infra-red sensing electronic instrument that measures the natural electron radiation, or heat, emitted from blood vessels behind the tympanic membrane. The FirstTemp Genius® tympanic thermometer registers a digital reading via the microprocessing unit in either Fahrenheit or Celsius, in less than two seconds. The otoscope-like probe tip is covered by a disposable speculum and has a limited depth of insertion into the auditory canal which results in obtaining the average temperature from the walls of the auditory canal as well as a portion of the tympanic membrane (Fraden, 1991; IMS, 1992). To minimize the effects of draw-down phenomenon, when the cooler probe tip contacts the warmer ear canal, the FirstTemp Genius® thermometer uses a scanning system that collects 16 temperatures in a pre-scan buffer and 16 temperature readings in a post-scan buffer, the highest of which is displayed as the temperature reading (IMS, 1992).

The FirstTemp Genius® tympanic thermometer can be used in a TYMPANIC mode for measuring ear temperatures or in a SURFACE mode for scanning skin surfaces for temperature change as in assessing wound healing or detecting infection. The thermometer also has four settings that provide temperature readings equivalent to oral, core, rectal, and calibration modes based on research-derived offsets. These offsets are mathematical adjustments that are programmed into the microprocessing unit to approximate the measurement of oral, core, or rectal temperatures from the measured tympanic temperature. The calibration mode is the absolute unadjusted temperature and should be used only for calibration. Many clinical settings prefer to use the tympanic thermometers in the oral equivalent mode as this is a more familiar point of reference for temperature measurement. Erickson and Kirklin (1993) suggest the use of tympanic thermometers in the core mode since the overall purpose of temperature measurement is to estimate core temperature. The FirstTemp Genius® thermometer was used in the core mode in this study.

The FirstTemp Genius® thermometer has a measurement range between 60 to 110°F and functions within ambient temperatures of 60 to 104°F (IMS, 1992). Accuracy is specified by the manufacturer within ±0.2°F between 98 to 102°F per ASTM standards. The unit is powered by a nine-volt alkaline or lithium battery that supplies enough power for 5,000 readings. The probe covers are rigid-walled, polyethylene speculums with a clear, pliable polyethylene membrane sealing the opening.

Instrument Testing

Although the accuracy of these instruments was specified by the respective manufacturers as within ± 0.2°F, the thermometers were tested for accuracy prior to the study, weekly throughout data collection, and immediately upon completion of the study using a stirred water bath (Model UH-1, Hannan Engineering, Buffalo, NY) over a temperature range of 94 to 104°F. A glass-mercury thermometer and an electronic thermometer traceable to the National Institute of Standards and Testing (NIST) of the National Bureau of Standards were used as reference instruments. According to Erickson (1980), calibration of research instruments before, during, and after a study validates the original manufacturer testing and provides presumptive evidence of reliability when obtaining temperature measurements.

According to the American Society for Testing and Materials (ASTM), the requirements for accuracy for electronic and infrared thermometers specified that no individual reading should exceed ±0.2°F between 95 to 102°F and ±0.3°F between 85 to 95°F or 102 to 105°F (Erickson & Yount, 1991; IMS, 1992). Five Dinamapp™ Vital Signs Monitors were tested; the electronic thermometer probes with covers were suspended in the water bath in the MONITOR or non-predictive mode. Temperature measurements were observed and recorded at intervals of 1°F over a 94 to 104°F range.

All five of the Dinamapp™ Vital Signs thermometers measured within the ASTM specifications.

The FirstTemp Genius® tympanic thermometer was tested in the water bath using a custom-designed plexiglass water bath adaptable black body fixture provided by the manufacturer. This fixture rests atop the water bath surface with a black- anodized aluminum cylinder emersed beneath it into the water. The cylinder equilibrated with the water temperature after approximately 30 minutes of exposure prior to thermometer testing and served as the source of infrared radiation for the tympanic probe for testing purposes. The FirstTemp Genius® tympanic thermometer was placed in the CALIBRATION mode and the probe was put snugly into the cylinder; temperatures were observed and recorded at 1°F increments over the range of 94 to 104°F. The tympanic thermometer measured ±0.2°F over all the entire temperature range thus well within the ASTM specifications.

The FirstTemp Genius® tympanic thermometer was also tested for calibration prior to use on each subject using an electronic black body calibrator provided by the manufacturer (Model 3000A-CL Black Body Calibration Reference, IMS, Carlsbad, CA). This calibration device is a precision temperature reference, traceable to the NIST. The unit contains a temperature controlled, black body reference made from hard, black-anodized aluminum which served as a heat target for the tympanic probe. When activated, a low setpoint of 98°F approximates normal body temperature and a high setpoint of 102°F typifies a febrile state for testing at various body temperatures (IMS, 1992). After the unit was allowed to equilibrate to the ambient environment for 30 minutes, the low setpoint button was depressed and the FirstTemp Genius® thermometer was put in the CALIBRATION equivalence mode and the probe with cover was placed snugly into the black body cylinder. The scan button was depressed and the reading was recorded. This procedure was repeated three times at both the low and high setpoints. The FirstTemp Genius® tympanic thermometer tested within ±0.2°F for all readings on every subject.

Procedures

Data collection process

Prior to initiation of the study, permission was obtained from the respective university and medical facility Institutional Review Boards (Appendix B). The obstetric health care providers at the medical center were informed of the investigation at a Perinatal Committee meeting preceding initiation of data collection. Data collection occurred between November 23, 1993 and January 10, 1994. Women who were due to deliver during the time frame of this study were notified of the study in advance via an informational flyer with a copy of the informed consent placed in their prenatal medical records (Appendices A and C). This information was distributed by obstetric health care providers at prenatal visits and women were encouraged to contact the researcher for any questions.

When a woman was admitted to the Labor and Delivery unit in active labor and met the inclusion criteria, the researcher was notified by a staff nurse. The researcher informed the woman and her significant other(s) about the purpose, methods, benefits, and risks involved in participating in the study as outlined in the prepared informed consent. Data collection was initiated once the informed consent was signed and a subject code number was designated.

Demographic data were obtained from the subject's obstetric medical record, specifically the admission history and labor record. This information provided a basis for describing the sample for this study according to the subject's age, number of previous deliveries, status of amniotic membrane (i.e. ruptured or intact), type of breathing (i.e. mouth or nose), cervical dilatation, admission temperature, administration of pitocin, oxygen, anesthesia, or analgesia, and frequency of uterine contractions. This information was recorded on the Data Collection Tool (Appendix D).

The patient was instructed not to eat or drink anything during the data collection. The FirstTemp Genius® tympanic thermometer was allowed to equilibrate to room temperature for 30 minutes and was tested for calibration using the Black Body Calibration Reference (Model 3000A, IMS, Carlsbad, CA) provided by the manufacturer as described previously. The calibration readings were recorded on the Data Collection Tool.

Simultaneous temperature measurements were taken at the tympanic, oral, and axillary sites. The first two temperature measurements at each site were obtained approximately 30 to 60 seconds apart allowing enough time between measurements for the thermometers to reset (Critikon, 1988; IMS, 1992). Three subsequent sets of temperature measurements were taken at 15 minute intervals for a total of five sets of temperature data obtained within approximately one hour of labor.

All temperatures were obtained by one researcher and were taken from the same side of the body, avoiding the arm with the intravenous (IV) site. Measurements were made during the period of relaxation between uterine contractions, at least one minute after the end of a contraction, to minimize any potential effects related to breathing technique or increased muscle activity associated with the contractions. The temperatures were recorded in Fahrenheit, for finer resolution than provided by the Celsius scale (Erickson & Yount, 1991). Any temperatures obtained during data collection that exceeded the admission temperature were reported to the attending nurse or physician. The procedures for temperature measurements are described in Appendices E, F, and G.

Statistical Analysis

Demographic Data

Demographic data were summarized using descriptive statistics to identify similarities or differences in the sample. Specific demographic data consisted of subject's age, ethnicity, parity, cervical dilatation, and the presence of labor conditions such as status of amniotic membranes, administration of pitocin, oxygen, anesthesia, or analgesia, and the use of nose or mouth breathing. This data was represented in two tables depicting the frequencies and percentages of their occurrence, as this is a common way to organize this type of information (Gravetter & Wallnau, 1992).

Temperature Data

Temperature data were analyzed using several techniques to address the research question, "What is the relationship between tympanic, oral, and axillary temperatures in women during labor." Temperature data consisted of 450 temperature measurements due to the five repeated measurements obtained for each subject. These values were entered into the Statistical Program for Social Sciences (SPSS) and the Statistix Program (Version 4.0, Analytical Software, St. Paul, MN) for analysis.

Summary statistics/ANOVA. Summary statistics for overall temperature data were calculated including the mean, standard deviation, and range for tympanic, oral, and axillary temperatures to analyze the variability within each temperature method. A repeated measures analysis of variance (ANOVA) was performed on each temperature method to evaluate for any significant variation in temperature readings over the five measurement times.

Relationship between pairs. To evaluate the relationship between paired temperature measurements, differences or offsets were calculated by subtracting oral temperatures from tympanic temperatures, axillary measurements from tympanic temperatures, and axillary temperatures from oral measurements. The mean differences, standard deviations, and range of differences were calculated for evaluation of the variation in agreement between the paired measurements. The mean differences were compared using a paired t-test for significance at the $\alpha = .05$ level. A Pearson Product Moment Correlation test was used to examine the strength of the linear relationship between paired measurements for overall pooled data as well as individual data.

Level of agreement. The relationship between tympanic, oral, and axillary temperatures in women during labor was also addressed by analyzing the level of agreement between paired temperature measurements using a statistical technique described by Bland and Altman (1986). These statisticians proposed the evaluation of the "level of agreement" rather than the "relationship" between measurements when comparing instruments that measure clinical physiologic processes such as temperature. Essentially, a correlation coefficient describes the strength of a linear relationship between two variables, not the agreement between them. Perfect agreement occurs if all values lie along the line of equality, whereas perfect correlation is present if the points lie along any straight line (Bland & Altman, 1986).

Paired temperature measurements were plotted against the line of identity, or line of perfect agreement ($\underline{X} = \underline{Y}$), for visual assessment of the relationship. The differences, or offsets, between paired temperature measurements were plotted against the mean of the paired temperatures to assess for the magnitude of disagreement and for outliers, as well as to detect trends (Bland & Altman, 1986; Nield & Gocka, 1993). This type of comparison allowed an evaluation of any possible relationship between measurement error and true value, which was estimated by the mean of the two measurements (Bland & Altman, 1986). The bias was estimated by the mean difference and plotted with limits of agreement which were calculated as two standard deviations above and below the bias. These limits describe how large the difference is between temperature methods, similar to a 95%

confidence interval, using the standard deviation rather than standard error (Nield & Gocka, 1993). The graphs were analyzed for level of agreement and a percentage was calculated based on the number of outliers noted, dividing the number within the limits by the total number of paired measurements (n = 30).

Additional Analysis

Additional analysis of the temperature data included assessing for repeatability between temperature measurements, for agreement between tympanic (oral-equivalent) temperatures and actual oral temperatures, and for any variation between temperatures in women with different labor conditions present.

Repeatability of temperature measurements. Repeatability is an important property of any instrument used to measure physiologic processes (Bland & Altman, 1986). The first and second temperature measurements for each method were obtained within 30 to 60 seconds of each other, allowing enough time for the thermometers to reset, and thus provided paired measurements for analysis of repeatability. The first and second temperature measurements for each method for all subjects were compared using a paired t-test and Pearson's Product Moment Correlation test for significance at the α = .05 level.

Differences were calculated between the two measurements for all subjects for each method and plotted against their means, biases, and limits of agreement as described previously (Bland & Altman, 1986). The percentage of agreement was calculated based on the number of outliers noted, dividing the number within the limits by the total number of paired measurements (n = 30).

Tympanic (oral-equivalent) versus oral temperatures. The oral-equivalent mode in the FirstTemp Genius tympanic thermometer provides a temperature measurement that approximates oral temperatures using a research-based mathematical offset of 0.8°F between tympanic and oral temperatures (Kaiser, 1994). Therefore, when the tympanic thermometer is used in the oral-equivalent setting, the readings should closely approximate oral temperature measurements (IMS, 1992).

To examine the relationship between tympanic temperatures in an oral-equivalent setting and oral temperature measurements in women during labor, 0.8°F was subtracted from every tympanic temperature measurement and the resulting "oral-equivalent" measurements were compared to oral temperature measurements as described previously.

Pearson Product Moment Correlation, paired t-test, and Bland and Altman (1986) techniques were used to describe the relationship and level of agreement between the paired temperature measurements. The offset or difference between the paired temperature measurements were plotted against the average of the paired measurements and compared to the bias or mean difference as well as to the upper and lower limits of agreement. The graph was analyzed for level of agreement and a percentage was calculated based on the number of outliers noted, dividing the number within the limits by the total number of paired measurements (n = 30).

Labor conditions. Analysis of variance (ANOVA) was performed for each temperature method for evaluation of variation between the temperatures in women with ruptured membranes versus intact membranes, who used nose versus mouth breathing, and for those who received pitocin, oxygen, epidural anesthesia, or analgesics versus those who did not. The means, standard deviations, and the F value were calculated for each condition as well and compared for significance at the α = .05 level.

CHAPTER III

PRESENTATION OF FINDINGS

Introduction

This chapter will focus on the presentation and analysis of the temperature data obtained in this study from women during labor. Characteristics of the subjects will be described and data will be examined separately for each temperature method over all five measurements and combined as paired temperature measurements for individual subjects and the entire group. Additional findings associated with the study will be presented as well.

Characteristics of the Subjects

Demographic Data

Thirty female subjects ranging in age from 18 to 37 (mean 26.7 years, ± 5.09) participated in the study (Table 1). Thirty-two subjects were enrolled initially, but two were not included due to the development of maternal and fetal complications. Ninety-four percent of the subjects were Caucasian (*n* = 28), one subject was Black-American (3%), and one was Hispanic (3%). Thirty-seven percent of the subjects were nulliparous (*n* = 11) and the remaining 63% (*n* = 19) were multiparous.

Table 1

Demographic Characteristics of the Subjects (N = 30)

Characteristic	n	% of sample
Age		
18 to 22	6	20%
23 to 27	13	43%
28 to 32	8	27%
33 to 37	3	10%
Ethnicity		
Caucasian	28	94%
Black-American	1	3%
Hispanic	1	3%
Parity		
Nullipara	11	37%
Multipara	19	63%

Labor Characteristics

Labor characteristics (Table 2) included the use of nose-breathing during uterine contractions in 20% (n = 6) of the subjects and the use of mouth breathing in the remaining 80% (n = 24). Amniotic membranes were intact in 27% (n = 8) of the subjects and ruptured in 73% (n = 22). Four subjects (13%) were given oxygen by mask and 17% (n = 5) received intravenous analgesics. Pitocin, or oxytocin, was administered intravenously to 12 (40%) of the subjects to induce or augment their labor patterns and 5 subjects (17%) received epidural anesthesia for pain relief.

All the subjects were in active labor, but the majority of subjects, 70% (n = 21), were either 4 or 5 centimeters dilated. Six subjects (20%) were 6 or 7 centimeters and the remaining 10% (n = 3) were of 8 centimeters dilatation.

