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**A STUDY OF VAGINAL BLEEDING
DURING FIRST TRIMESTER AND PREGNANCY OUTCOME**

A Thesis

Presented to

The Faculty of the Department of Nursing

San Jose State University

In Partial Fulfillment

of the Requirements for the Degree

Master of Science

By

Theresa Pittman

December 1994

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ABSTRACT

A STUDY OF VAGINAL BLEEDING DURING FIRST TRIMESTER AND PREGNANCY OUTCOME

By Theresa Pittman

This thesis investigated the relationship between first trimester vaginal bleeding and the outcome of the pregnancies in a population of previously infertile couples (N = 120). Utilizing a nonexperimental design, data were collected retrospectively from an infertility practice in Northern California.

Descriptive statistics were used to categorize the type of vaginal bleeding as (a) none, (b) spotting, (c) moderate, or (d) heavy. The pregnancy outcome was categorized as (a) viable delivery or (b) nonviable delivery. Data showed that women who had spotting had about equal chances of a viable versus nonviable outcome of the pregnancy. As the amount of bleeding increased, there was a trend towards an adverse outcome of pregnancy. Review of the findings generated recommendations for patient teaching and further study.

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To the graduate
faculty and students for
scholastic instruction
and guidance
and
to my husband and daughters
for all of the
sacrifices they made while
I sat at the computer every evening.

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Chapter 1

INTRODUCTION

The occurrence of vaginal bleeding in the first trimester often causes anxiety about the outcome of the pregnancy for the infertile couple. However, vaginal bleeding during the first trimester of pregnancy is a common occurrence (Goldman et al., 1988; Stabile, 1992). Approximately one third of first trimester bleeding happens in pregnancies that are otherwise normal (Yazigi, Saunders, & Gast, 1991). Additionally, no anatomical cause can be established in the vast majority of the pregnancies that are complicated by vaginal bleeding (Williams, Goldman, Mittendorf, Lieberman, & Monson, 1991). Half of the women who experience first trimester vaginal bleeding will continue their pregnancies, and the other half will experience an abortion (Kutteh & Carr, 1993). When bleeding results in a loss of a pregnancy, it usually represents a significant emotional disruption in a woman's life. Despite the outcome of the pregnancy, bleeding during pregnancy is alarming.

Pregnancy is always a significant event in a woman's life. When pregnancy occurs after infertility and its treatment, the emotional impact of success is complex and intense. Although fertility has been established, the patient still considers herself an infertility patient and is often labeled by providers as an infertility patient as well. This infertility patient is then faced with extraordinary anguish when vaginal bleeding accompanies her pregnancy. The emotional consequences of vaginal bleeding in the first trimester can represent threatened loss for many women. Bleeding creates an added burden of anxiety to the emotional one created by many months or years of attempting to begin

a pregnancy with infertility treatment. Appropriate counseling regarding bleeding in early pregnancy and the relationship to the possible outcome of that pregnancy could alleviate anxiety and assist previously infertile couples in coping with the possible consequences.

Problem Area

Vaginal bleeding in the first trimester is usually considered a relatively minor problem among ordinary obstetrical clients. After the onset of vaginal bleeding, there seems to be little that can be done to influence the outcome (Tippet, Jewell, Masson, & Elphinstone, 1989). The incidence of abortion varies in the literature from 15% to 40%, depending on the study (Yazigi et al., 1991). Of those pregnant women who have spotting in early pregnancy, 50% progress to term (Kutteh & Carr, 1993). Chromosomal abnormalities have been reported in 97% of first trimester spontaneous abortions; therefore, the abortions cannot be prevented or predicted (Stirrat, 1990).

When blood loss is not sufficient to rate an emergency, vaginal bleeding in the first trimester is usually not considered to be life threatening to the mother, and treatment is relatively uncomplicated. The treatment is often observation of symptoms by the patient and provider. There is nothing to suggest that hospital admission has any beneficial effect on either immediate or long term prognosis (Tippet et al., 1989).

The source of vaginal bleeding in early pregnancy has been examined by many medical specialties. Epidemiology (Stirrat, 1990), genetics (Drugan et al., 1990), pathology (Yazigi et al., 1991), reproductive endocrinology (Ninia, 1994), and immunology (Kutteh & Carr, 1993) have all examined this enigma. Regardless of the clinical and basic research, the causes of vaginal bleeding during the first trimester are

poorly understood. Despite the origin, bleeding in early pregnancy is often an indication of poor fetal and infant outcome even if the course of the pregnancy does not appear to be disturbed at the time (Williams, Goldman, Mittendorf, Lieberman, & Monson, 1991). Initially medical treatment can be straightforward with observation of the bleeding reported by the patient on an outpatient basis, then implementation of limited activity or bedrest for some cases. Furthermore, medical and pharmacology technologies have allowed the provider other treatment modalities. The use of sensitive serum assays and hormone supplementation have frequently aided in the alleviation of this bleeding (Yazigi et al., 1991). Despite these advances within the specialty of an infertility practice, bleeding in early pregnancy may be a sign of a significant reproductive failure (Bohrer & Kemmann, 1987; Mishell & Brenner, 1988).

