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Menstrual Hygiene Product Use and the Incidence of Abnormal Papanicolaou Smear Results

Sue K. Goebel

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MENSTRUAL HYGIENE PRODUCT USE AND
THE INCIDENCE OF ABNORMAL
PAPANICOLAOU SMEAR RESULTS

by

Sue K. Goebel

Bachelor of Science, University of North Dakota, 1984

A Thesis

Submitted to the Graduate Faculty

of the

University of North Dakota

in partial fulfillment of the requirements

for the degree of

Master of Science

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August

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This thesis, submitted by Sue Goebel in partial fulfillment of the requirements for the Degree of Master of Science from the University of North Dakota, has been read by the Faculty Advisory Committee under whom the work has been done and is hereby approved.

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This thesis meets the standards for appearance, conforms to the style and format requirements of the Graduate School of the University of North Dakota, and is hereby approved.

Harvey Knell
Dean of the Graduate School
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ABSTRACT

Today the majority of females fifteen years and older have used tampons. Since their introduction in 1933, tampons have changed greatly in composition: more absorbent synthetic fibers have replaced natural fibers, plastic applicators have joined cardboard, and some contain a fragrance. While changes in vaginal mucosa including inflammatory changes, lacerations, and micro-ulcerations as a result of tampon use have been documented, no research examining the use of menstrual hygiene products and their effect on cervical cytology was located.

The purpose of this study was to examine the association between menstrual hygiene product use and the incidence of abnormal Pap smear results, specifically that of benign cellular inflammatory changes and/or atypical squamous cell of undetermined significance (ASCUS). The Theory of Nursing as Human Science and Human Care as proposed by Jean Watson (1979) was the theoretical framework for this study.

Data were collected by chart audit review of 250 women, ages 14 to 36, who sought Pap smear screening at a Midwestern family planning clinic. The data collection

instrument was designed by the researcher. Data were analyzed using the Statistical Package for the Social Sciences (SPSS-X).

The association in Pap smear result by tampon applicator use, analyzed using Pearson Chi square, was found to be statistically significant ($X^2=18.53$; $df=4$; $p=0.003$). The difference in Pap smear result by type of tampon was also statistically significant ($X^2=48.06$; $df=3$; $p=0.000$). Reported use of plastic and/or deodorized tampon use by those subjects with inflammatory changes and/or ASCUS Pap results was three times that of those reporting cardboard applicator, non-deodorized tampon or sanitary pad use.

CHAPTER I

INTRODUCTION

The composition of tampons has changed greatly over the past fifty years: more absorbent synthetic fibers have replaced natural fibers, plastic applicators have replaced cardboard, and some contain a fragrance. These changes warrant new studies examining tampon use and the effects of tampon use. "Given the increasing use of this internal device and the rapidity with which new products are manufactured and marketed, medical practitioners should know what products are used, how often, and for what purposes" (Cibulka, 1985, p. 224).

In response to the use of tampons, vaginal mucosa has been examined via colposcopy and tissue biopsy with results varying from no observable changes to the identification of micro-ulcerations (Friedman, 1981; Friedrich & Siegesmund, 1980). No study exploring a relationship between tampon use and abnormal cervical cytology (Papanicolaou smear) was located.

History and Significance

Menstrual hygiene products. Today the majority of American females fifteen years and older have used tampons, which accounts in part for the billions of tampons

used in a year. First marketed in 1936, the original tampons were made of 100% surgical cotton in a two part cardboard applicator. The plastic applicator tampon was introduced in 1967, followed by the debut of the deodorant tampon in 1971.

In the case of the plastic applicator, its four to six cusps at the end of the inserter have been reported to cause vaginal and cervical lacerations (Barrett, Bledsoe, Greer, & Droegemueller, 1979; Collins, 1979). The deodorant tampon is not in any way medically beneficial and may instead present a health hazard because the perfume may irritate the vaginal mucosa and the cervix and disrupt the normal flora of the vagina (Hasselbring, Greenwood, and Castleman, 1987; Horos, 1975). Perfume products, demonstrated to cause irritation and inflammation when added to sanitary pads (Fischer, 1973; Larsen, 1979), have not been subject to study in tampons.