Table 2

Labor Characteristics of the Subjects (N = 30)

Characteristic	n	% of sample
Type of Breathing		
Nose	6	20%
Mouth	24	80%
Status of Membranes		
Intact	8	27%
Ruptured	22	73%
Oxygen Administration (Mask)	4	13%
Anesthesia (Epidural)	4	13%
Analgesia (Intravenous)	5	17%
Pitocin (IV Infusion)	12	40%
Cervical Dilatation		
4 to 5 centimeters	21	70%
6 to 7 centimeters	6	20%
8 centimeters	3	10%

Results of Data Analysis

Temperature Data

Oral temperatures of the subjects upon admission to the hospital were between 96.5°F to 100.0°F (mean 98.3°F, ± 1.02°F). Tympanic, oral, and axillary temperatures were measured five times for each subject yielding a total of 450 temperature measurements for data analysis, n = 150 for each method.

The research question was, "What is the relationship between tympanic, oral, and axillary temperatures in women during labor?" The relationship between the three temperatures measurements was evaluated by comparing summary statistics, repeated measures analysis of variance, differences or offsets, Pearson Product Moment Correlations, and paired t-tests. The level of significance was established at α = .05 for two-tailed analysis. Statistical analysis was performed using the Statistical Program for Social Sciences PC and Studentware Software (SPSS) and Statistix Program (Version 4.0, Analytical Software, St. Paul, MN).

Summary statistics. Tympanic temperature for all subjects (*N* = 30, *n* = 150) ranged from 98.2°F to 100.7°F with a mean of 99.6°F (± 0.62°F) (Tables 3 and 4). Oral temperatures (*n* = 150) ranged between 97.3°F to 99.9°F with an average of 98.5°F (± 0.53°F). The range of axillary temperatures (*n* = 150) was between 96.0°F and 99.2°F with a mean of 97.7°F (± 0.68°F).

Table 3

Comparison of Tympanic, Oral, and Axillary Temperatures

Method	*n*	*M* (*SD*)	Range
Tympanic	150	99.6 (0.62)	98.2 to 100.7
Oral	150	98.5 (0.53)	97.3 to 99.9
Axillary	150	97.7 (0.68)	96.0 to 99.1

Table 4

Comparison of Tympanic, Oral, and Axillary Temperatures by Measurement Times

Time	Method	*M* (*SD*)	Range
1 (Initial)	Tympanic	99.48 (0.65)	98.2 to 100.7
	Oral	98.41 (0.50)	97.6 to 99.6
	Axillary	97.74 (0.69)	96.1 to 99.1
2 (Repeat)	Tympanic	99.49 (0.65)	98.2 to 100.5
	Oral	98.51 (0.51)	97.6 to 99.6
	Axillary	97.66 (0.58)	96.8 to 99.0
3 (15 min)	Tympanic	99.53 (0.61)	98.5 to 100.7
	Oral	98.46 (0.61)	97.3 to 99.4
	Axillary	97.60 (0.76)	96.4 to 99.0
4 (30 min)	Tympanic	99.60 (0.60)	98.7 to 100.5
	Oral	98.60 (0.56)	97.3 to 99.9
	Axillary	97.58 (0.72)	96.0 to 98.0
5 (45 min)	Tympanic	99.62 (0.60)	98.5 to 100.5
	Oral	98.54 (0.47)	97.4 to 99.3
	Axillary	97.71 (0.68)	96.2 to 98.8

Tympanic temperatures were higher than oral temperatures in 93% of the paired measurements (*n* = 140), identical to oral temperature values in three measurements (*n* = 3) and lower in seven measurements (*n* = 7). The lower and identical temperature measurements occurred in the tympanic range between 98.0 to 98.9°F. All tympanic temperature values were higher than axillary temperature measurements. The majority of oral temperature values, 91% (*n* = 136), were higher than axillary temperatures, ten (*n* = 10) were lower, and four measurements (*n* = 4) were identical.

Temperature change over time. The range of temperature measurements for individual subjects for each temperature method was evaluated for any significant change over the five measurement times. Tympanic temperature differences appeared less variable with a range between 0.1 to 1.1°F for individual subjects and a mean difference of 0.48°F (±0.26). Oral temperatures were between 0.2 to 1.9°F for each subject (D = 0.75°F, ±0.41) and axillary measurements ranged from 0.3 to 1.4°F with a mean difference of 0.86°F (±0.29).

Repeated measures analysis of variance was performed on each temperature method to evaluate for any significant change in temperature over the five measurements using the data from Table 4. No statistically significant change in temperature over the measurement times was noted in any of the temperature methods with $F = 0.34$, $p=.86$ for tympanic measurements, $F = 0.56$, $p=0.69$ for oral temperatures, and $F = 0.73$, $p=0.44$ for axillary measurements. Body temperature was not expected to vary significantly over the 45 minute data collection period as supported by the results.

Temperature differences (offsets). To evaluate the relationship between paired temperature measurements, differences or offsets were calculated between tympanic-oral, tympanic-axillary, and oral-axillary temperature measurements at each of the five measurement times and are presented in Table 5.

Table 5

Differences (Offsets) of Paired Temperature Measurements

Paired Measurements	D Offset(SD)	Range
Tympanic-Oral	1.04 (0.57)	-0.5 to 2.2
Tympanic-Axillary	1.89 (0.75)	0.2 to 3.7
Oral-Axillary	0.85 (0.70)	-0.7 to 2.5

Tympanic temperatures averaged approximately 1°F higher than oral temperatures and almost 2°F higher than axillary measurements. Specifically, the mean tympanic-oral offset was 1.04°F (± 0.57) with a range of -0.5 to 2.2°F. Tympanic-axillary offsets ranged between 0.2 to 3.7°F with a mean offset of 1.89°F (± 0.75). Oral temperature measurements were almost 1°F higher than axillary temperature values with a mean oral-axillary offset of 0.85°F (± 0.70) and a range of -0.7 to 2.5°F.

Paired t-test. Paired t-tests were performed to test for significance between paired temperature measurement offsets. The difference between mean tympanic-oral temperature offsets was significant at $t(149) = 22.48$, $p<.05$, indicating that the mean of the differences of the pairs was not zero. Differences were significant as well for mean tympanic-axillary offsets with $t(149) = 30.99$, $p<.05$, and mean oral-axillary differences at $t(149) = 14.74$, $p<.05$.

Correlation. The relationship between paired temperature measurements was evaluated statistically using a Pearson Product Moment Correlation to examine the strength of the linear relationship. Paired temperature measurements were plotted prior to calculating correlation coefficients to assess for linearity and all demonstrated a fair to moderate degree of linear relationship (Figures 1, 2, and 3).

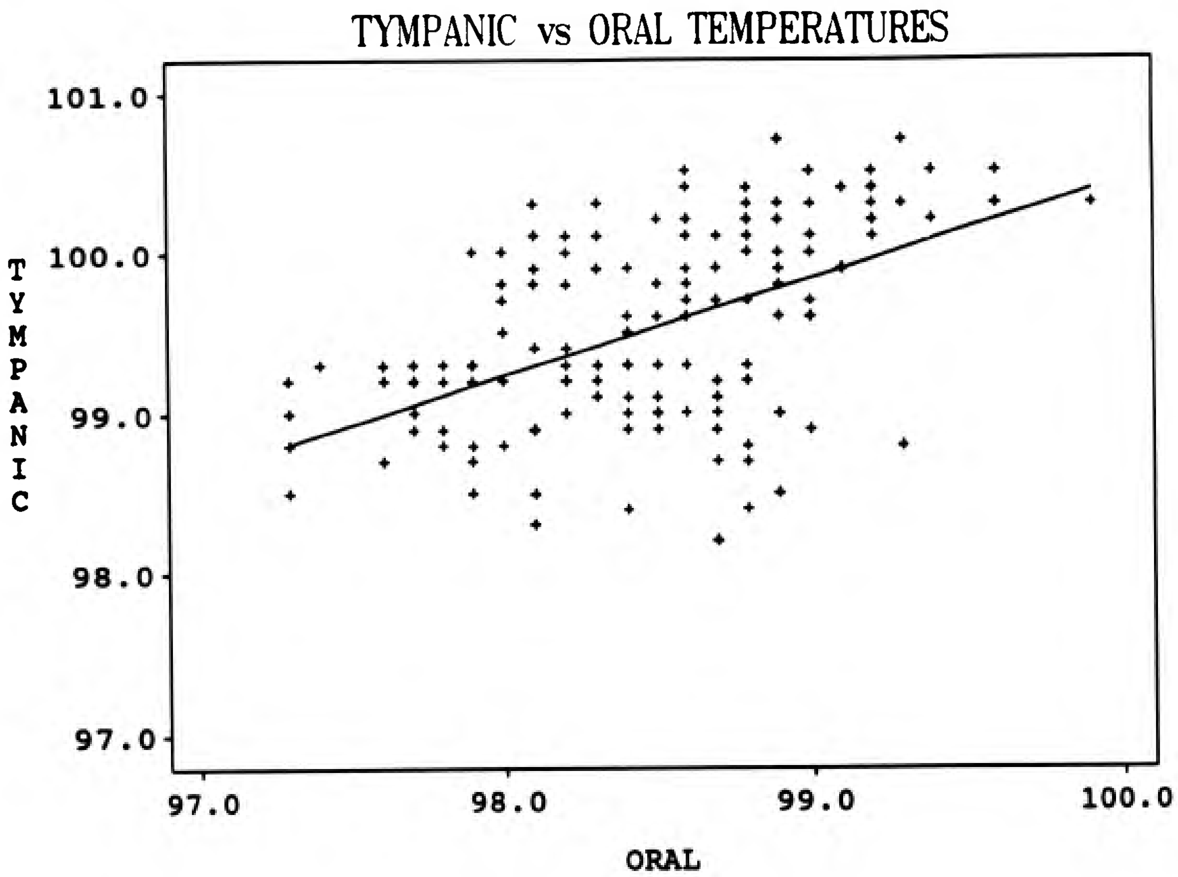


Figure 1

Scatter Diagram of Tympanic and Oral Temperatures with Regression Line

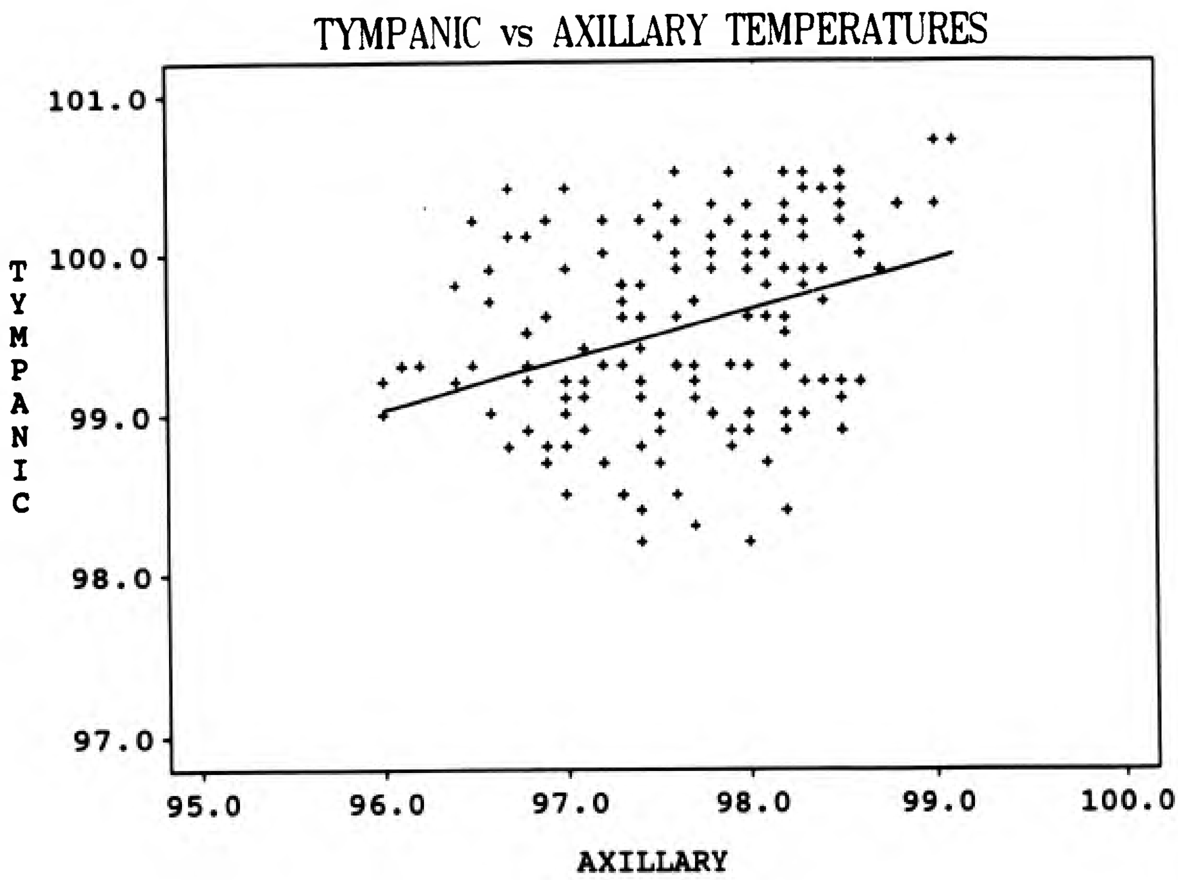


Figure 2

Scatter Diagram of Tympanic and Axillary Temperatures with Regression Line

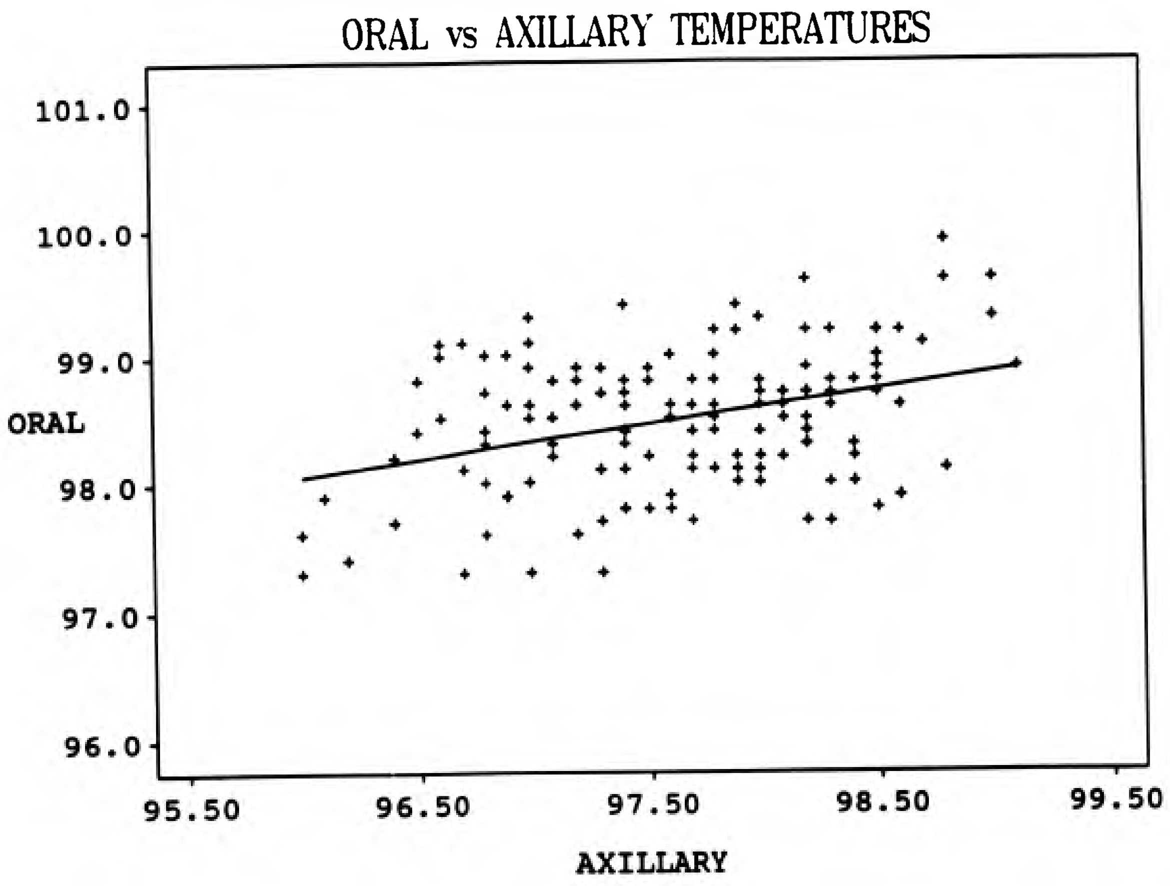


Figure 3

Scatter Diagram of Oral and Axillary Temperatures with Regression Line

Correlation coefficients for paired tympanic, oral, and axillary temperature measurements in the overall sample were low, between r = 0.34 to 0.52 (Table 6), suggesting a weak to moderate linear relationship between paired measurements. Specifically, the correlation coefficient for all tympanic-oral temperature measurements was $r(149) = 0.52$, $p<.05$ (Table 6), whereas the coefficients for paired temperatures at each measurement time were between $r(29) = 0.42$ to 0.59, $p<.05$ (Table 7). The correlation coefficients for individual subjects were greatly variable ranging from $r(4) = -0.85$ to 0.9873, $p<.05$ with only 30% (n = 7) of the correlations higher than r = 0.80 (Table 8).