Purpose and Need for the Study

The physiological conditions for fertility are quite complex. They involve very specific interrelationships of various organs and hormones for both male and female. Male fertility requires production of normal sperm in sufficient numbers and with sufficient motility. Problems may be found in areas of (a) sperm production, (b) transportation, (c) composition of seminal plasma, or (d) genital infections. Treatment methods for male infertility are relatively unsophisticated and frustrating for the infertile couple (Newton & Houle, 1993).

The conditions for female fertility include proper functioning and coordination of physiological changes in the (a) ovaries, (b) vagina, (c) uterus, and (d) fallopian tubes, as well as adequate production of hormones from the pituitary gland and hypothalamus (Yen

& Jaffe, 1991). The female reproductive system, therefore, is complex and has received more attention in an infertility evaluation than treatment for the male. Infertility treatment for women is more intensely involved in the diagnosis and the management process. Therefore, for each couple, infertility is a complex and painful adjustment, beginning with the decision to seek diagnosis, continuing through the treatment, and hopefully resulting in a pregnancy.

Research has addressed the psychosocial reaction of couples to infertility and treatment (Newton & Houle, 1993). As mentioned earlier, infertility has a major impact on a couple's life. Insecurity, aggressive and anxious behaviors, and an increase in neuroses are just a few of the responses that have been reported (Bernstein, Mattox, & Kellner, 1988). Olshansky (1988) described the work to correct infertility for couples as exacerbated cycles of hope and desperation. They have despair when treatments fail month after month, cycle after cycle. In addition to this stress and anxiety, couples who go on to lose their pregnancy only suffer more distress.

Infertile patients become fastidious observers of their menstrual cycles. The delayed menstrual period and subsequent positive pregnancy test may prompt an intense and sometimes distressing emotional reaction. Most often, the woman may have difficulty seeing herself as a normal pregnant woman (Black & Greenfeld, 1993). The pregnancy alone is often accompanied by a sense of anxiety secondary to feelings of an inadequate reproductive mechanism.

Vaginal bleeding in early pregnancy for the infertile patient evokes feelings of shock, disorganization, and guilt (Black & Greenfeld, 1993). There are reports of a

threefold increase in depression symptoms following an abortion (Neugebauer, Kline, & Susser, 1992). Poor overall physical health, weight gain, and unsatisfactory marital relationships are also created as a result of the loss (Toedter, Lasker, & Alhadeff, 1988).

Education may contribute a preventive component to prenatal anxiety by providing couples with information about normal reactions to bleeding with the potential for a pregnancy loss. The high rate of positive pregnancy outcomes, despite bleeding episodes, may be important for these couples.

The purpose of this study is to investigate the relationship between first trimester vaginal bleeding and the outcome of the pregnancies in a population of previously infertile couples. The goal of these findings is to provide information for more appropriate counseling for infertile couples. Information from the study may enable infertile clients to improve coping skills throughout the experience of vaginal bleeding in pregnancy.

Research Question

The research question for this study is as follows: Is there a relationship between first trimester bleeding and pregnancy outcome among infertile couples? The variables of this retrospective study are vaginal bleeding and outcome of pregnancy.

Definitions of Terms

For the purpose of this study, the following definitions are taken from Current Obstetric and Gynecologic Diagnosis and Treatment by Pernoll and Benson (1987):

1. Infertile patient is one who fails to achieve a pregnancy within 1 year of unprotected intercourse.

2. Spotting is bleeding reported by the patient as scant or traces of blood and visualized by the provider as scant blood or no blood in the vagina or the cervix.
3. Light bleeding is reported by the patient as “like a menses.” It is visualized by the provider as a small amount of blood in the vagina and at the cervix.
4. Heavy bleeding is reported by the patient as “more than a menses.” It is visualized by the provider as a moderate to heavy amount of blood in the vagina and at the cervix.
5. Normal term is a pregnancy that is greater than or equal to 36 weeks gestation.
6. Abortion is the spontaneous loss of a pregnancy before the fetus is viable. This includes the terms spontaneous abortion, missed abortion, and incomplete abortion. This term does not include therapeutic abortion.
7. Spontaneous abortion is defined as a birth process terminating before the 20th week of gestation. It implies the expulsion of all or any part of the placenta or membranes with or without an identifiable fetus.
8. Missed abortion is the identification of a pregnancy failure before the spontaneous expulsion of the fetal and placental tissues.
9. Incomplete abortion is the finding of a dilated cervix with or without retained products of conception.
10. Threatened abortion is vaginal bleeding prior to 28 weeks of gestation.
11. Therapeutic abortion is the intentional termination of a pregnancy.
12. Low birth weight (LBW) deliveries are those in which the newborn weighs less than 2500 grams.

13. Preterm deliveries are those that are less than 36 weeks of gestation as measured by day of ovulation.
14. Growth retardation at term are those pregnancies that are less than 36 weeks gestation and with a weight at birth of less than 2500 grams.
15. Perinatal deaths are considered stillbirths and neonatal deaths during the first 6 days of life.
16. Male factor is a deficiency in sperm production.