Cervical cytology report. The cytological descriptive diagnosis of interest is that of The Bethesda System (TBS; Appendix A) atypical squamous cells of undetermined significance (ASCUS), an epithelial cell change demonstrated by slight to moderate changes in nuclear size and morphology (Davis, Hernandez, Davis, Miyasawa, 1987; Montz, Monk, Fowler, Nguyen, 1992). The diagnosis ASCUS is limited to those cases in which cellular changes exceed those attributable to benign, reactive processes, but fall

short of a definitive diagnosis of squamous intraepithelial lesion (Knapp, 1993).

An ASCUS Pap smear result should be further qualified, when possible, as to whether a reactive or a premalignant/malignant process is favored. Reactive cellular changes are associated with inflammation while premalignant/malignant changes are associated with squamous intraepithelial lesions. Reported incidence rates of this diagnosis for all women range from 1.6% to 19% (Davis et al, 1987; DHHS, 1989; Gunn & Simpson 1992; Kaminski, Stevens, & Wheelock 1989; Pearlstone, Grigsby, & Mutch, 1992).

The Bethesda System for reporting cervical cytology, (commonly referred to as a Pap smear) provides a uniform format and a standardized lexicon, but it does not include guidelines for patient management based on TBS diagnosis. The contributing experts to TBS acknowledged certain unanswered questions exist regarding management of atypical cells of undetermined significance (ASCUS) and squamous intraepithelial lesion (SIL) (Koss, 1990).

Clinical management. Clinical management of patients with ASCUS Pap test results is a subject of debate. Some consider these minimal changes benign and recommend periodic repeat Pap smears at intervals ranging from three to twelve months. Others repeat the Pap smear immediately and recommend colposcopy and tissue biopsy if the atypia

persists (Davis et al, 1987; Kaminski et al, 1989; Montz et al, 1992).

Nurse clinicians often manage and counsel patients regarding abnormal Pap smear follow-up. Upon receiving word of her abnormal Pap smear result, a woman may express anxiety which can be compounded by the questionable etiology of the abnormality. The nurse clinician should provide information about causes, diagnostic implications, recommendations for follow-up care, and attempt to alleviate patients anxieties related to the abnormal result (Lauver & Rubin, 1991).

It is common for the nurse clinician to recommend the patient avoid plastic and/or deodorized tampons in the interim period (commonly three to six months) between the initial and repeat Pap smears. Additional education includes avoidance of coitus, douching, or vaginal medications for 24-48 hours before the Pap appointment (Schumaker, 1991).

The nurse clinician's recommendations are guided in part by protocol and in part by the following principles: (a) a healthy vagina is moist, self-cleansing and naturally protective against disease and odor causing germs (Horos, 1975), (b) menstrual flow has no odor while in the vagina and therefore a deodorant to mask odor is unnecessary (Friedman, 1981), (c) contact with any chemical or foreign object on the fragile vaginal mucosa and cervix can a cause

irritation and inflammation (Fisher, 1973; Friedrich & Siegesmund, 1980; Larsen, 1979), and (d) inflammation stimulates cell division and thus increases the chance for abnormal cell changes (Perez-Tamayo, 1985).

Purpose

The purpose of this study is to examine the association between menstrual hygiene product use and the incidence of Pap smear results of inflammation and/or atypical squamous cells of undetermined significance (ASCUS) in females between the ages of 14 and 36 years.

Research Question

This study will address the following question:

What is the association between menstrual hygiene product use and the incidence of the Pap smear results of benign cellular inflammatory changes and/or atypical squamous cells of undetermined significance for females, ages 14 to 36 years, seeking services in a family planning setting?

Research Hypothesis

Among females ages 14 to 36 years with Pap smear results of benign cellular inflammatory changes and/or atypical squamous cells of undetermined significance, reported use of plastic applicator and/or deodorized tampon use will be greater than reported use of cardboard applicator/non-deodorized and/or sanitary pads.

Theoretical Framework

Watson's (1979) Theory of Nursing as Human Science and Human Care lends itself well to the family planning setting. In daily conversation about sexuality issues, the nurse will draw on scientific principles and the ability to demonstrate transpersonal care in order to communicate about these historically taboo subjects (Delaney, Lupton, & Toth, 1976). Communication is key to providing optimal care, counsel and education in this nursing setting.