Table 6

Correlation Coefficients for Paired Temperature Measurements

Methods	n	r	p
Tympanic-Oral	150	0.52	<.05
Tympanic-Axillary	150	0.34	>.05
Oral-Axillary	150	0.35	>.05

Table 7

Mean Offsets and Correlation Coefficients for Paired Temperatures Methods at Each Measurement Time

Methods	D (SD)	r	p
Tympanic-Oral			
1	1.06 (0.60)	0.48	.007
2	0.97 (0.59)	0.51	.004
3	1.08 (0.55)	0.59	.001
4	1.00 (0.53)	0.57	.001
5	1.08 (0.59)	0.42	.022
Tympanic-Axillary			
1	1.73 (0.73)	0.41	.025
2	1.83 (0.73)	0.30	.106
3	1.93 (0.76)	0.40	.028
4	2.02 (0.78)	0.31	.092
5	1.91 (0.74)	0.33	.077
Oral-Axillary			
1	0.67 (0.69)	0.36	.052
2	0.85 (0.60)	0.40	.029
3	0.85 (0.81)	0.32	.071
4	1.02 (0.63)	0.54	.002
5	0.83 (0.75)	0.17	.375

Table 8

Correlation Coefficients for Individual Subjects for Paired Temperature Measurements

Subject Number	Correlation Coefficients ($\underline{r}$) Tympanic-Oral	Tympanic-Axillary	Oral-Axillary
1	0.49	0.34	-0.63
2	0.65	-0.30	0.13
3	0.88	0.96	0.89
4	0.02	0.76	-0.06
5	0.69	-0.28	-0.46
6	-0.05	0.29	-0.13
7	0.65	-0.43	0.26
8	0.30	-0.38	-0.93
9	0.59	0.08	0.67
10	0.91	0.84	0.95
11	0.42	0.33	0.97
12	0.61	0.52	0.50
13	-0.68	0.19	0.20
14	-0.82	0.09	0.12
15	-0.36	0.78	-0.73
16	0.63	-0.62	0.16
17	-0.08	-0.42	-0.46
18	0.95	1.00	0.95
19	0.90	-0.20	-0.46
20	0.64	-0.71	-0.98
21	0.70	0.56	-0.18
22	-0.85	-0.59	0.25
23	0.99	0.60	0.69
24	0.04	-0.88	0.07
25	0.07	0.82	-0.23
26	0.83	-0.62	-0.46
27	0.98	0.51	0.63
28	-0.41	-0.57	0.97
29	-0.37	0.92	-0.42
30	-0.21	-0.90	0.22

The overall tympanic-axillary temperature correlation coefficient was $\underline{r}(149) = 0.34$, $\underline{p} > .05$, and between $\underline{r}(29) = 0.17$ to 0.54, $\underline{p} = .002$ to .37, for each measurement time. Individual correlations ranged from $r(4) = 0.30$ to 0.41 with only 23% ($n = 7$) of the correlations higher than $r = 0.80$. There was one perfect correlation of $r = 1.00$ for tympanic-axillary temperature measurements.

The correlation coefficient for all oral-axillary pairs was $r(149) = 0.35$, $p<.05$. Coefficients ranged between $r(29) = 0.17$ to 0.54, $p= .002$ to .375, for the five measurement times and between $r(4) = -0.98$ to 0.97 for individual subjects. Again, only 23% ($n = 7$) of the paired measurement correlations were higher than $r = 0.80$.

Overall, statistical analysis of the relationship between tympanic, oral, and axillary temperature measurements in women during labor indicated that there was no significant variability of each temperature method over time. Additionally, differences between paired measurements was statistically significant and linear relationships between tympanic-oral, tympanic-axillary, and oral-axillary temperatures were fair to moderate.

Level of agreement. The relationship between tympanic, oral, and axillary temperatures in women during labor was also evaluated for level of agreement between paired measurements. Bland and Altman (1986) proposed the evaluation of the "level of agreement" rather than the "relationship" between measurements when comparing instruments that measure clinical physiologic processes such as temperature. Essentially, a correlation coefficient describes the strength of a linear relationship between two variables, not the agreement between them. Perfect agreement occurs if all values lie along the line of equality, whereas perfect correlation is present if the points lie along any straight line (Bland & Altman, 1986).

Paired temperature measurements was plotted against the line of identity, or line of perfect agreement ($X = Y$), for visual assessment of the relationship (Figures 4, 5, 6). Few measurements fell along the line of identity for tympanic-oral and oral-axillary temperatures (n = 3 and 4 respectively), and none for tympanic-axillary measurements.