Summary

The causes and complications of first trimester vaginal bleeding are poorly understood. Because poor fetal and infant outcome has been associated with bleeding in many cases, any bleeding during pregnancy may cause anxiety to the pregnant infertility couple. If research could establish that there is no relationship between first trimester vaginal bleeding and an adverse pregnancy outcome, the information could be used during prenatal counseling to decrease anxiety for the pregnant couple. This research investigated a relationship between vaginal bleeding and pregnancy outcome.

Chapter 2

CONCEPTUAL FRAMEWORK AND REVIEW OF LITERATURE

Review of Literature

Pregnancy is a psychologically significant event, but it is additionally momentous for the infertile couple who has had difficulty conceiving. A pregnancy conceived and then complicated by vaginal bleeding or loss, or both, may create more agony than pregnancies unattained (Jansen, 1982). The couple desires to know why and how the event transpired, whatever the outcome. Frequently, there are no answers. Although an abortion can be regarded as a positive prognosis for further pregnancies, most infertility patients are unable to see past the immediate reactions of grief and disappointment.

Few studies have shown any association between bleeding in the first trimester and outcome of the pregnancy. Strobino et al. (1986) were able to elicit a pattern of five traits that were characteristic of women who were seeking prenatal care after having had repeated abortions due to a single etiology. Five characteristics were shown to be associated with recurrent spontaneous abortion: (a) chromosomally normal karyotype of the abortus, (b) abortions that occur after the 14th week of pregnancy, (c) delay greater than 2 years in conceiving a pregnancy, (d) a diagnosis of cervical incompetence, and (e) previous premature delivery. Vaginal bleeding was not specifically addressed; however, the characteristic of delayed conception defines infertility and thus is important to the infertility patient. Delayed conception stood apart from the other factors since it

was shown to be independently related to spontaneous abortions according to Strobino et al.'s interpretation.

Williams, Goldman, Mittendorf, & Monson (1991) investigated a population of 3,622 nondiabetic married women who had planned their pregnancies. The design was a cross-sectional investigation of maternal risk factors for adverse pregnancy outcomes. Information was obtained regarding (a) reproductive and medical history, (b) antenatal care, (c) previous contraceptive practice, and (d) smoking habits. Vaginal bleeding was not considered as a variable in this study. Infertility was found to be a predictor of low birth weight deliveries. It was concluded that the association between infertility, or subfertility, and low birth weight may result from endocrinological, immunological, cervical, or other factors that interfere with optimal fetal growth.

One of the early original studies by Hack, Brish, Serr, Insler, and Lunenfeld (1970) assessed the outcome of pregnancies following ovulation induced by menotropins and chorionic gonadotropin. They reviewed 78 pregnancies and found that a high abortion rate (29%) and high fetal and neonatal loss (27%) accompany a high multiple pregnancy rate (39.7%) and prematurity rate. Despite these findings, the researchers were able to demonstrate a normal postnatal development of babies born after the treatment with menotropins and chorionic gonadotropin.

Berkowitz, Harlap, Beck, Freeman, and Baras (1983) explored the significance of vaginal bleeding in both the first and second trimesters within a fertile population. They observed a positive association between first trimester bleeding and low birth weight

(LBW) among mothers who had not been treated with hormones for bleeding. Preterm delivery and LBW also occurred significantly more frequently among mothers who had not been treated with hormones for the bleeding than those who had been treated with hormones.

Batzofin, Fielding, and Friedman (1984) suggested that the greatest risk to the pregnancy complicated by vaginal bleeding before 20 weeks was a premature delivery which was defined as a gestation less than 37 weeks. The authors examined 7,486 women who had delivered at a Boston, Massachusetts, hospital. This factor alone, according to their research among a population of normal pregnant women, could be responsible for other findings including (a) LBW, (b) depressed Apgar scores, and (c) increased perinatal mortality.

Strobino and Pantel-Silverman (1989) examined a sample of women that were not specifically infertile. They reported that light bleeding during pregnancy was not associated with LBW or preterm delivery. However, heavy bleeding was associated with an increased risk for LBW. Upon further examination, the researchers were unable to find any maternal characteristics that were predictive of bleeding.

Williams, Goldman, Mittendorf, Lieberman, and Monson (1991) assessed the association between first trimester vaginal bleeding and single infant outcomes in a routine population of pregnant women. LBW, preterm delivery, and neonatal death occurred more often in those women who reported first trimester bleeding. The data analyses demonstrated that these women had double the risk of delivery of a preterm infant

compared with those who experienced no bleeding. Their research illustrated that first trimester vaginal bleeding is an important predictor of adverse fetal outcomes.