Person is viewed as a "being-in-the-world" (Watson, 1985, p. 54-55); the three spheres of 'being'--the mind, body and soul--are influenced by the concept of 'self'. The 'self' is the "subjective center that experiences and lives within the sum total of body parts, thoughts, sensations, desires, memories, life history and so forth". The concept of self is central to the family planning nurse in empowering the client's decision making for her 'self'.

Environment consists of an internal and an external environment. The internal environment is that of mental and spiritual well-being and sociocultural beliefs. The external environment includes the variables of comfort, stress, privacy, safety, cleanliness and aesthetics (Watson, 1979). Choice of menstrual hygiene product and feelings related to a female's menstrual cycle are integral to the internal and external environments as described by Watson.

Health is an elusive, relative concept and is individually defined. It is, Watson (1979, p. 219) states, the "process of adapting, coping and growing that goes on from conception to death".

Nursing is a "therapeutic interpersonal process" (Watson, 1979, p. 7). Nursing is involved with the restoration, maintenance, and promotion of health and prevention of illness. Watson speaks of nursing as an art and a science, more specifically a human science.

The structure for studying and understanding nursing as a science of caring is formed by Watson's ten carative factors (Watson, 1979, pp. 9-10). Two factors have significance for this study. They are as follow:

1. Carative Factor 6: The systematic use of the scientific problem-solving method for decision making; and
2. Carative Factor 7: The promotion of interpersonal teaching-learning.

The family planning nurse will gather data from the client, i. e., Pap smear, menstrual history, psycho-sexual history, and menstrual hygiene practices. Applying the scientific problem solving method, the nurse will examine the association between the use of plastic applicator and/or deodorant tampons and the incidence of ASCUS Pap

smears. Abnormal Pap smear follow-up counsel and education will, in part, reflect the findings of this study.

Definitions

The following terms have been defined for the purposes of this study:

Papanicolaou (Pap) smear consists of a sample of cells from the epithelial surfaces of the uterine cervix placed on a microscope slide, stained and studied under a microscope by a cytopathologist or cytotechnologist. It is a simple screening tool for cervical neoplasia and other abnormalities (Koss, 1990). This specimen is also called a cervical cytological smear.

Abnormal Pap smear includes only those Pap smear results with either reported benign cellular inflammatory changes or the TBS descriptive diagnosis of atypical squamous cells of undetermined significance (ASCUS). Previously this abnormal finding was classified as a Class II Pap smear based on the Papanicolaou Classification System (see Appendix B).

Tampon refers to a plug made of cotton and/or synthetic fibers introduced into the vagina typically to absorb menstrual flow. The term "type of applicator" refers to plastic, cardboard or non-applicator tampons. The term "type of tampon" refers to deodorized or non-deodorized tampons.

Cardboard applicator refers to a tampon contained within a cardboard applicator.

Plastic applicator tampon refers to a tampon contained within a plastic applicator intended to ease insertion.

Deodorant tampon refers to a tampon containing a fragrance intended to mask odor of menstrual flow.

Adolescent Onset (AO) appears on the data collection instrument and refers to age at initiation of sexual intercourse; in this case, prior to the age of 19 years.

Birth control method (BCM) appears on the data collection instrument and refers to any intervention including hormonal, barrier, or fertility awareness, used to control a woman's fertility.

Multiple Contacts (MC) appears on the data collection instrument and refers to number of lifetime sexual partners; in this case, greater than one sexual partner in preceding seven years.

Sexually Active (SA) appears on the data collection instrument. The frequency of sexual activity will be described as frequent: greater or equal to two acts of intercourse per week or infrequent: less than two acts of intercourse per week.

Limitations

Generalizability of findings may be limited due to self-selection of patients served at this family planning clinic.

CHAPTER II

REVIEW OF LITERATURE

This review of selected references will provide background information on cervical cytology specifically the Papanicolaou smear (Pap smear), its reporting system, previously identified predictors of abnormal cervical cytology, and menstrual hygiene products with emphasis on tampons.