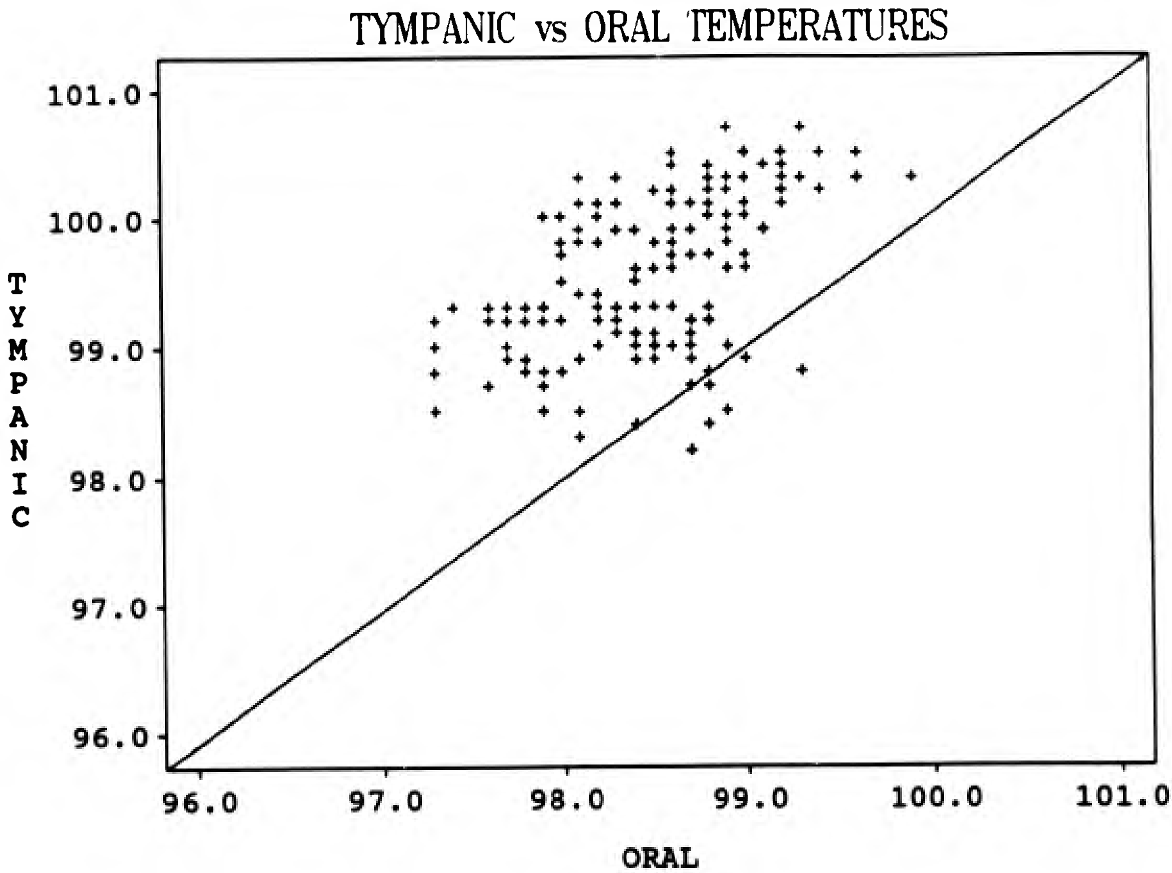


Figure 4

Scatter Diagram of Tympanic and Oral Temperatures Against a Line of Identity

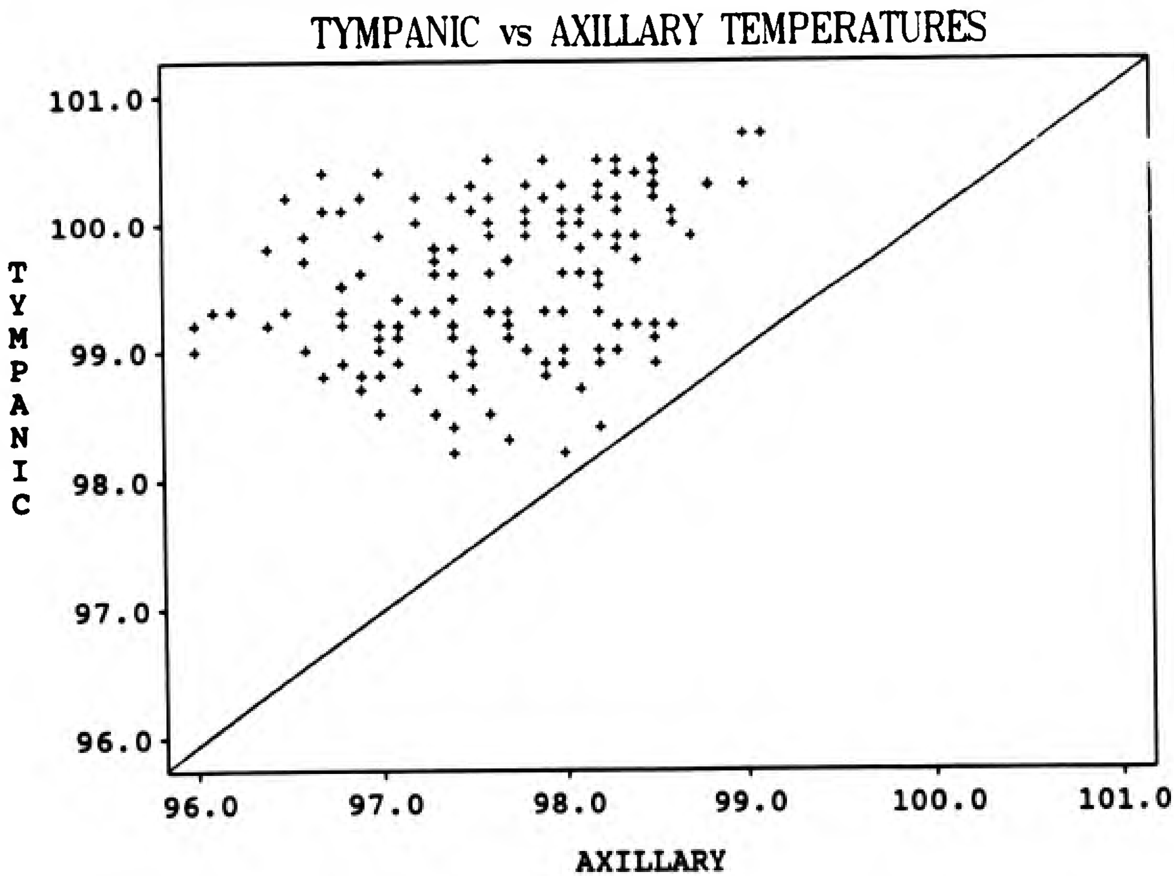


Figure 5

Scatter Diagram of Tympanic and Axillary Temperatures Against a Line of Identity

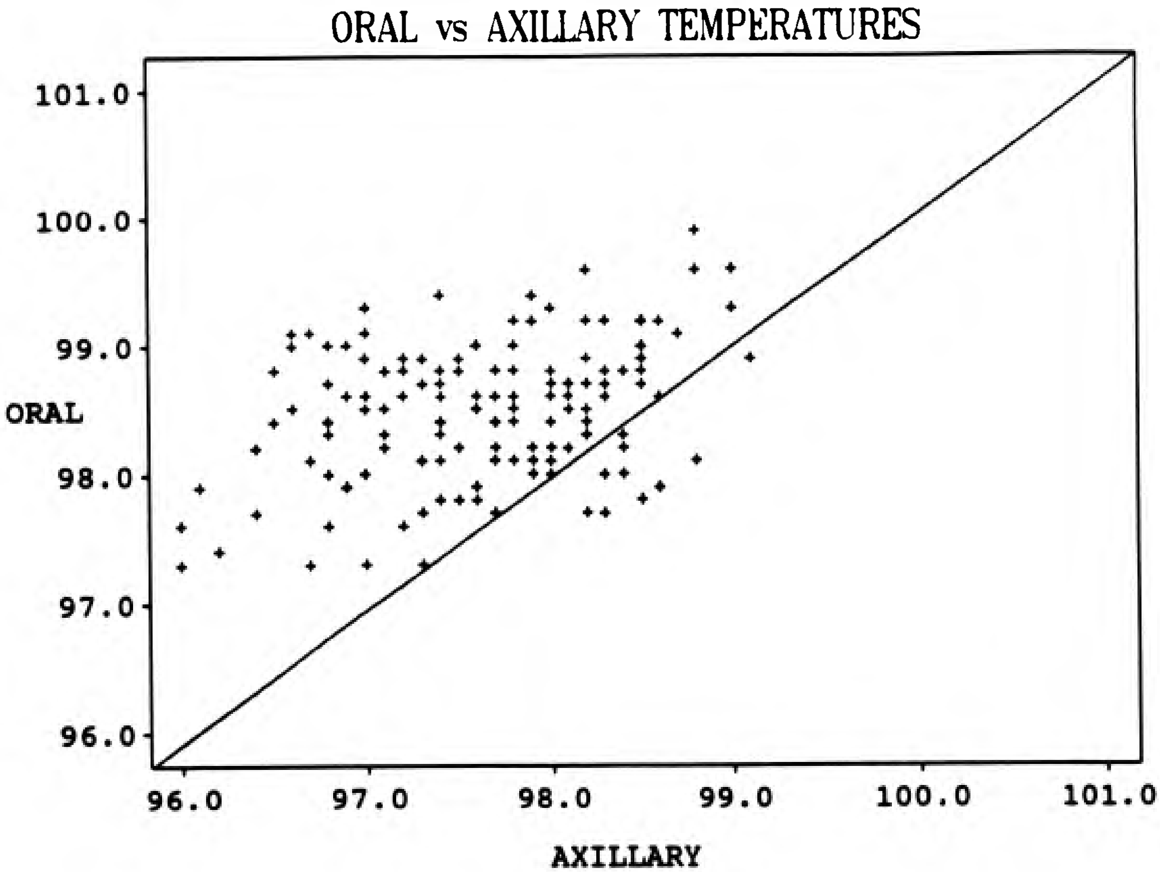
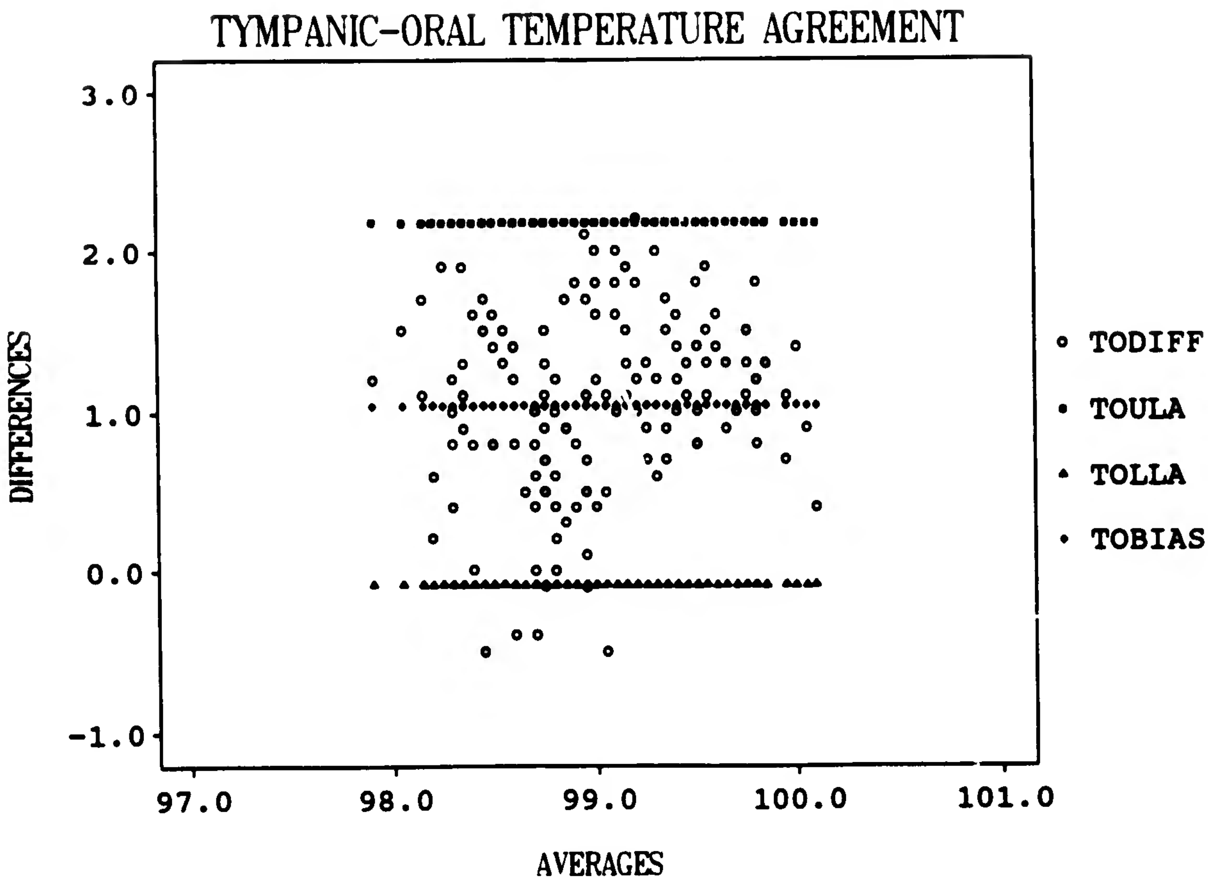


Figure 6

Scatter Diagram of Oral and Axillary Temperatures Against a Line of Identity

The differences, or offsets, between paired temperature measurements were plotted against the mean of the paired temperatures to assess for the magnitude of disagreement and for outliers, as well as to detect trends (Bland & Altman, 1986; Nield & Gocka, 1993) (Figures 7, 8, 9). This type of comparison allowed an evaluation of possible relationships between measurement error and true value, which was estimated by the mean of the two measurements (Bland & Altman, 1986). The bias was estimated by the mean difference and plotted with limits of agreement utilizing data from Table 5. The upper and lower limits of agreement were calculated as two standard deviations above and below the bias, and describe how large the difference is between temperature methods, similar to a 95% confidence interval, using the standard deviation rather than standard error.

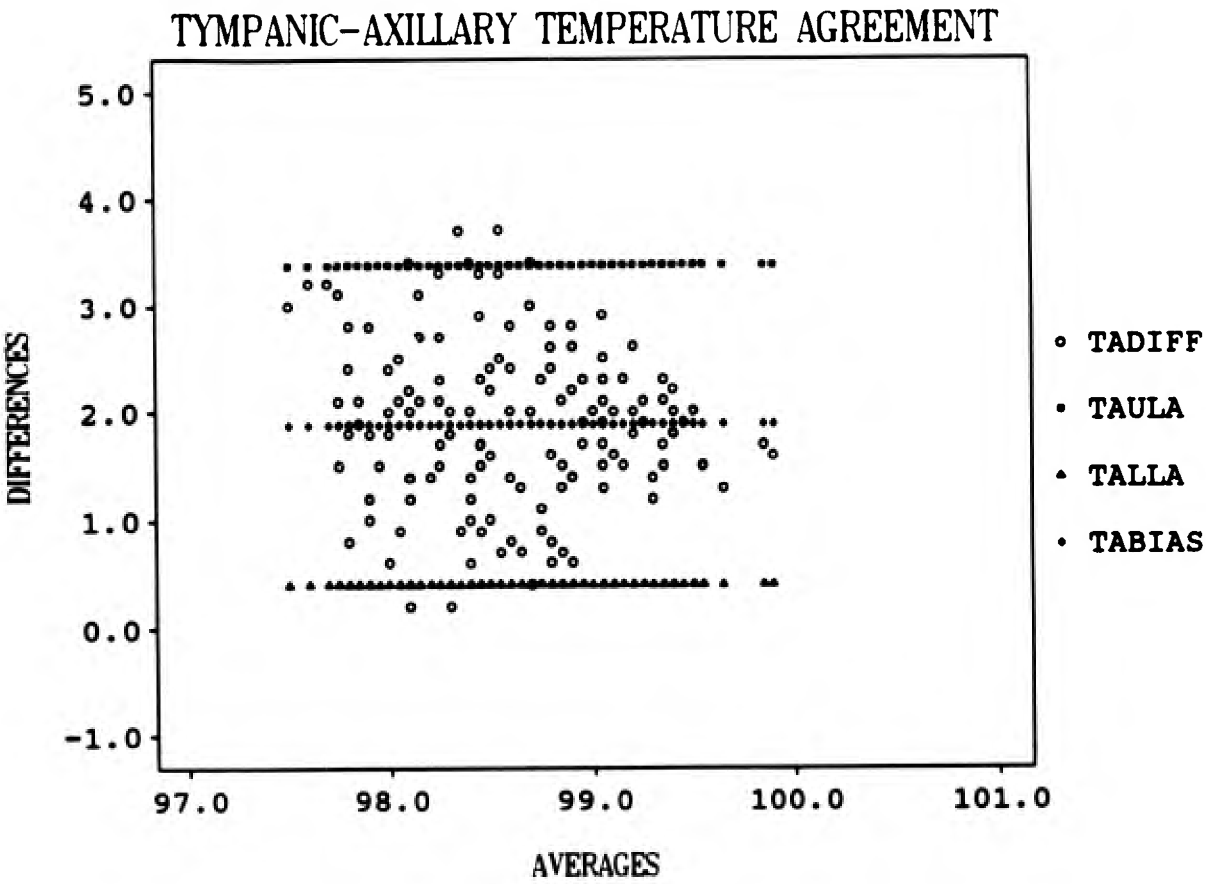
No significant trends were noted for either the tympanic-oral pairs or the oral-axillary pairs, however, the spread of differences was considerably smaller with higher mean tympanic-axillary measurements. There were five (n = 5) outliers noted in the tympanic-oral temperature plot, therefore only 83% of the differences were within the limits of agreement. Six (n = 6) outliers were observed for the paired tympanic-axillary measurements, and nine (n = 9) oral-axillary temperature outliers, indicating that only 80% of tympanic-axillary differences and 70% of oral-axillary differences were within the limits of agreement.



TODIFF = Tympanic-Oral Differences Plotted Against Tympanic-Oral Averages
TOBIAS = Mean Tympanic-Oral Difference
TOULA = Tympanic-Oral Upper Limit of Agreement
TOLLA = Tympanic-Oral Lower Limit of Agreement

Figure 7

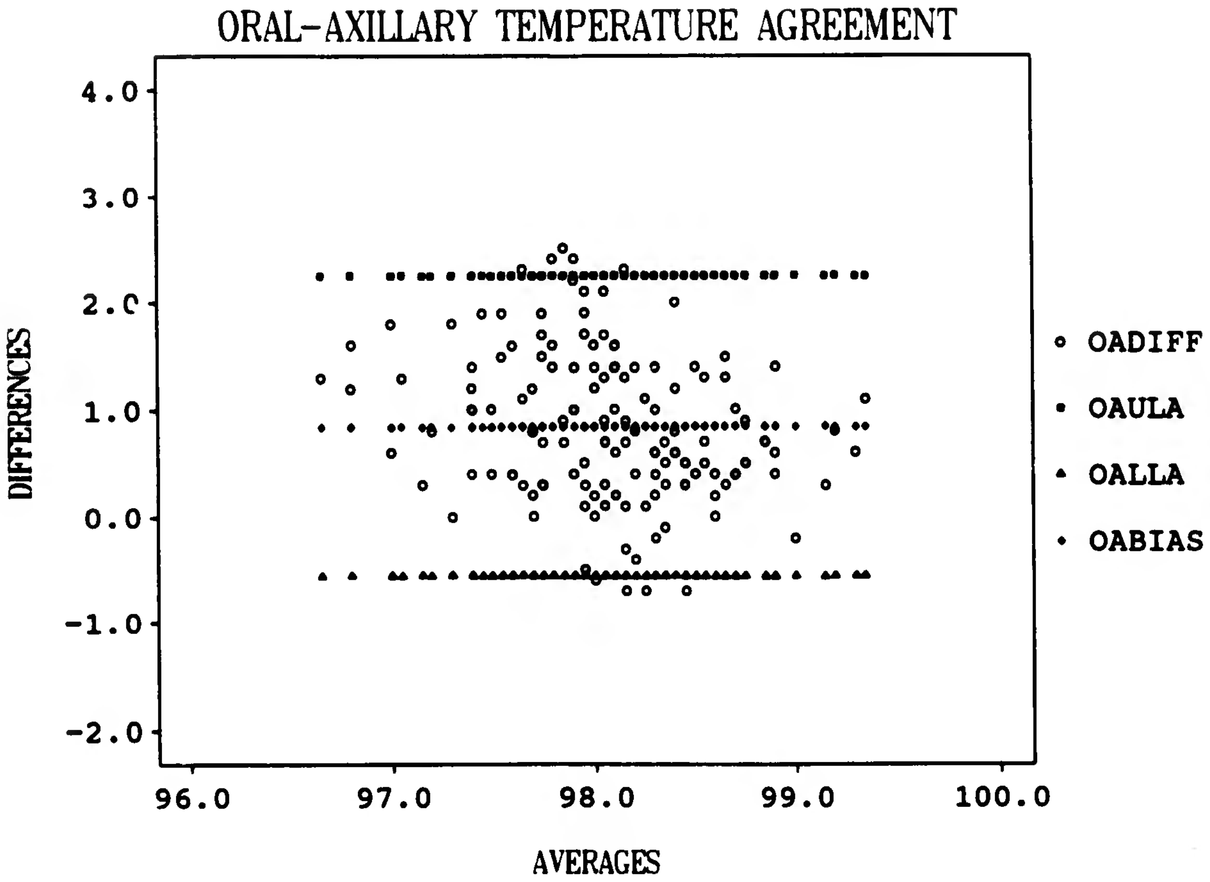
Scatter Diagram of Differences Versus Averages for Tympanic and Oral Temperatures Against the Bias and Limits of Agreement.



TADIFF = Tympanic-Axillary Differences Plotted Against Tympanic-Axillary Averages
TABIAS = Mean Tympanic-Axillary Difference
TAULA = Tympanic-Axillary Upper Limit of Agreement
TALLA = Tympanic-Axillary Lower Limit of Agreement

Figure 8

Scatter Diagram of Differences Versus Averages for Tympanic and Axillary Temperatures Against the Bias and Limits of Agreement.



OADIFF = Oral-Axillary Differences Plotted Against Oral-Axillary Averages
OABIAS = Mean Oral-Axillary Difference
OAULA = Oral-Axillary Upper Limit of Agreement
OALLA = Oral-Axillary Lower Limit of Agreement

Figure 9

Scatter Diagram of Differences Versus Averages for Oral and Axillary Temperatures Against the Bias and Limits of Agreement.

According to these results, differences from -0.08 to 2.16 were noted between tympanic and oral temperature measurements in women during labor, from 0.39 to 3.39 for tympanic and axillary measurements, and between -0.55 to 2.25 for oral and axillary temperatures, all of which exceed ±0.5°F as specified at the onset of this study. Such variability could significantly affect clinical treatment decisions and must be taken into consideration when measuring temperature in women during labor.

Additional Findings

Additional analysis was performed on the temperature data obtained in this study to evaluate the level of agreement between repeated temperature measurements in women during labor and the relationship between tympanic temperature measurements adjusted to oral-equivalent values as compared to oral temperatures obtained in the study. The difference between temperatures of women who had particular labor conditions present during labor was evaluated as well. These specific labor conditions included rupture of membranes, epidural anesthesia, nose versus mouth-breathing, intravenous pitocin, oxygen administration, and intravenous administration of analgesics.

Repeatability of Temperature Measurements

Repeatability is an important property of any instrument used to measure physiologic processes (Bland & Altman, 1986). The first and second temperature measurements for each method were obtained within 30 to 60 seconds of each other, allowing enough time for the thermometers to reset, and thus provided paired measurements for analysis of repeatability. Paired t-tests, Pearson Product Moment Correlations, and Bland and Altman (1986) techniques were performed on the first and second measurements for each temperature method. Table 9 depicts the mean temperatures and the mean offsets between the first and second measurements for each method, as well as the paired t-test results and correlation coefficients.