An abnormal progesterone level in the first trimester has been shown to be predictive of gestational pathology. The normal plasma levels for progesterone during the first trimester of pregnancy range between 20-30 ng/ml (Speroff, Glass, & Kase, 1984). Both the studies by Cunningham, Brodnik, Rayl, Brown, and Hansen (1993) and Mathews, Coulson, and Wild (1986) had data illustrating that values less than 10 ng/ml were generally incompatible with a normal gestation. They were able to show that a low progesterone level predicts an unfavorable outcome in the presence of vaginal bleeding. It was also notable that the researchers suggested that a single biochemical test would never be absolutely predictive of pathologic gestation in part due to (a) population differences, (b) laboratory variations, and (c) fluctuations in steroid secretions. Despite these studies, an ideal progesterone value during the first trimester of pregnancy has not been consistent in illustrating a problem pregnancy (Buck, Joubert, Friedman, & Gradstein, 1982).

Many forms of infertility treatment have demonstrated an increased risk of abortion among the pregnancies that occur. The increased risk may be due to a partially treated reproductive problem or due to the treatment itself. Unfortunately, few studies have shown any association between bleeding in the first trimester of pregnancy and outcome in an infertile population. The summarized studies have illustrated an association between bleeding in early pregnancy and gestational complications with a sample from women in the general population. Findings are inconsistent. Studies done on a normal

pregnant population have shown an association between bleeding in early pregnancy and an unfavorable outcome. This may be useful in detecting pregnancies at risk (Strobino & Pantel-Silverman, 1989; Williams, Goldman, Mittendorf, & Monson, 1991). However, most studies have investigated this incidence in fertile women. There appears to be a lack of literature examining an infertile population. First trimester vaginal bleeding could possibly have a role as a predictor of pregnancy outcome in the infertile couple.

Conceptual Framework

Malcolm Knowles' adult learning theory was selected as the conceptual framework for this study. Knowles (1990), one of the modern theorists, believed that adults are motivated to learn if this learning fulfills their needs. Adult learning is life-centered, hence, learning should be realistic and appropriate to real life situations.

Learning is a process of active inquiry, not a passive encounter (Knowles, 1990). Most patients are motivated to learn especially if it fulfills their needs. The more mature learner is directed to learn skills for immediate application (Brunton, 1984). The patient's past experiences may be the best resource for their learning. Adults have a desire to be self-directing; therefore, the function of any teacher should be to facilitate learning rather than direct learning (Knowles, 1990).

Nearly every aspect of health care relies heavily on educational interventions for success. Today with the upsurge of "consumer mentality," there is a desire by patients to be more assertive in the therapeutic relationship (Brunton, 1984). The traditional passive and dependent role of the patient continues to be discouraged by both patient and

provider. Despite this trend, the patient's desire for knowledge and the provider's ability to communicate information are to a large extent responsible for the degree of satisfaction and compliance that can be attained. Increased patient participation in clinical decision-making may enhance the benefits to the provider and the patient. Through this relationship, providers can assist their patients to examine more realistic expectations about the outcomes and alternatives available.

Each time a provider interacts with a patient, that provider is in a position to determine the educational approach to be used. Providers are important agents of change who have significant influence over their patients. This influence may often be the core of the patient's ability to attain and maintain health. Together both provider and patient can set mutual health goals or work towards positive health behavior. However, to become a capable teacher, the provider must recognize the learning needs of the patient and use methods that will meet the patient's needs (Brunton, 1984).

Malcolm Knowles (1990) first used the term andragogy in the 1960s. Andragogy is a student-centered theoretic basis for teaching adults. Knowles was able to illustrate that the adult learner has distinct and different learning needs than those of children. Medical educators are now suggesting that andragogy be considered in patient teaching as well because the majority of patients are adults, and because the results of research confirm the usefulness of this approach (Knowles, 1990). However, currently the educational theory most familiar to providers and the one most frequently applied with educating patients is pedagogy. Andragogy differs from pedagogy basically in its

assumption regarding the teacher-learner relationship. In the pedagogic model, the relationship between the teacher and learner is based on an authoritative expertise, such as the relationship of the parent to child. Pedagogy literally means the art and science of teaching children. The pedagogy approach was historically the only existing theoretical framework for all levels of education (Knowles, 1990). In the andragogic model, the teacher-learner relationship is one of shared participation. Andragogy is student-centered and problem oriented.

The major assumptions of Knowles' (1990) adult learning theory are based on the learner's need to know and the role of the learner's experience. The learner often does bring quite different views to the clinical encounter than those held by the teacher (Kidd, 1973). This possible tension is not necessarily undesirable and can be the basis for effective learning by both parties, the teacher and the learner. They both play a crucial role in their readiness to learn. The goal is towards doing everything possible to encourage the learners to take responsibility for their own learning.

Infertility patients are excellent examples of patients who gain from taking an active part in the provider-patient relationship. These patients generally understand their illness and participate in and adhere to their treatment regimen (Olshansky, 1988). These patients can spend anywhere from 10 to 50 hours attending clinics for tests and treatments. For each couple, because of the complexity and painful adjustments of infertility management beginning with the decision to seek medical diagnosis, they are often eager to gain any information regarding their diagnosis. Patients can acquire

knowledge through (a) books, (b) journals, (c) infertility support groups, (d) lay infertility conferences, and (e) patient education from the nurse. The high initiative of these patients in acquiring knowledge and competence makes them ready candidates for active participation in their treatment. Patients who accept and understand their illness and participate in understanding and adhering to their treatment regimen are able to make decisions that are consistent with their emotional capabilities.