Cervical Cytologic Smear Reporting System

The cervical/vaginal cytologic smear, commonly known as a Pap smear, was first introduced in 1943 by Dr. George Papanicolaou, hence its name. Cell samples, obtained from the cervix and vagina, are stained by the Papanicolaou method, microscopically examined, and interpreted by a cytopathologist. The screening test is largely responsible for the 70% decrease in morbidity and mortality resulting from cervical cancer over the past forty years (Koss, 1990; Lundberg, 1989; U. S. DHHS, 1989). The Pap smear is simple, painless and "one of the most accurate and cost effective medical tests" (DHHS, p. 3).

Papanicolaou classification system. According to Koss (1990 p. 988), Papanicolaou recognized "that he was not qualified to render diagnostic verdicts based on the

smear". Thus, he devised a five class system of reporting Pap smear results (Appendix B). This system has been widely accepted in the United States; however, laboratories may differ in the way in which they use the system's terminology. These variations may significantly alter the clinical implications of the Pap smear report. Recent controversy regarding the Pap system of reporting, its varied and sometimes ambiguous terminology, and quality assurance are reflected in the literature (Koss, 1989; Lundberg, 1989).

The Bethesda System. Under the auspices of the National Cancer Institute, a multidisciplinary group of experts convened in Bethesda, Maryland, in December of 1988. The purpose of the meeting was to address the standardization of cervical/vaginal cytology reports. The resulting system, The Bethesda System was adopted by consensus and gained widespread support in laboratory practice. TBS offers a uniform format and provides a standardized lexicon for cervical cytology reports, specifically emphasizing communication of clinically relevant information (Knapp, 1993).

Re-evaluation and revisions to TBS were made when the group reconvened in 1991. While TBS does not include guidelines for patient management, the desire for such guidelines was emphasized at this second meeting. The contributors called for additional research and clinical

trials to resolve certain unanswered questions regarding management of ASCUS and low grade lesions (Knapp, 1993).

Predictors of Abnormal Cervical Cytology

Sexual factors. Various indicators of sexual activity have long been known to be associated with cervical cancer, and a large number of epidemiological studies have been carried out on this subject. Studies indicate that age at first intercourse, multiple sexual partners, and having a male partner with multiple partners are associated with the risk of developing cervical cancer. This has prompted a search for one or more sexually transmitted diseases (STDs) which play a role in the pathogenesis of cervical cell abnormalities (Berger, 1978; Buckley, Doll, Harris, 1981; Clarke, Hatcher, McKeon-Eyssen, 1985; Montz, Monk, Fowler, Nguyen, 1992; Slattery, Overall, Abbott, French, Robison, & Garner, 1989; Vessey & Williams, 1981; Wright & Riopel, 1984; Wynder, 1969).

Contraceptives. Several epidemiological studies of the relationship between oral contraceptives (OC) and cervical neoplasia have yielded conflicting results. This may be in part due to the fact that OC use is strongly correlated with the aforementioned key sexual risk factors and the degree of adjustment for these confounding variables among studies (Brinton, et al., 1986; Clarke, Hatcher, McKeown-Eyssen, & Lickrish, 1985; Irwin, et al., 1988).

If an STD is the major cause of cervical cancer, a protective effect of barrier contraception should be expected. Spermicides and condoms may be protective (Celentano, Klassen, Weisman, & Rosenhein, 1987), while the cervical cap may actually increase the risk of cervical cell abnormalities (Berstein, 1986).

Smoking. An association between cigarette smoking and cervical cancer was first proposed over 15 years ago. Recent studies revealed an approximately two-fold increase in risk for smokers versus non-smokers, and a clear dose-response relationship was observed in two of these studies (Brinton, Schairer, Haenszel, Stolley, Lehman, Levine, & Savitz, 1986; Clark, Hatcher, McKeown-Eyssen, & Lickrish, 1985; Mitchell, Sandella & White, 1992; and Trevathan et al., 1983).

Tampons

Historical perspective. Although "invented" in 1933 by an American physician, documentation of tampon use by women dates back to the fifteenth century B.C. Tampon composition varied among cultures. Roman women used soft wool; Egyptian women, papyrus; Japanese women chose paper; and women of African and Asian cultures used a variety of plants to construct internal vaginal guards to be worn during menstruation (Delaney, Lupton, & Toth, 1976,; Friedman, 1981).