Table 9

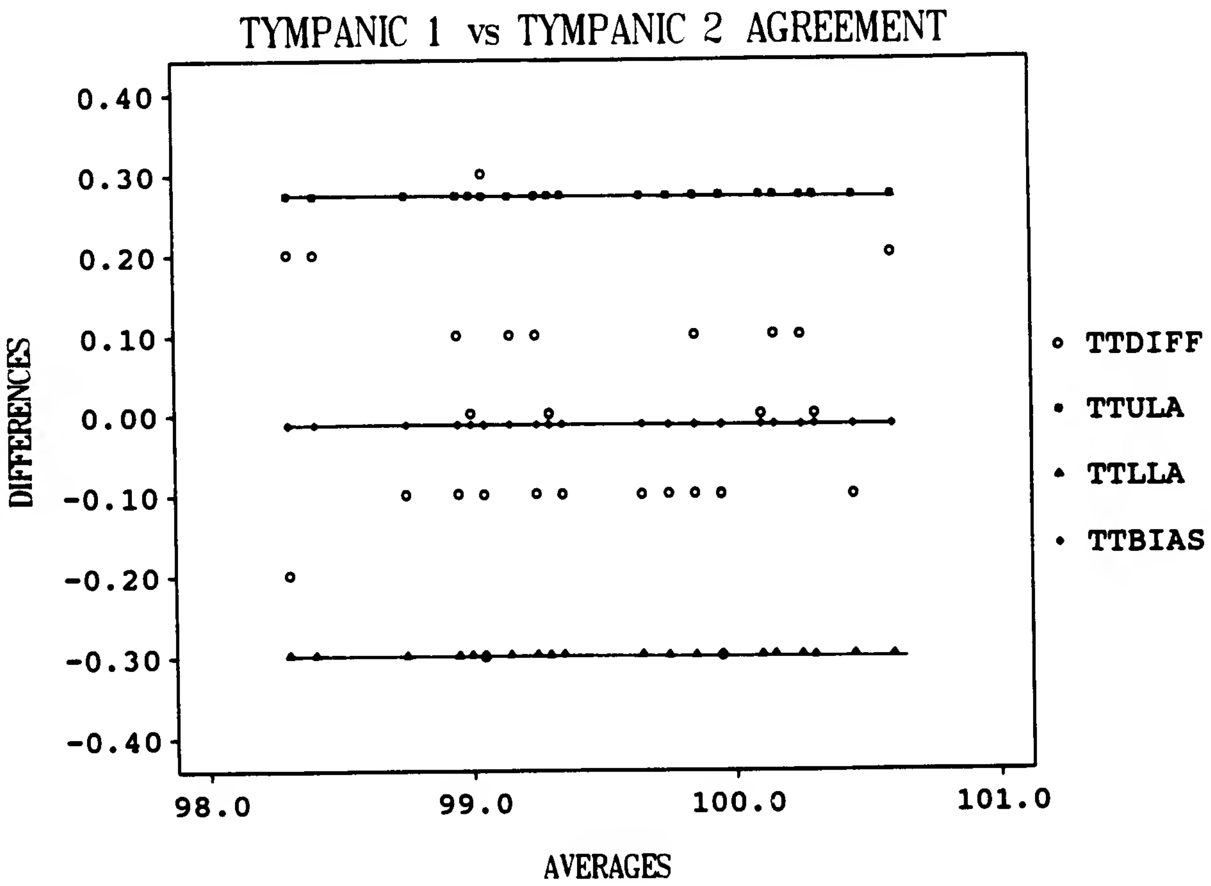
Comparison of First and Second Temperature Measurements

Method	*M*	*D* (*SD*)	*t*(df)	*p*	*r**
Tympanic					
1	99.48	-0.01(0.14)	-0.51(29)	.613	0.98
2	99.49				
Oral					
1	98.41	-0.10(0.18)	-3.10(29)	.004	0.94
2	98.51				
Axillary					
1	97.74	0.08(0.37)	1.16(29)	.256	0.84
2	97.66				

* two-tailed probability - p = .0001

Paired t-test and correlation. The mean difference between the two tympanic measurements was -0.01 and was not statistically significant at t = -0.51, p=.61. The first and second axillary pairs were different by a mean of 0.08 and were also not statistically significant with a t = 1.16, p=.26. However, the paired oral temperature measurements differed by -0.10 and were significant at t = -3.10, p=.004, indicating that the mean of the difference of the pair was not zero. Correlation coefficients were high for all three methods with tympanic at r = 0.97, oral at r = 0.94, and axillary at r = 0.84, suggesting a strong linear relationship between the first and second temperature measurements.

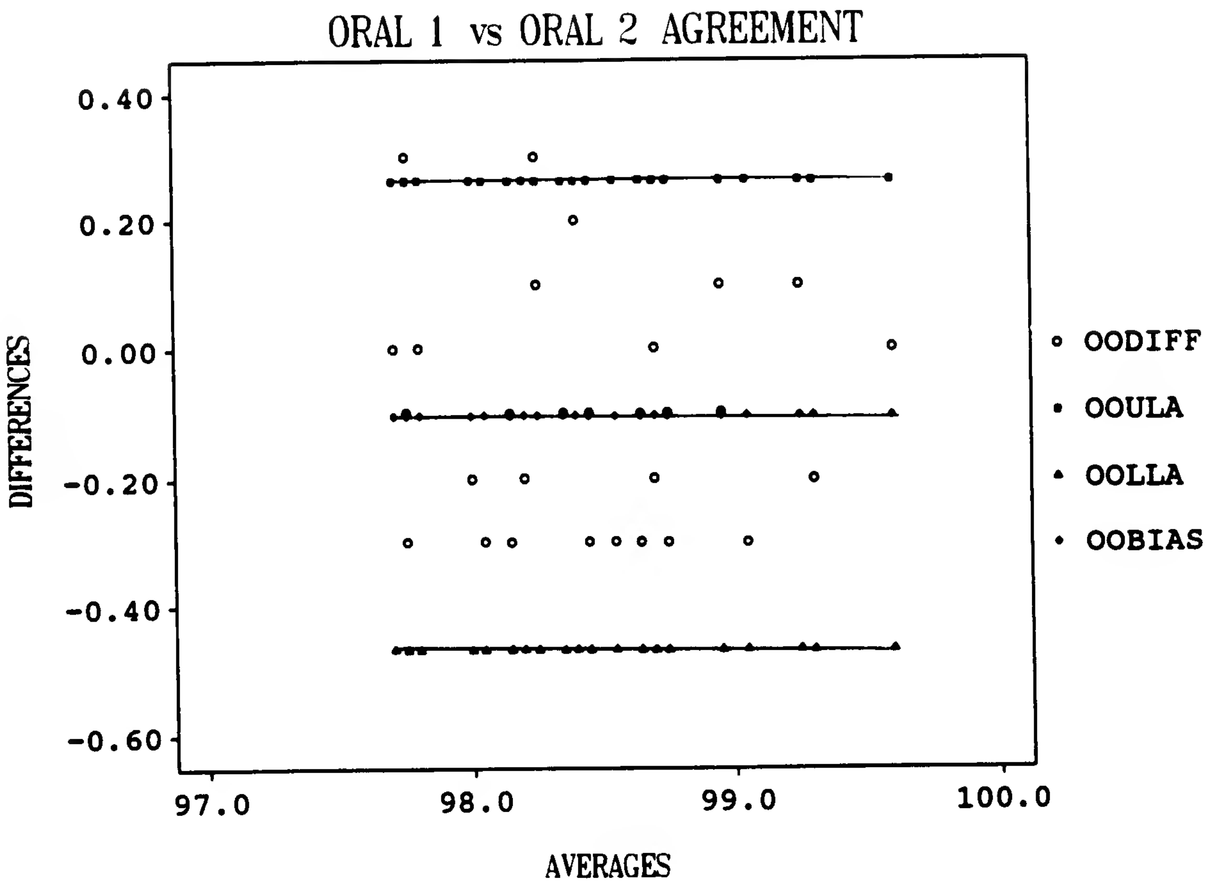
Level of agreement. First and second temperature measurements for all three methods were compared using the technique described by Bland and Altman (1986) to assess the level of agreement between them. The offset or difference between the paired temperature measurements were plotted against the average of the paired measurements and compared to the mean difference (or bias) from Table 9 as well as to the upper and lower limits of agreement, which were estimated as two standard deviations above and below the bias (Figures 10, 11, and 12).



TTDIFF = Tympanic 1 - Tympanic 2 Differences Plotted Against their Averages
TTBIAS = Mean Tympanic 1 - Tympanic 2 Difference
TTULA = Tympanic 1- Tympanic 2 Upper Limit of Agreement
TTLLA = Tympanic 1- Tympanic 2 Lower Limit of Agreement

Figure 10

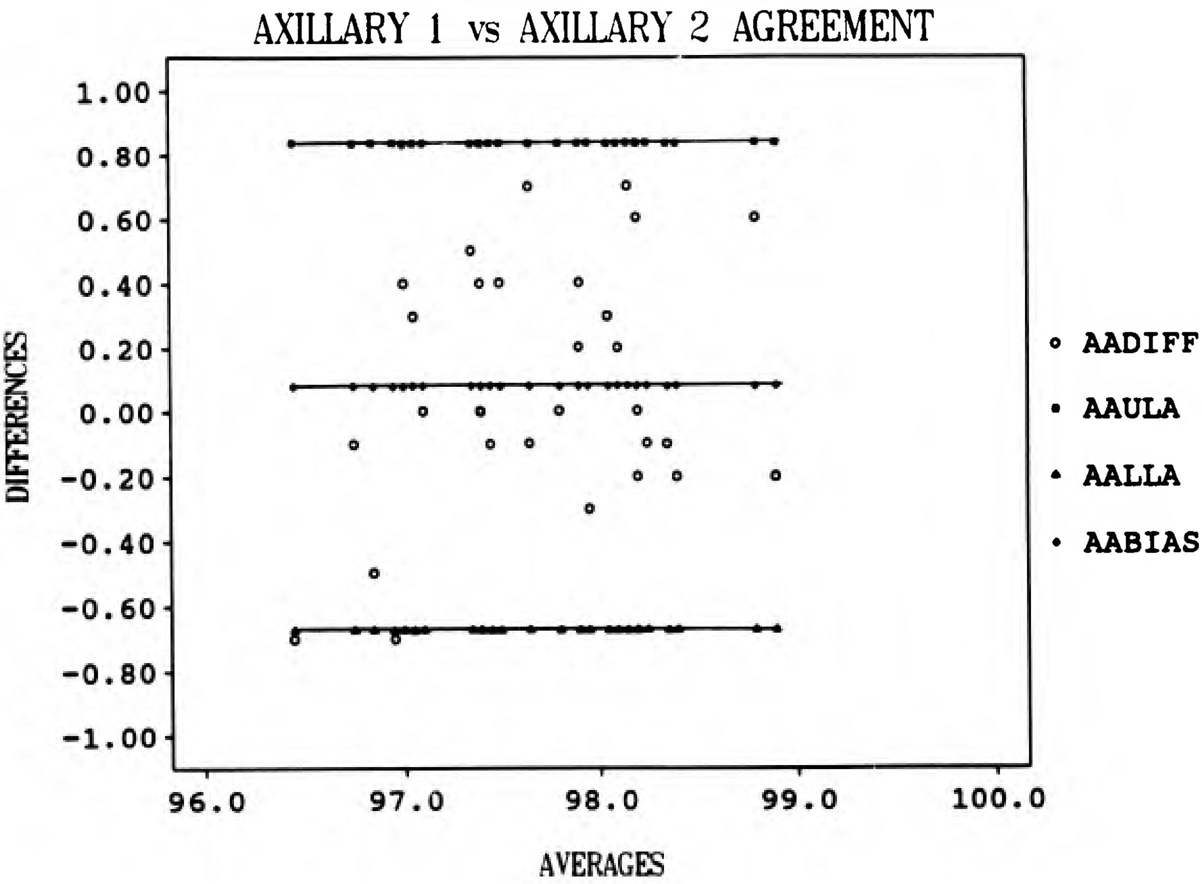
Scatter Diagram of Differences Versus Averages for Tympanic Temperatures Against the Bias and Limits of Agreement.



OODIFF = Oral 1 - Oral 2 Differences Plotted Against their Averages
OOBIAS = Mean Oral 1 - Oral 2 Difference
OOULA = Oral 1 - Oral 2 Upper Limit of Agreement
OOLLA = Oral 1 - Oral 2 Lower Limit of Agreement

Figure 11

Scatter Diagram of Differences Versus Averages for Oral Temperatures Against the Bias and Limits of Agreement.



AADIFF = Axillary 1 - Axillary 2 Differences Plotted Against their Averages
AABIAS = Mean Axillary 1 - Axillary 2 Difference
AAULA = Axillary 1- Axillary 2 Upper Limit of Agreement
AALLA = Axillary 1- Axillary 2 Lower Limit of Agreement

Figure 12

Scatter Diagram of Differences Versus Averages for Axillary Temperatures Against the Bias and Limits of Agreement.

The definition of repeatability described by the British Standards Institution (1979, cited in Altman & Bland, 1983) stated that 95% of the differences between two measurements should fall within two standard deviations of the mean. No significant temperature offset trends were noted for any pair of measurements. There was only one (*n* = 1) outlier noted in the tympanic temperature pairs, which indicated that 96% of the temperature differences (29/30) were within the limits of agreement and the range of differences was small (±0.28°F). Repeated tympanic temperatures in women during labor in this study fell within the levels of agreement for repeatability.

Two (*n* = 2) outliers were noted in the comparison of oral temperature pairs, indicating that only 93% of the temperature differences (28/30) were within the limits of agreement, although the range of differences was small (±0.36°F). Thus, the results demonstrate that repeated oral temperatures in women during labor in this study did not fall within the limits of agreement for repeatability.

Two (*n* = 2) outliers were noted in axillary pairs, thus only 93% of the temperature differences were within the limits of agreement. The range of differences was considerably greater in axillary temperatures when compared to tympanic and oral temperatures (±0.74°F).

Tympanic (Oral-Equivalent) Temperature Comparison

Tympanic thermometers are often used in an "oral-equivalent" setting due to the familiarity of measuring and interpreting oral temperatures (Erickson & Meyer, 1994). The oral-equivalent setting in the FirstTemp Genius® tympanic thermometer provides a temperature measurement that approximates oral temperatures using a research-based mathematical offset of 0.8°F between tympanic and oral temperatures (Kaiser, 1994). Therefore, when the tympanic thermometer is used in the oral-equivalent setting, the readings should closely approximate oral temperature measurements (Intelligent Medical Systems, 1992).

In order to examine the relationship between tympanic temperatures in the oral-equivalent mode and oral temperature measurements in women during labor, 0.8°F was subtracted from every tympanic temperature measurement and the resulting "oral-equivalent" values were compared to oral temperature measurements as in the initial data analysis. Pearson Product Moment Correlation, paired t-test, and Bland and Altman (1986) techniques were used to describe the relationship and level of agreement between the paired temperature measurements.