According to adult learning theory, adults need their learning to be problem-centered and personalized. They are generally accepting of their need for self-direction and often take personal responsibility towards learning. Learning is a means to an end, not an end in itself. Most learners alternate between individual and social kinds of learning experience (Tough, 1971). This is especially true for the infertility patient. They come to an infertility practice with the natural instinct of procreation imposed by society and their own individual past experiences.

The goal of this research is to provide information that can be presented to the infertility patients in order to assist in decreasing their anxiety should they experience bleeding in their early pregnancy. Because Knowles' educational model is problem centered, it will build on the patient's life experience and should also aid the patient in taking an active part in the provider-patient relationship.

Chapter 3

RESEARCH DESIGN

The objective of this research was to determine if there is a relationship between vaginal bleeding in the first trimester and adverse pregnancy outcome within a sample of infertile clients. The goal of these findings was to provide information to enable suitable counseling for couples when the pregnant woman experiences early vaginal bleeding.

Design

The design of the study is nonexperimental. According to LoBiondo-Wood and Haber (1990), nonexperimental research designs may be used in studies that illustrate an image, idea, or concept as it occurs. They are often used to show a relationship. These types of design attempt to trace the interrelationships between variables. The independent variable is a history of vaginal bleeding. The dependent variable is the outcome of the pregnancy. Retrospective data from patient records were used as a source for data collection.

Sample and Setting

The study sample was drawn retrospectively from an infertility practice in Northern California from August, 1988, through November, 1993. One-hundred-twenty infertility patients, as defined by American Fertility Society standards with failure to achieve a recognized pregnancy within 1 year of unprotected intercourse, were selected for the study after a positive test for pregnancy. A control group was not utilized for this study.

Data Collection

Patients who met the criteria of (a) infertility, (b) positive pregnancy test, and (c) documented pregnancy outcome were chosen from the charts of the infertility practice. The exclusion criteria were (a) the diagnosis of male factor and (b) ectopic pregnancy.

As obtained from existing charts, the vaginal bleeding histories included the date of onset of the bleeding in days/weeks from last menstrual period and the severity of bleeding. Bleeding was categorized as spotting, moderate, or heavy. Age and underlying cause of infertility were gathered as descriptive data for the sample.

The outcome of the pregnancy was categorized as (a) terminated, (b) preterm delivery, (c) growth retardation at term, (d) congenital malformations, (e) perinatal death, or (f) normal term. These data were obtained retrospectively from the mother's hospital discharge summary found in the patient's record. Identification of the individuals in the sample was not recorded after the data were gathered for this study.

Human Subjects Approval

Human subjects approval was granted by the Institutional Review Board for Human Subjects at San Jose State University and the infertility practice. There were no benefits, anticipated risks, or compensation to any individual subject that participated in the study. The subject names were not identified since a coding system was employed.

Data Analyses

Descriptive statistics, frequencies, percentages, and means were used to describe the sample and the occurrence of the variables. Chi-square analysis was to be used to suggest whether the frequency found was different than that which would be expected by

chance. A significant chi-square would suggest that the frequencies found would not be expected by chance alone, thereby supporting the association between the two variables and answering the research question (LoBiondo-Wood & Haber, 1990). Symphony (Lotus Development Corporation, Cambridge, Massachusetts) was used for data entry and analyses. Subjects were categorized as to the type of bleeding that occurred: (a) spotting, (b) moderate, or (c) heavy. Subjects were also categorized by pregnancy outcome as (a) terminated, (b) preterm delivery, (c) growth retardation at term, (d) congenital malformations, (e) perinatal death, or (f) normal term.

Chapter 4

FINDINGS AND INTERPRETATION

This chapter is a summary of data collected to investigate first trimester vaginal bleeding and pregnancy outcome. Data from previously infertile patients were used to explore an association between vaginal bleeding in early pregnancy and an adverse pregnancy outcome.

Demographics

Demographic data included (a) age, (b) number of months of treatment before conception, (c) causes of infertility, and (d) treatment modalities for the infertility. Other demographic data on (a) marital status, (b) weight, (c) race, (d) education, or (e) occupation were not gathered because of inconsistent data in the records. Data from medical records of 120 pregnant women were entered in the study.

Table 1 shows that the age of most of the subjects was in the early 30s. There were 33 (27%) who were age 29 or under. The most common age group was 30 to 34 years at 39% ($n=47$). There were 26 (22%) between the age of 35 to 39. The least common age group was 40 years and above at 12% ($n=14$).