The first tampons to be marketed in the United States were made of 100% cotton; most were compressed within a two part cardboard applicator. By the 1970s, rayon was combined with or replaced cotton in nearly every tampon on the market. The tampons of today are made of combinations of rayon and synthetic fibers, and can be purchased with a cardboard or plastic applicator, or with no applicator at all. (Delaney et al., 1976, 1988; Friedman, 1981, Friefeld, 1984). Fragrance first appeared in tampons in 1971. The intent was that American women could have a the combination of a "soft and gentle" tampon with a "fresh, delicate scent" (Friedman, 1981, p. 51). A perfumed product was, and still is, promoted as a deodorant product.

Tampons were classified by the Food and Drug Administration (FDA) as a cosmetic from 1938 to 1968. As a cosmetic, tampons were considered outside the realm of federal regulation. In 1968, tampons became a Class I medical device, and in 1980 were reclassified as a Class II medical device, thereby subject to FDA performance standards, if and when such standards are developed. Cibulka (1983) reports consumer groups are advocating the change from a Class II to a Class III medical device. This change would subject tampons to rigorous pre-market testing for effectiveness and safety.

In 1982, the FDA required tampon manufacturers to include standardized warning labels and package inserts

advising consumers of the risks and symptoms of Toxic Shock Syndrome (TSS), a rare but sometimes fatal disease associated with tampon use. The FDA also recommended those women using tampons use the least absorbent tampon necessary for absorption of menstrual flow. (Consumer Reports, 1986; Friefeld, 1984; Nightingale, 1990).

FDA testing demonstrated that terms used to signify absorbency such as "regular" and "super" varied in meaning among tampon manufacturers. As a result of the findings, the FDA ruled that beginning March 1, 1990, the following terms would be uniform among tampon manufacturers and were to appear on package labeling: junior (6 grams or less of fluid absorbed per tampon; regular (6 to 9 grams); super (9 to 12 grams); and super plus (12 to 15 grams) (Consumer Reports, 1986, 1990; Nightingale, 1990). Tampon manufacturers are not required to list ingredients, including composition of fibers or perfume additives, at this time.

Composition. Prior to 1977, tampons were made of cotton, rayon, or a combination of the two. Since then, the composition of tampons has changed to include more absorbent synthetic materials. In some tampon users this increased absorbency has been detrimental. Extensive research supports the association between absorbency and an increased risk for TSS. Toxin producing *Staphylococcus aureus* and tampon use have been implicated as causative

factors in the development of TSS; the exact nature of the relationship is not yet clearly understood (Cibulka, 1983; Consumer Reports, 1986; Finkelstein & Von Eye, 1990; Friefeld, 1984; Irwin & Millstein, 1982; Nightingale, 1990).

Perfume was added to tampons in 1971 and the product was designated a deodorant (not scented) tampon (Friedman, 1981; Larsen, 1979). Fisher (1973) reported that several documented cases of irritation and dermatitis secondary to use of perfumed feminine hygiene sprays appear in the literature. Larsen documents the occurrence of vulvar dermatitis which was a result of the perfume in a deodorant sanitary napkin.

Absorbency. The concept of absorbency is the focus of several reports on tampons. Early researchers regarded absorbency in terms of "complete protection" (Arnold and Hegele, 1938, p. 792) or the ability of a tampon to absorb the menstrual flow without the additional use of a sanitary napkin. The studies of Arnold and Hegele and Thornton (1943) suggest that early tampons, made of cotton fibers, did not afford complete protection for the majority of women using them. Based on their limited knowledge of how susceptible the vaginal mucosa was to repeated irritation, the early researchers concluded that "when tampons are used

regularly during the menstrual period, periodic examination of the vagina should be made to ascertain whether the mucosa remains normal" (Arnold & Hegele, 1938, p. 791).

Friedrich and Siegesmund (1980) examined absorbency of tampons in relation to alterations in vaginal mucosa revealed by colposcopic evaluation. The researchers conducted a blind, random study of one hundred and sixty women using tampons either during periods or between periods. Tampons were identified as either "superabsorbent" or "non-superabsorbent"; no deodorant tampons were used. The researchers concluded that superabsorbent tampons are significantly more likely to produce micro-ulcerations than non-superabsorbant tampons when used intermenstrually. Furthermore, chronic production of these alterations could lead to clinically visible lesions of the vagina.