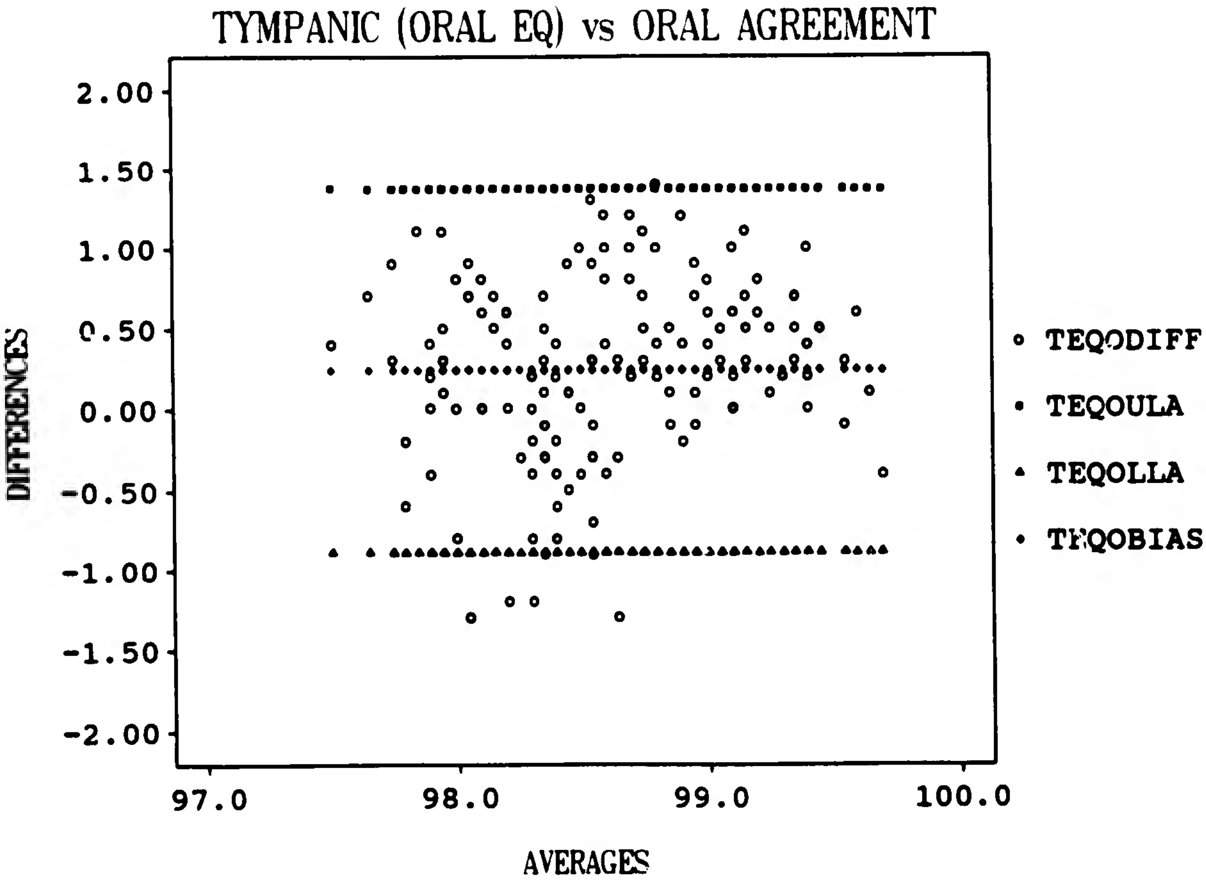
The mean tympanic (oral-equivalent) temperature measurement was 98.75°F, ±0.62 with a range of 97.4°F to 99.9°F. Paired tympanic (oral-equivalent) and oral temperatures had a mean offset of 0.24°F, ±0.57°F, with a range of -1.3°F to 1.4°F (Table 10). The paired t-test result was significant at t = 5.20, p<.05 indicating that the mean of the differences was not zero. The correlation coefficient of r = 0.52 demonstrated a moderate linear relationship between tympanic temperatures in the oral-equivalent mode and actual oral temperatures.

Table 10

Comparison of Tympanic (Oral-Equivalent) and Oral Temperatures (n = 150)

Method	M (SD)	D (SD)	t	p	r
Tympanic	98.75 (0.62)				
		0.24 (0.57)	5.20	<.05	0.52
Oral	98.51 (0.53)				

Level of agreement. Tympanic temperature measurements in the oral equivalent mode were also compared to oral temperature measurements using the technique described by Bland and Altman (1986) to assess their level of agreement. The offset or difference between the paired temperature measurements were plotted against the average of the paired measurements and compared to the mean difference, or bias as taken from Table 10, as well as to the upper and lower limits of agreement, which were estimated as two standard deviations above and below the bias (Figure 13).



TEQODIFF = Tympanic (Oral-Equivalent) and Oral Differences Plotted Against their Averages
TEQOBIAS = Tympanic (Oral-Equivalent) and Oral Mean Difference or Bias
TEQOULA = Tympanic (Oral-Equivalent) and Oral Upper Limit of Agreement
TEQOLLA = Tympanic (Oral-Equivalent) and Oral Lower Limit of Agreement

Figure 13

Scatter Diagram of Differences Versus Averages for Tympanic (Oral-Equivalent) and Oral Temperatures Against the Bias and Limits of Agreement.

Five (n = 5) outliers were noted in the tympanic (oral-equivalent) and oral temperature pairs indicating that only 85% of the temperature differences lie within the limits of agreement (±1.12). The range of differences (-1.3 to 1.4°F) is also clinically significant, suggesting that tympanic temperatures, in a calculated oral-equivalent mode, and oral temperatures in women during labor in this study do not fall within the limits of agreement.

Comparison of Temperatures by Labor Conditions

The final additional analysis of the study data involved evaluating whether there was any significant difference between tympanic, oral, and axillary temperatures of women who had the following conditions present during labor: rupture of membranes, epidural anesthesia, nose versus mouth-breathing, intravenous pitocin, oxygen administration, or intravenous analgesics. Analysis of variance (ANOVA) was performed for each temperature method for the specified conditions present during labor. Tables 11, 12, and 13 depict the mean, standard deviation, and the F value for each labor characteristic.

ANOVA results. The effect of intact versus ruptured amniotic membranes on tympanic, oral, and axillary temperature was not statistically significant with F = 0.05 to 2.38, p=.13 to .83. The difference in mean temperatures between subjects who used nose or mouth breathing was not statistically significant for tympanic temperatures

(F = 0.16, p=.69), but was significantly different for oral and axillary temperatures which were lower in women who used nose breathing (F = 6.10, p=.02 and F = 23.22, p=.001 respectively).

Tympanic, oral, and axillary temperatures were significantly lower in women who received oxygen by mask (F = 7.13 to 56.13 for all methods, p=.001 to .01). Axillary temperatures were significantly lower in subjects receiving pitocin intravenously (F = 4.42, p=.04) and in subjects who received epidural anesthesia (F = 4.80, p=.03). Intravenous administration of analgesics did not have a statistically significant effect on tympanic, oral, or axillary temperatures (F = 0.17 to 3.22, p=.07 to .68).

Table 11

The Effect of Labor Conditions on Tympanic Temperature

Condition	M (SD)	n	F	p
Membranes				
Intact	99.53 (0.48)	40	0.05	.83
Ruptured	99.55 (0.66)	110		
Type of Breathing				
Nose	99.51 (0.57)	30	0.16	.69
Mouth	99.55 (0.63)	120		
Oxygen (Mask)				
Yes	99.32 (0.45)	20	7.13	.01
No	99.58 (0.63)	130		
Pitocin (Oxytocin)				
Yes	99.47 (0.54)	60	1.74	.19
No	99.59 (0.66)	90		

Table 11 (continued)

The Effect of Labor Conditions on Tympanic Temperature

Condition	M (SD)	n	F	p
Epidural				
Yes	99.69 (0.57)	20	2.55	.11
No	99.52 (0.62)	130		
Analgesia (IV)				
Yes	99.70 (0.58)	25	3.22	.07
No	99.52 (0.62)	125		

Table 12

The Effect of Labor Conditions on Oral Temperature

Condition	M (SD)	n	F	p
Membranes				
Intact	98.60 (0.49)	40	2.38	.13
Ruptured	98.47 (0.54)	110		
Type of Breathing				
Nose	98.34 (0.71)	30	6.10	.02
Mouth	98.55 (0.47)	120		
Oxygen (Mask)				
Yes	97.98 (0.55,	20	56.13	.00
No	98.59 (0.48)	130		
Pitocin (Oxytocin)				
Yes	98.47 (0.54)	60	0.51	.47
No	98.53 (0.52)	90		
Epidural				
Yes	98.39 (0.73)	20	2.39	.13
No	98.52 (0.49)	130		
Analgesia (IV)				
Yes	98.48 (0.55)	25	0.17	.68
No	98.51 (0.53)	125		

Table 13

The Effect of Labor Conditions on Axillary Temperature

Condition	*M* (*SD*)	*n*	*F*	*p*
Membranes				
Intact	97.72 (0.71)	40	0.67	.42
Ruptured	97.64 (0.68)	110		
Type of Breathing				
Nose	97.25 (0.73)	30	23.22	.001
Mouth	97.76 (0.63)	120		
Oxygen (Mask)				
Yes	97.06 (0.70)	20	43.71	.001
No	97.76 (0.63)	130		
Pitocin (Oxytocin)				
Yes	97.52 (0.68)	60	4.42	.04
No	97.75 (0.67)	90		
Epidural				
Yes	97.45 (0.78)	20	4.80	.03
No	97.69 (0.66)	130		
Analgesia (IV)				
Yes	97.73 (0.67)	25	0.59	.44
No	97.65 (0.69)	125		

Conclusion

Temperature measurement in women during labor is an essential aspect of nursing care upon which many clinical decisions and interventions are based. Therefore, it is imperative to evaluate the relationship and level of agreement between temperature measuring methods in order to have a basis for understanding temperature results in women during the physiological changes of labor. Significant variability and lack of agreement could affect clinical treatment decisions and must be taken into consideration when measuring temperature in women during labor.

CHAPTER IV

DISCUSSION OF FINDINGS

Introduction

The purpose of this study was to describe the relationship and level of agreement between tympanic, oral, and axillary temperatures in women during labor. In this chapter, the results of the study will be discussed and compared to other research findings. In addition, the scope, limitations, and implications of this study will be presented.

Characteristic of the Subjects

Evaluation of the demographic and labor characteristics of the subjects did not show any significant difference related to age, parity or labor conditions. Due to the small sample size (n = 30), the predominance of Caucasian subjects (94%) and the lower occurrence of certain labor conditions in this study, such as epidural anesthesia (13%), may not be truly reflective of the total population of women in labor. It would, however, be considered representative of the population of women in labor at this military installation.

Tympanic, Oral, and Axillary Temperatures

Interpreting the findings from this study, it would appear that tympanic temperature was approximately 1°F higher than oral (D = 1.04°F) and 2°F higher than axillary temperatures (D = 1.89°F) in women during labor. As would be expected, temperature measurements for each method did not vary significantly during the data collection period (F = 0.34 to 0.73, p>.05) suggesting the relative stability of the temperature measurements over time.

Overall correlations between paired temperature measurements were fair to moderate (r = 0.34 to 0.52) with t-test results indicating that mean differences were statistically significant for all pairs (t = 14.74 to 30.99, p<.05). Evaluation of paired temperature measurements using techniques described by Bland and Altman (1986), indicated that although paired temperatures were fair to moderately correlated, few measurement values approximated the line of identity, or line of "perfect agreement". Interpretation of this finding suggests that correlation of temperature measurements in women during labor is not a good indicator of the level of agreement between two temperature methods, which is clinically more significant when comparing two physiological measurements (Bland & Altman, 1986). In addition, none of the paired temperature methods fell within the limits of agreement determined as two standard deviations above and below the mean difference of the two temperature methods. These limits of agreement are similar to the 95% confidence interval, thus suggesting that there is significant variability between the paired measurements.

Such variation in agreement between temperature measurements in women during labor was also described by

Goodlin and Chapin (1982) when comparing 50 women with and without pain relief during labor. They reported lower tympanic and vaginal temperatures in women without pain relief, attributing this to a higher incidence of hyperventilation and sweating as a response to labor pain. The researchers concluded that maternal temperature during labor depends on the degree of pain relief, sweating, and hyperventilation, and thus temperature recordings are relatively "uninterpretable" in many women during labor (Goodlin & Chapin, 1982).

The findings of this study may also reflect the effect of various physiologic responses on body temperature at different sites in women during labor, including hyperventilation, sweating, and increased muscular activity. Since it is not feasible to control for these effects, this may indicate that it is not clinically appropriate to compare temperatures obtained from different body sites in women during labor.

Additional Analysis

Repeatability of Temperature Measurements

The first and second temperature measurements for each method were compared for repeatability, as they were taken within 30 seconds of each other. Tympanic, oral, and axillary measurements were highly correlated with r = 0.97, 0.94, 0.84 respectively. Seventy-seven percent (77%) of tympanic measurements were reproduced within ±0.1°F and 100%

within ±0.3°F. According to the results of this study, 96% of repeated tympanic measurements fell within the limits of agreement for repeatability, while only 93% of oral and axillary temperatures were within the limits, suggesting relative accuracy and stability in tympanic temperature measurement in women during labor.

Variability in repeated oral and axillary temperature measurements could be related to a "drawdown" effect in which repeated measurements at the same site may cause cooling of the surrounding tissue. Similarly, exposure of the axilla to the environment for intermittent measurements may also affect the repeatability of axillary temperatures (Erickson & Kirklin, 1993). Variation in temperature measurement techniques, such as an inadequate seal or improper probe placement, may also contribute to decreased repeatability of temperature measurements. Such variation in repeated measurements of temperature could affect clinical treatment decisions and must be taken into consideration when evaluating temperatures obtained by these methods in women during labor.

Tympanic (Oral-Equivalent) and Oral Temperatures

Comparison of tympanic temperatures in a calculated oral-equivalent mode to actual oral temperatures obtained in this study resulted in a mean difference of 0.24°F and the same moderate correlation (r = 0.52) between the paired temperatures as in the core mode. The differences were statistically significant (t = 5.20, p=.001) and only 85% of the offsets were within the limits of agreement.

Analysis of the findings show significant variation when comparing tympanic temperatures in the oral-equivalent mode to actual oral temperatures obtained in women during labor. In addition to the effects of physiologic responses to labor as described previously, another factor that may contribute to this variation is the possibility that the specific oral-equivalent offset used in the FirstTemp Genius® tympanic thermometer, which is based on research findings that do not include laboring women, may not reflect the oral differences of women during labor. These findings should be taken into consideration when using the tympanic thermometer in the oral-equivalent mode to monitor temperature in women during labor.

Presence of Labor Conditions

The results of the analysis of variance between the temperatures of women who had certain labor conditions were of particular interest, although in no way conclusive of specific related effects since these variables were not controlled. There were no significant differences between tympanic, oral, and axillary temperatures in women who had ruptured membranes or who had received analgesics intravenously. Axillary temperatures were significantly lower in women who had received epidural anesthesia or intravenous pitocin during labor.

Both oral and axillary temperature measurements were higher and thus statistically significant in women who used mouth breathing during labor. Tympanic, oral, and axillary temperature measurements were significantly lower in women who received oxygen by face mask during labor. Hasler and Cohen (1982) reported that there was no significant effect of oxygen administration on oral temperatures in the 40 healthy adults studied. Neff et al. (1989) found a significant effect of open mouth breathing on oral temperatures and not on tympanic temperatures in an experimental study on 78 healthy subjects.

Comparison of Specific Results to Other Research Findings

Many of the specific findings of this study differ from the results reported by other researchers measuring tympanic, oral, and/or axillary temperatures in other patient populations. As this is one of the first studies to compare three temperature sites in women during labor, the most significant factor to consider is the inherent difference in study populations. The physiological changes that occur during labor differ considerably from the physiologic and metabolic states of adult patients who receive health care in other clinical settings and should be considered when reviewing these findings.

Tympanic-Oral Temperatures

In this study, tympanic temperature measurements averaged approximately 1°F higher than oral temperatures in

93% of the subjects, with a mean offset of 1.04°F and a relatively stable range of offsets between 0.98 to 1.08°F over the five measurement times. The correlation coefficient for overall pooled data in this study was $r(149) = 0.52$ and between $r = 0.41$ to 0.59 at individual measurement times. Correlations for individual subjects were even more variable with only 30% higher than $r = 0.80$. The significant paired t-test results ($t = 22.48$, $p<.05$) provides evidence that the mean of the tympanic-oral temperature differences is not zero and thus support the fair correlations observed.