The length of time it took to conceive a pregnancy after seeking advice on infertility was part of the descriptive demographic data. Table 2 shows that over half of the previously infertile patients conceived within 24 months of treatment. Twenty-seven percent ($n=33$) conceived in 1 to 12 months. The most common period of time prior to conception was 13 to 24 months at 32% ($n=38$). Another 20% ($n=24$) took 25-36 months

Table 1

Subject Age Categories (N = 120)

Age Groups	Frequency	Percent
29 and under	33	27%
30-34	47	39%
35-39	26	22%
40 and above	<u>14</u>	<u>12%</u>
Total	120	100%

Table 2

Number of Months to Conceive (N = 120)

Months	Frequency	Percent
1-12	33	27%
13-24	38	32%
25-36	24	20%
37-48	10	8%
49 and above	<u>15</u>	<u>13%</u>
Total	120	100%

to conceive. The number of conceptions decreased as the length of treatment time increased with 8% ($\underline{n}=10$) of the couples taking 37 to 48 months and 13% ($\underline{n}=15$) taking more than 48 months to conceive.

The causes of infertility are represented in Table 3. Women with the diagnosis of male factor were excluded because of inconsistent data in the records, and pregnancies resulting in an ectopic pregnancy were also excluded. The causes of infertility were classified as either (a) pelvic, (b) endocrine, or (c) unexplained. The category of pelvic included those women diagnosed with (a) endometriosis, (b) peritoneal and/or tubal adhesions, (c) uterine myomas, (d) any tubal disease, (e) adenomyosis, and (f) Asherman's

Table 3

Causes of Infertility (N =120)

Cause	Frequency	Percent
Pelvic origin	42	35%
Endocrine origin	64	53%
Unexplained origin	<u>14</u>	<u>12%</u>
Total	120	100%

syndrome. Table 3 shows that 35% ($\underline{n}=42$) of the women were diagnosed with infertility problems of pelvic origin. The endocrine category included (a) any ovulatory defect, (b) hyperprolactinemia, (c) thyroid disorders, and (d) those women who were 40 and above. The majority of women (53%, $\underline{n}=64$) had diagnoses relating their infertility to an endocrine origin. The unexplained category (12%, $\underline{n}=14$) included those diagnoses listed as simply unexplained and those with recurrent spontaneous abortion.

Treatments for infertility were classified in three sections: (a) natural cycle or no medication, (b) clomiphene citrate cycle or oral medication, and (c) gonadotropin cycle or injectable medication. Patients undergoing in vitro fertilization were excluded from this population. Table 4 shows that 48% ($\underline{n}=58$) of the women were able to conceive on a natural cycle with no ovulation medication. Specific treatment dosages of the oral and injectable ovulation medications were not entered as part of the data for the categories of

Table 4

Infertility Treatment (N = 120)

Treatment	Frequency	Percent
Natural cycle (no medication)	58	48%
Clomiphene Citrate cycle (oral medication)	32	27%
Gonadotropin cycle (injectable medication)	<u>30</u>	<u>25%</u>
Total	120	100%

clomiphene citrate and gonadotropins; however, 27% ($\underline{n}=32$) of the patients received oral medication, and 25% ($\underline{n}=30$) of the patients received injectable medication.

First Trimester Vaginal Bleeding

The independent variable was the occurrence of vaginal bleeding during the first trimester of pregnancy. As shown in Table 5, the data were separated into the categories of: (a) none, (b) spotting, (c) moderate, and (d) heavy. Most of the women (59%, $\underline{n}=70$) did not bleed. There were 26% ($\underline{n}=32$) who only had spotting. Another 10% ($\underline{n}=12$) had moderate bleeding. The least frequent occurrence was heavy bleeding (5%, $\underline{n}=6$).

Pregnancy Outcome

The dependent variable was the outcome of the pregnancy specifically related to viability of the infant. Table 6 shows the pregnancy outcome diagnoses. Of the nonviable

Table 5

Vaginal Bleeding During First Trimester (N = 120)

Amount	Frequency	Percent
None	70	59%
Spotting	32	26%
Moderate	12	10%
Heavy	<u>6</u>	<u>5%</u>
Total	120	100%

Table 6

Pregnancy Outcome (N = 120)

Outcome	Frequency	Percent
Abortion	44	36%
Perinatal Death	1	1%
Normal Term	73	61%
Preterm	1	1%
Congenital Malformation	1	1%
Growth Retardation	<u>0</u>	<u>0%</u>
Total	120	100%

outcomes, 36% ($\underline{n}=44$) resulted from abortion or the spontaneous loss of a pregnancy.

There was only 1 (1%) perinatal death, which was a term stillborn delivery. The majority of pregnancy outcomes were normal term deliveries (61%, $\underline{n}=73$). The preterm delivery (1%, $\underline{n}=1$) was a set of twins. The congenital malformation (1%, $\underline{n}=1$) was an infant diagnosed with patent ductus arteriosus.

Table 7 shows the outcomes in terms of multiple births and gender. For the singleton births, 40% ($\underline{n}=26$) were female and 60% ($\underline{n}=40$) were male. The majority of deliveries were singleton births (89%, $\underline{n}=66$). There were 6 (8%) deliveries of twins and 2 (3%) deliveries of triplets.