Safety and comfort. Concepts of safety and comfort are addressed in early literature about tampons. Most researchers reported in favor of tampon use and found that, among their subjects, tampons were a generally safe, comfortable, effective way of managing menstrual flow (Arnold & Hegele, 1938; Barton, 1942; Dickinson, 1945; Magid & Geiger, 1942; Thornton, 1943; Wheatley, Menkin, Bardes, & Rock, 1965; Widenius, 1944).

Moral implications. The use of tampons created a moral dilemma for some, including clergy, physicians and

consumers. It was believed a tampon could possibly rupture the vaginal hymen of a virginal woman thereby being an agent of defloration (Barton, 1942; Singleton & Vanorden, 1943). In 1945, Dr. Karnaky, who had conducted a five year study of 42 women, declared the tampon safe for "unmarried women" (Friedman, 1981, p. 45). In a review paper, Dickinson (1945, p. 490) explored and compared the eroticism of the "internal and external menstrual guards".

Therapeutic use. Researchers in the late 1950s and early 1960s advocated the use of tampons in the treatment of vaginitis (Friedman, 1981; Karnaky, 1956). According to Friedman, Karnaky also recommended tampon use as an aid in managing infertility, but, he did not provide specific support for this recommendation. Rutherford, Banks and Coburn (1962) advocated the therapeutic use of tampons in postpartum lochia flow. Lamb and Berg (1985) examined the potential role of vaginal tampons in women with endometriosis.

Injuries. Several case studies describing the incidence of tampon associated ulcerations and lacerations appear in the literature (Barrett, Bledsoe, Greer, & DroegemueLLer, 1977; Collins, 1979; Jimerson & Becker, 1980; Weissberg & Dodson, 1980). Barrett et al. suggest pressure necrosis or chemical irritation as the mechanism of ulcer formation in the cases they reported. Collins (1979, p. 127) attributed a one to two millimeter tear

which resulted in "a life threatening hemorrhage" to the cusp of a plastic inserter and asserted that foreign body insertion is the major noncoital cause of vaginal injury".

Related variables. The studies of Irwin and Millstein (1982) and Finkelstein and Von Eye (1990) suggest that physicians and nurses do not fully understand the relationships of age, racial-ethnic differences, patterns of sanitary product use, and the role they play in the production of TSS. The researchers encouraged further study of sanitary product use with consideration of additional variables including socioeconomic status.

CHAPTER III

METHODOLOGY

The purpose of this study was to describe the association between menstrual hygiene product use and the incidence of Pap smear results of inflammatory changes and/or atypical squamous cells of undetermined significance. In this chapter the study sample, methodology, and proposed data analysis will be described.

Population

The target population was females, ages 14 to 36 years, who use tampons during a menstrual period. The accessible population was that of females, ages 14 to 36 years, who sought services at a Midwestern family planning clinic.

Study Design

The study was non-experimental in nature. It was a retrospective exploratory study of menstrual hygiene product use and the resulting incidence of abnormal Pap smear results.

Sampling method. The sample group was 250 females, who sought a Pap smear in the 6 month time period of November, 1992 through April, 1993. Subjects were selected at random from the 1364 women whose names appeared in the

clinic lab log. Entries were numbered consecutively, and a table of random numbers used to select cases for study. Of the 400 charts selected 150 were excluded from the study for the following reasons: abnormal Pap smear within the preceding 15 months, (n=25; 7%); repeat Pap smear following an abnormal (n=57; 38%); age (n=7; 5%); and incomplete data base (n=61; 40%). The remaining 250 charts were used in data collection.

Protection of human subjects. The study was in compliance with the legal requirements governing human subjects research, as set forth by both the Institutional Review Board and the Department of Health and Human Services (Department of Health and Human Services 1990; Institutional Review Board, 1989). This project was subject to "exempt" review because it is a study of existing data, documents or records.

Data Collection Method

Data were collected by chart audit review. Responses to questions regarding menstrual hygiene product use are recorded in each client's chart as part of the health history. Data were located and transferred to the data sheet described below. Data collection began upon approval from the Human Subjects Review Board and the participating agency.