Erickson and Yount (1991) reported that tympanic temperature was higher than oral temperature in 99% of their measurements in perioperative subjects. The mean tympanic-oral offset of their study was 1.1 to 1.5°F over four measurement times. These researchers also found moderately high correlations between tympanic and oral temperatures at each measurement time ($r = 0.77$ to 0.85, $p<.0001$) and that 95% of the individual correlations were above $r = 0.80$. Green, Danzl, and Praszkier (1989) noted a correlation of $r = 0.77$ ($r^2 = 0.599$) between tympanic and oral temperatures in 411 emergency department patients, with a significant difference indicated by paired t-test results of $t = 25.685$, $p<.05$.

Such variation between research findings could be related to several factors, including the difference in patient populations as described previously, the greater length of time between temperature measurements and the influence of cooler ambient temperatures or rewarming procedures on the perioperative subjects in the study by Erickson and Yount (1991), or the difference in type of predictive thermometer used in the investigation by Green et al. (1989).

Tympanic-Axillary Temperatures

Tympanic temperature measurements were approximately 2°F (1.89°F) higher than axillary temperatures in this study with a correlation coefficient of $r = 0.34$, $p > .05$. These findings differ considerably from the results observed by other researchers. Mahan (1991) compared tympanic, axillary and pulmonary artery temperatures in critically ill adults and found that axillary temperatures were 0.20°F higher than tympanic temperatures with a correlation coefficient of $r = 0.84$, $p < .00001$. Erickson and Meyer (1994) compared tympanic, axillary, and oral temperatures to pulmonary artery temperatures in critically ill adults and it was noted that tympanic was approximately 0.78°F higher than axillary. Another study by Cork et al. (1983) reported differences between tympanic and axillary temperatures of 2.7 to 3.42°F in non-cardiac surgical patients, with correlation coefficients plotted between $r = 0.30$ to 0.65. Results of a study by Summers (1991) indicate that tympanic temperatures were 1.8 to 2.24°F higher than axillary in 96 postanesthesia patients.

Such variation in results could be related to the difference in patient populations as previously discussed or to specific differences in technique. The studies by Erickson and Meyer (1994) and by Cork et al. (1983), used continuous axillary temperature measurement to avoid the effects of exposing the axilla to the environment rather than intermittent axillary temperature monitoring as used in this study and routinely in clinical areas. The use of different brands of thermometers within the studies may account for some of the variation as well.

Oral-Axillary Temperatures

Oral temperatures averaged 0.85°F higher than axillary temperatures in women during labor in this study which approximates the 0.5 to 1.0°F oral-axillary difference as described in many nursing references (Kozier & Erb, 1989; Lewis & Timby, 1988; Lipsky, 1986). Correlation between oral-axillary temperatures was fair with $r(149) = 0.35$, $p<.05$ and t-test results indicated that the differences were significant ($t = 14.74$, $p<.05$). Nichols, Ruskin, Glor, and Kelly (1966) reported that differences between simultaneous oral and axillary temperatures in 60 afebrile adults ranged from 0 to 4.2°F, with 62% of the subjects having a difference of less than or equal to 1.0°F.

Conclusion and Implications of the Study

Temperature measurement in women during labor is an essential aspect of nursing care upon which many important clinical decisions and interventions are based. Since there were no other studies that compared tympanic, oral, and axillary temperatures in women during labor, the purpose of this investigation was to describe the relationship of these temperature methods in women during labor. Therefore, the results of this study provide a basis upon which to evaluate temperature measurements obtained in this population of patients.

The overall findings of this study provide evidence that tympanic temperature measurements were approximately 1°F higher than oral temperatures and almost 2°F higher than axillary temperatures in women during labor and showed less variation than either of the other two temperature methods. The tympanic site is faster and less intrusive for measuring temperature in women during labor and should be considered for use in this clinical setting.

Temperature measurements must be accurate enough to detect clinically significant changes in temperature and must not be considerably affected by variations within the patient, the environment, and measurement techniques that are difficult to control in a clinical setting (Erickson & Kirklin, 1993). Comparison of the differences between paired tympanic-oral, tympanic (oral-equivalent)-oral, tympanic-axillary, and oral-axillary temperature measurements demonstrated considerable variation in agreement. However, it is important to realize that all temperature methods are considered estimates of core temperature and that some variability will occur in comparing clinical temperature measurements due to regional changes in blood perfusion, especially during labor (Holtzclaw, 1993; Houdas & Ring, 1982). Thus it is questionable whether these different sites can be compared for absolute agreement in women during labor when they are potentially affected by such physiological changes during labor. It is also necessary to decide how much variability is significant in particular clinical settings, such as one providing care for low-risk versus high-risk women during labor.

Variations in the findings of this study can be attributed to several factors which should be taken into consideration when obtaining temperatures in women during labor and especially before making treatment decisions based on specific temperature measurements. The most significant factor affecting temperature measurement is the effect of physiological responses to the labor process on the different temperature sites. These physiological responses include hyperventilation, mouth breathing, sweating, and increased muscular activity and cannot be controlled.

Other factors that may cause variation in the temperature measurements involve measurement technique, equipment differences, or specific effects at the particular sites. Although only one researcher obtained all of the temperature measurements and attempted to maintain correct technique throughout data collection, any variation in temperature measurement technique related to proper probe placement or ensuring adequate seals could cause significant differences in temperature results. Repeated measurements of oral and axillary temperatures could be affected by cooling of the involved tissue due to a "draw-down" effect. In addition, exposure of the axilla to the environment with intermittent temperature measurements could have altered axillary temperatures. An additional consideration is that the oral offset values programmed into the tympanic thermometer may not reflect tympanic-oral temperature differences in women during labor.

Scope and Limitations of the Study

The scope of this study comprised a small (n = 30), non-random, convenience sample of afebrile, low-risk women in active labor receiving medical care in a Midwest military medical facility. Thus the generalizability of these findings are limited to low-risk obstetric populations with similar demographics receiving health care in medical facilities with similar policies, procedures, and equipment.

Other limitations of this study were inherent in the design and analysis procedures used. Inability to control the physiological process of labor, including uterine contractions, status of membranes, and type or rate of breathing, which are unique for each subject and may affect body temperature, limit the comparison of these findings to other patient populations.

Another limitation of this study is that it was conducted in a clinical setting rather than in a controlled laboratory environment. This may have limited the control of extraneous factors, such as ambient temperature and interaction of other health care providers during data collection, that may have had an effect on temperature measurement. Moreover, although all of the thermometers were within specifications when tested in vitro, two different predictive thermometers were used to measure oral and axillary temperatures simultaneously for each subject and may have had an effect on temperature measurement as well.

Although tympanic temperatures have been shown to be equivalent to other core methods, the lack of comparison to other core temperature methods such as pulmonary artery, esophageal, or rectal sites, limited the interpretation of accuracy between tympanic, oral, and axillary temperatures in women during labor. However, these types of temperature measurements are invasive and not routinely used in low-risk obstetric populations. Glass thermometers were not used, although considered the "gold standard" for comparing temperature sites, due to the potential for breakage and injury in this study population. Axillary temperatures were obtained intermittently with an electronic thermometer in the predictive mode as performed routinely in clinical practice, rather than in the manual or constant reading mode. The possibility for error or variation in calibration of thermometers or in temperature taking technique by the researcher would limit the accuracy of the results as well.

CHAPTER V

SUMMARY OF THE STUDY

Review of the Problem

Accurate measurement and interpretation of body temperature is essential for making appropriate treatment decisions in all clinical areas. Body temperature changes that occur in women during labor may reflect normal physiological alterations resulting from increased muscular activity, dehydration, or prolonged physical exertion, or the changes may be indicative of more serious conditions, such as infection or hyperthermia, which pose significant maternal and fetal risk. Therefore, measurement of body temperature is a required standard of practice in obstetric settings (ACOG, 1992; NAACOG, 1991).

Presently, the most common routes of temperature measurement in obstetric settings are oral and axillary, with a recent impetus toward using ear-based or "tympanic" temperatures due to the reported advantages of increased comfort, speed, and accuracy in reflecting core temperature non-invasively. However, many factors may affect the accuracy of temperature measurement during labor and must be taken into consideration when making treatment decisions.

Numerous studies have reported that hyperventilation, oral intake, oxygen administration, and mouth breathing may alter oral temperatures, while excessive perspiration or changes in environmental temperature can affect axillary temperatures. Considerable research has supported the use of the tympanic route for temperature measurement in pediatric, perioperative, intensive care and emergency department settings, however, there is little research comparing temperature sites in women during labor. Considering the significance of accurate temperature monitoring, the potential inaccuracies of oral and axillary routes, and the lack of research on temperature measurement in the obstetric population, it is important to evaluate the measurement of tympanic, oral, and axillary temperature in the obstetric population.

Purpose of the Study

The purpose of this study was to compare tympanic, oral, and axillary temperature measurements in women during labor. This comparison established a clinical basis of information to facilitate the evaluation and interpretation of temperature measurements in women during labor.

Review of the Literature

Previous Studies

Considerable research has focused on determining the most accurate routes for measuring core temperature in different patient populations. Pulmonary artery, bladder, rectal, and esophageal sites have been considered the most accurate reflections of core temperature, however, these methods are invasive, costly, and not practical for routine use in most clinical settings. Oral, axillary, and tympanic routes have been compared to other core sites with conflicting findings noted.

Oral temperatures were found to be moderately to highly correlated with pulmonary artery temperatures (r = 0.46 to 0.98) in several studies (Audiss et al., 1989; Laurent, 1979; Raulerson, 1982). Durham et al. (1986) and Tandberg and Sklar (1983) noted significant effects of tachypnea and mouth breathing on oral temperatures in patients seen in an emergency department and medical intensive care unit.

Conflicting results were noted in several studies comparing axillary temperatures to pulmonary artery measurements. Giuffre et al. (1990) and Fullbrook (1992) noted high correlations between axillary and pulmonary artery temperatures with mean differences of ±0.19°C to 0.33°C, while Cork et al. (1983) and Erickson and Meyer (1994) noted significant differences between the two methods.

Early tympanic thermometry for body temperature measurement used probes that were in direct contact with the tympanic membrane which posed a significant risk of injury, discomfort, and infection (Williams & Thompson, 1948). Benzinger (1969) and Baker et al. (1972) pioneered early studies supporting the use of tympanic membrane temperatures as accurate reflections of hypothalamic temperature.

In more recent studies, tympanic temperature, as measured with non-invasive infrared sensing instruments, was compared to pulmonary artery temperatures and found to be highly correlated in surgical and intensive care patients (Erickson & Kirklin, 1993; Erickson & Meyer, 1994; Erickson & Yount, 1991; Ferrara-Love, 1991; Shinozaki et al., 1988; Summers, 1991). Nierman (1991) reported a mean difference between tympanic and pulmonary artery temperatures of -0.38°C whereas Erickson and Meyer (1994) noted a mean difference of 0.07°C.

Overall review of the literature supports the measurement of tympanic temperature as an accurate reflection of core temperature as compared with esophageal, bladder, and pulmonary artery temperatures in perioperative and intensive care populations. However, comprehensive review of the literature was unable to locate any research studies that compared tympanic, oral, and axillary temperatures in the labor and delivery setting, thus supporting the need for this type of research study.

Theoretical Rationale

Body temperature reflects the balance of heat production and heat loss within the human body and is regulated by feedback mechanisms operating through the hypothalamus (Ganong, 1989; Marieb, 1989). Core temperature is that of the cranial cavity, abdominal organs, and deep tissues and remains relatively constant. However, a thermal gradient exists throughout the body, with temperature being lowest at the periphery where most body heat is dissipated (Ganong, 1989; Schoenbaum & Lomax, 1990).

During pregnancy, heat production increases by up to 35 percent due to hormonal, metabolic, and physiological changes, such as increased muscle mass and fetal-placental heat dissipation (Blackburn & Loper, 1992). Additional temperature elevations are noted during labor with an increase in metabolic and physical activity. Consequently, an elevated temperature related to illness, infection, or excessive activity may reduce maternal heat dissipating capacity resulting in potential risk to herself and the fetus (Blackburn & Loper, 1992; Mittelmark et al., 1991).

Research Question

This study was designed to investigate the relationship between tympanic, oral, and axillary temperature measurements in women during labor. The research question stated, "What is the relationship between tympanic, oral, and axillary temperature measurements in women during labor?" More specifically, the study examined the variability within tympanic, oral, and axillary temperature measurements obtained in women during labor, the relationship between paired temperature measurements of tympanic-oral, tympanic-axillary, and oral-axillary in women during labor, and the level of agreement between paired temperature measurements of tympanic-oral, tympanic-axillary, oral-axillary.

Review of Design, Setting, Subjects, and Procedures

A prospective, descriptive design was used to examine the relationship between tympanic, oral, and axillary temperatures in women during labor. The location of the study was a military medical center located in the midwestern United States. The subjects comprised a convenience sample of 30 afebrile women between the ages of 18 to 37, who had uncomplicated pregnancies, no recent history of ear infection or trauma, and were admitted to the medical center in active labor as determined by the attending nurse or physician.

Tympanic, oral, and axillary temperatures were measured simultaneously five times within an hour on each woman during labor; twice initially, allowing approximately 30 seconds for the thermometers to reset, followed by three more measurements 15 minutes apart. The FirstTemp Genius® tympanic thermometer (Model 3000A, IMS, Carlsbad, CA) was used to measure tympanic temperatures and Dinamapp™ Vital Signs Monitors (Model 8100T, Critikon, Tampa, FL) were used for oral and axillary temperature measurement. All instruments were tested for accuracy in a water bath before the study, weekly during data collection, and immediately upon completion of the study and all instruments were within ASTM specifications.

Review of Data Analysis and Results

The temperature data were analyzed in several ways to address the research question, "What is the relationship between tympanic, oral, and axillary temperature measurements in women during labor." Repeated measures analysis of variance showed no statistically significant variation in temperature over the five measurement times for all three temperature methods (F = 0.34 to 0.73, p>.05), suggesting relative stability over this measurement period. Differences between paired temperature measurements, specifically tympanic-oral, tympanic-axillary, and oral-axillary, were calculated and tympanic temperature were found to be approximately 1°F (1.09°F) higher than oral temperatures and 2°F (1.89°F) higher than axillary temperatures in women during labor.

Additional Analysis

Correlation results between paired temperature measurements, using the Pearson Product Moment test, were fair to moderate (r = 0.34 to 0.52) and paired t-test findings indicated significant differences between all pairs (t = 14.74 to 30.99, p<.05). In addition, none of the paired temperature measurement differences fell within the limits of agreement, defined as two standard deviations above and below the mean difference (Bland & Altman, 1986), suggesting significant variability between the paired methods when measured in this sample of women during labor.

Additional analysis of the data included the comparison of tympanic (oral-equivalent) temperature measurements to oral temperatures, assessment of repeatability within each method, and evaluation of temperature differences in the presence of certain labor conditions. Tympanic temperatures were calculated from core equivalent values to oral equivalent values by subtracting the numerical offset of 0.8°F (Kaiser, 1994). Comparison of these tympanic-oral equivalent temperatures and actual oral temperature measurements resulted in a mean difference of 0.24°F and statistical significance ($\underline{t}$ = 5.20, $\underline{p}$<.05) between the measurements, although the difference may be clinically insignificant. These findings may indicate that the specific mathematical oral offset used in the tympanic thermometer may not reflect the oral differences in women during labor and should be taken into consideration when evaluating temperature measurements obtained in the oral-equivalent mode.

Repeatability of temperature measurements was assessed by comparing the first and second measurements for each temperature method, as they were obtained within 30 seconds of each other. High correlations were noted for all three methods ($\underline{r}$ = 0.84 to 0.97). Ninety-six percent of tympanic measurements fell within the limits of agreement suggesting relative reliability and stability of this method in women during labor, while only 93% of the oral and axillary measurements were within the limits.