Table 7

Deliveries (n = 74)

Birth	Frequency	Percent
Type of Births		
Singleton	66	89%
Twins	6	8%
Triplets	<u>2</u>	<u>3%</u>
Total	74*	100%
Gender		
Female	36	40%
Male	<u>48</u>	<u>60%</u>
Total	84**	100%

Note. * Forty-six women of the total sample of 120 did not deliver live infants so were not included in the delivery category.

** This table includes total infants rather than deliveries (66 singleton infants + 12 twin infants + 6 triplet infants). Therefore, frequencies of infants exceed the 120 deliveries.

To investigate for a relationship of vaginal bleeding and pregnancy outcomes, the outcome categories were collapsed into two categories: (a) nonviable deliveries and (b) viable deliveries. The data for abortions and perinatal death were combined to form the nonviable outcomes category. The preterm and congenital malformation were added to the delivery category to form the viable outcome category since these infants were viable and survived. The amount of bleeding was recorded as (a) none or no bleeding, (b) spotting, described as scant or trace of blood, (c) moderate, described as bleeding like a menses, or (d) heavy, described as bleeding that was more than a menses.

Descriptive data of the relationship of first trimester vaginal bleeding and pregnancy outcome is shown in Table 8. Chi-square analysis was not done because there were insufficient data to meet requirements for cell frequencies. Of the women who had no bleeding, 83% ($n=58$) delivered a viable baby and 17% ($n=12$) had a nonviable outcome to their pregnancy. When the women reported spotting during the first trimester, 47% ($n=15$) had a viable outcome and 53% ($n=17$) had a nonviable outcome. In the case of moderate bleeding, there was only 1 viable birth (8%, $n=1$), while 11 births (92%) were nonviable. With heavy bleeding, again there was only 1 viable outcome (17%, $n=1$) and 5 (83%) nonviable outcomes. That is, those women who had spotting had about equal chances of a viable versus nonviable outcome of the pregnancy (47% delivered a viable infant, 53% delivered a nonviable infant). With moderate or heavy bleeding, the chances of an abortion or nonviable outcome increased substantially.

These statistics illustrate a trend towards an adverse outcome of pregnancy with an increase in bleeding. In other words, the heavier a woman bled in the first trimester of

Table 8

First Trimester Vaginal Bleeding and Pregnancy Outcome (N = 120)

Amount of Bleeding	Pregnancy Outcome	
	Nonviable Deliveries	Viable Deliveries
None	12 (17%)	58 (83%)
Spotting	17 (53%)	15 (47%)
Moderate	11 (92%)	1 (8%)
Heavy	<u>5 (83%)</u>	<u>1 (17%)</u>
Total (120)	45 (38%)	75 (62%)

pregnancy, the more likely the chance of abortion. The largest percentage of those women that bled were in the spotting outcome category, and this is equally important. There appears to be no major difference between the likelihood of a nonviable verses a viable pregnancy outcome (53% verses 47% within this category). Simply explained to patients, with respect to outcome, women in this study who spotted during the first trimester of pregnancy had approximately a 50% chance of a delivery.

Summary

In summary, a sample of 120 previously infertile women with a positive pregnancy test were categorized and described. The demographics were illustrated in numerous tables. Following the compiling of the descriptive data of the relationship of first trimester

vaginal bleeding and pregnancy outcome, a recognizable trend was indicated. As the amount of bleeding increased in women in the first trimester, the more likely the chance of abortion.

Chapter 5

CONCLUSIONS AND RECOMMENDATIONS

Summary

The purpose of this study was to investigate the relationship between first trimester vaginal bleeding and the outcome of pregnancy in a population of previously infertile women. The goal of this study was to provide a basis for more appropriate counseling for infertile couples. This information may enable a couple experiencing their first pregnancy to improve coping skills if they encounter vaginal bleeding during pregnancy. This chapter describes the conclusions reached from this study, suggests ways it can be applied in patient education, and makes recommendations for further research in this area.

A trend was noted towards an adverse pregnancy outcome as the amount of vaginal bleeding increased. The probability of abortion increased as the amount of bleeding increased during pregnancy.

The most common bleeding category among this population was the spotting category. There appeared to be no noticeable difference in the outcome among women who presented with spotting than those without spotting. They had an approximately 50% chance of a viable delivery despite the occurrence of vaginal spotting. Although the sample was small in the moderate and heavy bleeding categories, the percentages of abortions were higher in those categories than in the spotting category.

Conclusions

Pregnancies after a period of infertility are frequently believed to be at risk. There are reports in the literature of increased incidence of (a) chromosomal abnormalities (Milles et al., 1990), (b) preterm delivery and low birth weight (Strobino & Pantel-Silverman, 1989), (c) congenital abnormalities (Hack et al., 1970), and (d) vaginal bleeding (Williams, Goldman, Mittendorf, Lieberman, & Monson, 1991). Despite numerous studies, evidence remains inconclusive regarding an increased risk among previously infertile pregnant women when compared to a fertile population in contrast to the popular belief.