Instrument

The data collection instrument was designed by the researcher (Appendix C). It included data related to age, adolescent onset of sexual intercourse, history of multiple sexual partners, frequency of sexual activity, birth control method, menstrual hygiene product use, age at first use, smoking status and the Pap smear result.

Data Analysis

The association between menstrual hygiene product use and non-malignant Pap smear results was evaluated by Pearson Chi square analysis of the cross classification of the two factors (Kirk, 1990). Separate analysis were conducted for applicator type and deodorant presence in tampons. The overall Type I error rate (alpha) was set at .05; Bonferroni's approach, was used to control the experiment wise Type I error rate (Kirk, 1982), so the nominal alpha was .025 for each test. Other data were analyzed using the Student's t-test and descriptive statistics including means, standard deviations, frequencies and percentages.

Chapter IV

RESULTS

In this chapter the findings of data analysis will be presented. The sample profile will be discussed followed by the research question and hypothesis outcomes, and additional findings of interest. Data were analyzed using the Statistical Package for the Social Sciences--Revised (SPSS-X).

Sample Profile

The sample profile results are portrayed in Table 1. The subjects ranged in age from 14 to 36 years ($\bar{X}=22.2$ years; $N=250$; $SD=4.3$). Nearly three fourths of the females reported adolescent onset of intercourse ($n=185$; 74%), compared to 65 (26%) who had abstained until the age of 19 years. Multiple sexual contacts were reported by 198 (79%) respondents while 52 (21%) reported only one lifetime sexual partner. Eighty three (33%) respondents report frequency of sexual intercourse to be less than two acts of intercourse per week, while sixty one (25%) reported intercourse occurred two or more times per week; missing data ($n=106$; 42%). The vast majority of females used oral contraceptives as a birth control method ($n=224$; 90%), while 11 (4%) used condoms, 2 (1%) used spermicides, 2 (1%)

used diaphragms, and 11 (4%) relied on other birth control methods (e. g. fertility awareness, sponge, sterilization, withdrawal, and none). Cigarette smoking was reported by 53 (21%) of the females; the remaining 197 (79%) were non-smokers.

Tampon use was reported by 189 (76%; n=250) of the females while 61 (24%) used sanitary pads only. Age of first use of tampons ranged from 9 to 21 years with a mean of 14 years (SD=6.5; n=250). With regard to tampon applicator type 76 (27%) used plastic applicators, 88 (35%) used cardboard applicators, 29 (12%) used either applicator, (2%) used non-applicator tampons. With regard to type of tampon the majority of females selected non-deodorized tampons (n=131, 52%), compared to those who used deodorized tampons (n=38; 15%), either type (n=20; 8%). One hundred twenty five of the females reported using 0 to 4 tampons per day (50%) compared to 61 (24%) who used 5 and 8 tampons per day, and 3 (1%) who used 9 to 12 tampons per day.

Sanitary pad use was reported by 221 (88%) of the females compared to 29 (12%) who reported non-use of pads (n=250). Non-deodorant pads were used by the vast majority (n=211; 84%). Deodorant pads were used by 4 (2%) females and 6 (2%) reported using either type of product.

Pap smear results of within normal limits (WNL) were reported in 201 (80%) of the cases, compared with 30 (12%)

ASCUS results, 4 (2%) LSIL results, 11 (4%) benign cellular inflammatory changes, and 4 (2%) other results. Combining the Pap results of ASCUS and benign cellular inflammatory changes, a total of 41 (16%) Pap results met the criteria of the Pap results of interest.