Results of the analysis of variance between temperatures of women who had certain labor conditions showed no significant differences between tympanic, oral, and axillary temperatures in women with ruptured membranes or who had received analgesics intravenously. Axillary temperatures were lower in women who received epidural anesthesia or pitocin, while both oral and axillary measurements were higher in women who used mouth breathing during labor. Tympanic, oral, and axillary temperatures were lower with oxygen administration by face mask.

Conclusion and Implications

Temperature measurement in women during labor is an essential aspect of nursing care upon which many important clinical decisions and interventions are based. The purpose of this investigation was to describe the relationship of tympanic, oral, and axillary temperature methods in women during labor. The results of this study provide a basis upon which to evaluate temperature measurements obtained in this population of patients.

Interpretation of the overall findings suggest that tympanic temperature measurements were less variable than either oral or axillary when compared in women during labor. The tympanic site was faster and less intrusive in measuring temperature in this sample of women during labor and should be considered for use in obstetric settings.

Comparison of the differences between paired measurements demonstrated considerable variation in agreement. However, it is questionable whether these three sites can be compared for absolute agreement in women during labor when they may be affected differently by physiological changes during labor. It is also necessary for clinicians to decide how much variability is clinically significant in particular settings, such as one providing care for low-risk versus high-risk women during labor.

Variations in the findings of this study can be attributed to several factors which should be taken into consideration when obtaining temperatures in women during labor and especially before making treatment decisions based on specific temperature measurements. The most significant factor affecting temperature measurement is the effect of physiological responses to the labor process on the different temperature sites, including hyperventilation, mouth breathing, sweating, and increased muscular activity. Other factors include variations in measurement technique, equipment differences, or specific effects at the particular sites, including cooling of the involved tissue due to a "draw-down" effect from repeated measurements or due to exposure to the environment.

The small convenience sample of women used in this study limits the generalizability of the findings to women in active labor with similar demographic and labor characteristics who receive care in a medical facility with similar policies, procedures, and equipment. Since another core temperature method was not used as a reference, the researcher was not able to make any absolute conclusions regarding the accuracy of the three temperature methods. Inability to control for the physiological responses of labor also limited the interpretation of these findings to this population of patients.

Recommendations for Further Study

Implications for further research include replication of this study using a larger sample in different labor settings to determine if the findings of this investigation are supported. Future replications might also include obtaining more than five temperature measurements over a longer period of time, using different thermometers, or even monitoring temperatures during the second stage of labor.

Women with complicated or high-risk pregnancies should also be included in future research studies to establish a basis for interpretation of temperatures in this population of obstetric women. Comparison of tympanic, oral, and axillary temperatures against another core temperature, such as a pulmonary artery catheter, would be beneficial for determining the accuracy of these routes in reflecting core temperature changes.

A quasi-experimental design could be used to investigate the difference in temperature between various labor conditions, such as in women who use open versus closed mouth breathing or those receiving oxygen versus no oxygen. Continuous monitoring of axillary temperatures versus intermittent measurements are recommended to decrease the effect of environmental exposure on the axilla. And finally, it would be of interest to measure tympanic and oral temperatures throughout the course of labor to evaluate more long-term responses to various labor conditions.

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APPENDIX A

INFORMED CONSENT STATEMENT

INFORMED CONSENT STATEMENT

A COMPARISON OF TYMPANIC, ORAL, AND AXILLARY TEMPERATURE MEASUREMENT IN WOMEN DURING ACTIVE LABOR

I. INTRODUCTORY PARAGRAPH

Before agreeing to participate in this study, it is important that the following explanation of the proposed procedures be read and understood. It describes the purpose, procedures, benefits, risks, discomforts, and precautions of the study. It also describes alternative procedures available and the right to withdraw from the study at any time. It is important to understand that no guarantee or assurance can be made as to the results. It is also understood that refusal to participate in this study will not influence standard treatment for the subject.

II. OBJECTIVES OF THE STUDY

I __________________________, agree to participate in a research study, the purpose of which is to compare three methods of temperature measurement to examine what the relationship is between them in a woman experiencing labor. I understand that correct (and comfortable) temperature measurement during labor is important for ensuring the health of both mom and baby.

III. PROCEDURES

I will be participating in this study for approximately one hour during my labor. If there is significant variance from the stated time period, I will be notified. I will have my body temperature measured by mouth (orally), in my external ear canal (tympanic), and under my arm (axillary) five separate times, twice initially and then three times every 15 minutes for a total of approximately one hour; an explanation and demonstration of temperature monitoring at each site will be given if I feel this is necessary prior to agreeing to participate. I will not be allowed to eat or drink anything during this period as it may affect temperature readings. This study will benefit me by validating my body temperature during this time period with several different measurements, but the ultimate benefit will be additional information available to health care providers about temperature measurement in women during labor. If I refuse or withdraw from participation, the standard method of temperature measurement utilized by the Labor and Delivery Unit will be performed by the staff and I will not be treated any differently.

IV. RISKS

I understand that temperature monitoring is a routine assessment performed during labor and that the risks involved in this study are the same that each patient in the hospital is subjected to with routine temperature assessment. These risks are minimal but include potential injury to the mouth, ear canal, or axilla and a potential for infection related to an injury in these areas. I understand that participation in the study may also involve risks which are currently unforeseeable. If I or my baby develop any complications during labor, I may also be excluded from the study.

V. <u>PREGNANCY</u>

There is no unusual risk to me or my fetus by participation in this study.

VI. <u>CONFIDENTIALITY OF RECORDS</u>

My name will not appear anywhere in this study. A subject number will be assigned to the data collected about me and my name will not appear in any data released by the researcher. The researcher is the only person who will have access to my identifying information. Other information such as my age, length of my pregnancy, and other information (oxygen administration, anesthesia, etc) may also be recorded for statistical purposes.

VII. <u>AVAILABILITY OF INFORMATION</u>

Any questions that I may have concerning any aspect of this investigation will be answered by **Captain Nancy Dezell, USAF, NC, (513) 748-0195.**

VIII. <u>COMPENSATION</u>

The Medical Center follows a policy of making all decisions concerning compensation and medical treatment for injuries occurring during or caused by participation in biomedical or behavioral research on an individual basis. If I believe I have been injured as a result of research, I will contact Captain Dezell.

IX. FISCAL RESPONSIBILITY

Tests, procedures, or other costs incurred solely for purposes of research will not be my financial responsibility. If I have questions about this I may contact Captain Dezell.

X. THE RIGHT TO WITHDRAW

"I am free to withdraw from this investigation at any time. Should I wish to withdraw, I have been assured that standard therapy for my condition will remain available to me. I have been informed of any probable consequences of my withdrawal from the study."

XI. IS THE SUBJECT CURRENTLY PARTICIPATING IN ANOTHER STUDY?

______ Yes. If yes, please provide the principle investigators's name and title of the study.

______ No.

XII. WITNESSING AND SIGNATURES

Subject's Signature Indicating Assent ______ Date ______

☐ CHECK BOX IF VERBAL ASSENT OBTAINED BY INVESTIGATOR

Legal Representative/Parent ______ Date ______

Investigator ______ Date ______

Witness ______ Date ______

APPENDIX B

INSTITUTIONAL REVIEW BOARD APPROVALS:

UNIVERSITY OF CINCINNATI

HOSPITAL

University of Cincinnati
Medical Center

College of Nursing and Health
William Cooper Procter Hall
Cincinnati, Ohio 45221-0038

August 3, 1993

To: Nancy Dezell

From: Carol Deets, EdD, RN
Chair, Nursing Research and Human Subjects Committee

RE:#93-7-9-SP "Comparison of Tympanic, Oral, and Axillary Temperature in Women During Labor"

Upon careful review of your protocol the Committee has decided to award you unconditional approval of your protocol. If you should have any questions or comments please feel free to contact me.

cc: Gunderson
Kenner
Weitkamp

DEPARTMENT OF THE AIR FORCE
HEADQUARTERS AIR FORCE MATERIEL COMMAND
WRIGHT-PATTERSON AIR FORCE BASE, OHIO

14 September 1993

645th Medical Group/SGE
Clinical Investigations Office
4881 Sugar Maple Drive
Wright Patterson AFB OH 45433-5529

Capt Nancy Dezell
125 Tanglewood Drive
Springboro OH 45066

Dear Capt Dezell

Your Clinical Investigation protocol, "Comparison of Tympanic, Oral, and Axillary Temperature Measurement in Women During Labor," was reviewed by the Institutional Review Board of Wright-Patterson Medical Center on 13 September 1994. The following action was taken by the committee:

> Your protocol was determined to be an exempt study under AFR 169-6 and MCR 169-2. The committee approved your study unconditionally and you may proceed as outlined. If the nature or scope of your study changes, you must advise this office to make sure that further review is not required. If your study leads to an article or abstract for publication or presentation, the article must be submitted to SGE (Medical Education) for approval IAW AFR 190-1 and MCR 190-2.

If you have any questions, please call the Clinical Investigations Office at 74242.

Sincerely,

Cherie Miller

CHERIE MILLER
Clinical Investigations Coordinator

PAUL R. GLOWIENKA, Lt Col, USAF, MC
Chair, Institutional Review Board

APPENDIX C

INFORMATIONAL RECRUITMENT FLYER

GREETINGS!!

I am Capt Nancy Dezell, a Registered Nurse, and I will be conducting a research study in the labor and delivery unit at this medical center to compare three methods of temperature measurement on women during labor, namely temperature in the mouth (oral), under the arm (axillary), and in the outer ear (tympanic). Correct temperature measurement during labor is very important to help ensure the health of both you and your baby. Thus the goal of this study is to evaluate the temperature methods most commonly used during labor to provide important information about these temperature measurements for your health care providers.

Your ear temperature can be taken in about 2 seconds and is not affected by mouth breathing, taking ice or water by mouth, or sweating as are oral and axillary temperatures. It has been the method preferred in many health care areas and is used on the Labor & Delivery Unit here at Wright-Patterson Medical Center.

You may be invited to participate in the study if you come to the hospital in labor in late November or December, unless you have certain pregnancy complications (such as preterm labor or infection) or if the OB provider does not permit it. A copy of the Consent Form is attached for your review so that you will be aware of the study before coming to the hospital in labor. With your permission, the temperature measurements will be taken just 5 times from your mouth, ear, and under your arm. Each measurement will take just a few minutes of your time and less than 1 hour overall. Your participation will not interfere at all with your medical care during labor and you have every right to refuse to participate or to stop participating at any time during the study. Please feel free to call me at 748-0195 if you have any questions.

Thank you!

NANCY A. DEZELL, CAPT, USAF, NC

APPENDIX D

DATA COLLECTION TOOL

SUBJECT DATA COLLECTION TOOL

SUBJECT #__________ DATE OF DATA COLLECTION:_______________

AGE:__________ GRAVIDA:________ PARA:__________

CERVICAL DILATATION:___________ FREQUENCY OF UCS:__________

ADMITTING TEMPERATURE:__________ GESTATION:_____________

TYPE OF BREATHING: OPEN MOUTH NOSE

STATUS OF MEMBRANES: INTACT RUPTURED (TIME:______)

OXYGEN ADMINISTRATION: _________ LITERS/MIN MASK NC

TYPE OF ANALGESIA OR ANESTHESIA:_______________________

IV SITE (EXTREMITY): RIGHT LEFT ; INFUSION HEPLOCK

SIDE TEMPS TAKEN: RIGHT LEFT

TEMPERATURE MEASUREMENTS: DINAMAPP #s:________

TIMING	TYMPANIC	ORAL	AXILLARY
(1) Initial			
(2) Repeat			
(3) 15 minutes			
(4) 30 minutes			
(5) 45 minutes			

CALIBRATION (3 Temps): LOW:______________ CONTROL:_______
HIGH:______________ CONTROL:_______

APPENDIX E

PROCEDURE FOR PERFORMING TYMPANIC TEMPERATURE MEASUREMENT

PROCEDURE FOR PERFORMING TYMPANIC TEMPERATURE MEASUREMENT

Tympanic temperature will be measured with a FirstTemp Genius® infrared thermometer (Model 3000A, Intelligent Medical Systems, Carlsbad, CA) using the tympanic mode in its core setting according to manufacturers instructions as follows:

1. Remove probe from the base unit by lifting firmly near the RELEASE button.
2. Note equivalence setting on display: Core, Rectal, Calibrate. Select CORE.
3. Select TYMPANIC mode by pressing the MODE button (if tympanic not already displayed).
4. Place a disposable cover on the probe tip.
5. Place the probe in the ear canal (same side as the oral and axillary temperature measurements);seal the opening.
6. Press and release the SCAN button.
7. Remove probe from the ear as soon as triple beep tones are heard and display flashes DONE (about 2 seconds).
8. Press blue RELEASE button to discard the probe cover.
9. Return probe to base unit for storage and recharging.
10. Record temperature in Fahrenheit on Data Collection Tool
11. Repeat this procedure simultaneously with oral and axillary measurements every 15 minutes for a total of five measurements.
12. Refer to the Operation Manual for interpretation of any displays other than as described above.

APPENDIX F

PROCEDURE FOR PERFORMING ORAL TEMPERATURE MEASUREMENT

PROCEDURE FOR PERFORMING ORAL TEMPERATURE MEASUREMENT

Oral temperature will be measured with the predictive temperature probe from the Dinamapp™ Vital Signs Monitor (Model 8100T, Critikon, Tampa, FL) set on the NORMAL mode as follows:

1. Assure that a blue temperature probe assembly is connected to the Dinamapp™ Vital Signs Monitor.
2. Place a disposable plastic cover over the probe tip.
3. Ask the subject to open her mouth and slowly insert the probe under the tongue into the deep sublingual pocket on the same side as the tympanic and axillary measurements. Ask the subject to close her lips, not her teeth, tightly around the probe.
4. Press the START button; a short beep will sound and a series of dashes will appear in the TEMPERATURE display as the temperature is measured (about 20 to 30 seconds).
5. Hold the probe steady until a double beep is heard.
6. Remove the probe, discard the cover by pressing the button on the handle.
7. Record temperature in Fahrenheit and the number of the Dinamapp™ Monitor on the Data Collection Tool.
8. Repeat this procedure simultaneously with tympanic and axillary measurements every 15 minutes for a total of five measurements.
9. Refer to the Operation Manual for interpretation of any displays other than as described above.

APPENDIX G

PROCEDURE FOR PERFORMING AXILLARY TEMPERATURE MEASUREMENT

PROCEDURE FOR PERFORMING AXILLARY TEMPERATURE MEASUREMENT

Axillary temperature will be measured with the predictive temperature probe from the Dinamapp™ Vital Signs Monitor (Model 8100T, Critikon, Tampa, FL) set on the NORMAL mode as follows:

1. Assure that a blue temperature probe assembly is connected to the Dinamapp™ Vital Signs Monitor.
2. Place a disposable plastic cover over the probe tip.
3. Abduct the arm on the same side as the tympanic and oral temperature measurements. Pat dry any excess moisture as this might affect temperature measurement (Kozier & Erb, 1989).
4. Place temperature probe high in axilla and assist patient to hold arm tightly to her body to hold thermometer in place.
5. Press the START button; a short beep will sound and a series of dashes will appear in the TEMPERATURE display as the temperature is measured (about 20 to 30 seconds).
6. Hold the probe steady until a double beep is heard.
7. Remove the probe, discard the cover.
8. Record temperature in Fahrenheit on and the number of the Dinamapp™ thermometer on the Data Collection Tool.
9. Repeat this procedure simultaneously with tympanic and oral measurements every 15 minutes for a total of five.
10. Refer to the Operation Manual for interpretation of any displays other than as described above.