This study demonstrated that bleeding in early pregnancy is no greater than expected by chance within a fertile population. In the literature, of the fertile pregnant women who have spotting in early pregnancy, 50% progress to term (Berkowitz et al., 1983; Cunningham et al., 1993; Kutteh & Carr, 1993). This is congruent with this researcher's analysis that 47% of those women who spotted subsequently delivered a viable infant. Although concern about the prognosis is understandable, 50% of the pregnancies continue despite the presence of vaginal spotting.

Yazigi et al. (1991) reported that about one third of all pregnancies will be affected by some form of vaginal bleeding in the first trimester. Those patients whose pregnancy outcome was abortion varied from 15% to 40%, depending on the study (Cunningham et al., 1993; Strobino & Pantel-Silverman, 1989; Yazigi et al., 1991). In comparison, approximately two-fifths, or 41%, of the women within this sample had vaginal bleeding in the first trimester. The percentage of women that bled and aborted was 27.5 %. The

percentage that aborted was 38%. These percentages are not substantially different from the 15% to 40% reported earlier for fertile couples (Cunningham et al., 1993; Strobino & Pantel-Silverman, 1989; Yazigi et al., 1991). Furthermore, there was not an increased incidence of congenital malformations, growth retardation, or perinatal death among this sample.

In the present study there was a trend towards an adverse outcome of pregnancy with an increase in bleeding. In other words, the heavier a woman bled in the first trimester of pregnancy, the more likely the chance of abortion. The difference in this study when compared to previous research seems to be those with moderate or heavy bleeding and outcome. They had a much higher chance of abortion (92% and 83%, see Table 8). This area needs further study since the sample utilized was insufficient to draw statistically significant conclusions.

Suggestions for Patient Education

Health care professionals who understand the psychosocial impact of pregnancy and pregnancy loss after infertility can translate their knowledge into basic clinical strategies, education, and support. These couples present a challenge that requires information related to their special condition. They need learning to be problem-centered and personalized. When couples are experiencing the problem of vaginal bleeding, education regarding possible pregnancy outcome could assist them to cope with their concerns about the possibility of abortion. Health care professionals can respond therapeutically by being active listeners who can help the infertile couple sort through their

feelings. The provider can bring together a sensitive combination of education and support to thereby help couples face this dilemma.

For the infertile couple, knowing that their complaints of vaginal bleeding are not necessarily linked only to the infertility diagnosis could help the couple deal with feelings of guilt and frustration. Further, the couple may be reassured to know that slight bleeding or spotting does not put them at more risk than a fertile couple.

Scope and Limitations

The study was limited by sample, design, and analysis. These conclusions were limited with respect to the possible pathological process underlying existing conditions. Conditions such as (a) maternal age, (b) uterine pathology, (c) previous spontaneous abortions, (d) cervical inflammatory conditions, and (e) endocrine abnormalities were not identified specifically in the sample for analysis. Infertility encompasses a broad heterogeneous group of physiological factors. The identification of these factors is beyond the scope of this investigation. Additional major risk factors (cigarette smoking, maternal weight, ethnicity, and socioeconomic status) have already been acknowledged by many previous studies for low birth weight and preterm delivery (Strobino & Pantel-Silverman, 1989; Williams, Goldman, Mittendorf, & Monson, 1991), and they were not controlled in this investigation.

This investigation was limited by the small sample, thereby decreasing the ability to generalize. The sample utilized was a convenience sample which was an additional limitation. The use of a private practice for the selection of the sample could limit social

class and occupation to those who could easily afford the added expense of health care insurance or infertility treatment.

The design and the analysis used precluded any determination of cause and effect. The sample size caused a decreased cell size and did not meet criteria for chi square analysis. Therefore, descriptive statistics were used.

Lastly, it will be difficult to truly compare these results concerning outcome since there are few investigations that have specifically examined the population of previously infertile couples. Recruitment of a larger sample with similar diagnoses is of sufficient cost and complexity that a multicenter trial would be necessary for more conclusive findings (Stovall & Guzick, 1994).

Recommendations for Further Study

A recommendation for further study is to replicate the study. Future studies would need a larger sample size in order to be able to generalize to a larger population of infertile couples. Replication of this study including demographics such as race, socioeconomic status, occupation, underlying pathology and parity would be advantageous. Couples with different types of infertility diagnoses may have different risks of adverse outcomes in subsequent pregnancies (Williams, Goldman, Mittendorf, & Monson, 1991). A more specific database as well as the other mentioned demographics could determine if any of these factors effect the relationship between first trimester bleeding and pregnancy outcome.

The specific protocols for ovulation induction could also be evaluated. Certain researchers have concluded that the abortion incidence is high with the use of

gonadotropins (Hack et al., 1970; Jansen, 1982; Bohrer & Kemmann, 1987). Additional studies would be necessary to determine the cause and effect of vaginal bleeding in early pregnancy on the pregnancy outcome.

Psychologic support in the form of frequent discussions and sympathetic counseling can be crucial to the successful evaluation and treatment of the anxious pregnant patient. It is important that there is continued education of nurses and pregnant patients to recognize that first trimester bleeding does not always result in an undesired outcome.

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