Table 1

Sample Profile

Characteristic	%	n
Adolescent Onset of Intercourse		
Yes	74	185
No	26	65
Multiple Contacts		
Yes	79	198
No		
Sexual Activity		
< 2 times/wk	33	83
≥ 2 times/wk	25	61
Missing Data	42	106

(Table 1, Sample Profile, continued)

<u>Characteristic</u>	<u>%</u>	<u>n</u>
Birth Control Method		
Oral Contraceptives	90	224
Condom	4	11
Spermicide	1	2
Diaphragm	1	2
Natural Family Planning and Other	4	11
Applicator Type		
Plastic	27	67
Cardboard	35	88
Either	12	29
Non Applicator	2	5
Non Use	24	61
Type of Tampon		
Deodorant	15	38
Non Deodorant	52	131
Both	8	20
Non Use	25	61
Number of Tampons Used Per Day		
0-4	50	125
5-8	24	61
9-12	1	3
Non Use	25	61

(Table 1, Sample Profile, continued)

<u>Characteristic</u>	<u>%</u>	<u>n</u>
Pads		
Deodorant	2	4
Non-Deodorant	84	211
Either	2	6
Non-Use	12	29
Pap Results		
WNL	80	201
ASCUS	12	30
LSIL	2	4
INFLAM	4	11
Other	2	4
Smoker		
Yes	21	53
No	79	197

<u>Characteristic</u>	<u>Mean</u>	<u>SD</u>	<u>Range</u>	<u>n</u>
Age	22.2	4.3	14-36 yrs	250
Age At First Tampon Use	14.6	1.9	9-21 yrs	250

N=250

Examination of the Research Question and Hypothesis

The research question was: What is the association between the type of menstrual hygiene product used and the incidence of the Pap smear results of benign cellular inflammatory changes and/or atypical squamous cells of undetermined significance for females, ages 14 to 16 years, in a family planning setting?

The research hypothesis was: Among females ages 14 to 36 years with Pap smear results of benign cellular inflammatory changes and/or atypical squamous cells of undetermined significance, reported use of plastic applicator and/or deodorized tampons will be greater than reported use of cardboard applicator/non-deodorized and/or sanitary pads.

Eight cases were excluded in statistical analysis: Pap results of low grade squamous intraepithelial lesions (n=4; 2%) and Pap results of "other" (n=4; 2%). Tables 2 and 3 list the cross-tabulation of abnormal Pap smear results with applicator type and deodorant type, respectively. The research hypotheses regarding applicator and deodorant type were supported from a statistical perspective. Pap smear results by type of applicator (plastic, cardboard, non-applicator) used were significantly different as noted by Pearson Chi square results ($X^2=18.853$; $df=4$; $p=0.003$; $N=242$).

Pap smear results by deodorant type used were significantly different ($\chi^2=48.06$; $df=3$; $p=0.000$; $N=242$).

Among those subjects with abnormal Pap results ($n=41$) reported use of plastic applicators ($n=17$; 41%) was nearly three times that of use of cardboard applicators ($n=6$; 14%); and twice that of reported use of pads ($n=9$; 22%). Furthermore, among these same subjects reported use of deodorant tampons ($n=17$; 41%) was nearly three times that of non-deodorant ($n=6$; 14.6%); and twice that of reported use of pads ($n=9$; 15%).

Table 2Chi Square Pap Result By Menstrual Hygiene Product

Non-malignant Pap Results			
Count Row Pct Col Pct	Normal	Abnormal	ROW TOTAL
Applicator			
Plastic	47 73.4 23.4	17 26.6 41.5	64 26.4
Cardboard	80 93.0 39.8	6 7.0 14.6	86 35.5
Either	19 67.9 9.5	9 32.1 22.0	28 11.6
Non-Applicator	4 100.0 2.0		4 1.7
Non-Use (pads)	51 85.0 25.4	9 15.0 22.0	60 24.8
COLUMN TOTAL	201 83.1	41 16.9	242 100.0

	<u>Value</u>	<u>df</u>	<u>p</u>
Pearson Chi Square	15.9	4	0.003

Table 3

Chi Square Pap Result Differences By Type Of Tampon

Non-malignant Pap Results			
Count Row Pct Col Pct	0	1	ROW TOTAL
Tampon type	Normal	Abnormal	
Deodorant	20 54.1 10.0	17 45.9 41.5	37 15.3
Non-Deodorant	120 95.2 59.7	6 4.8 14.6	126 52.1
Either	10 52.6 5.0	9 47.4 22.0	19 7.9
Non-Use	51 85.0 25.4	9 15.0 22.0	60 24.8
COLUMN TOTAL	201 83.1	41 16.9	242 100.0

	<u>Value</u>	<u>df</u>	<u>p</u>
Pearson Chi Square	48.06	3	0.0000

Additional Findings

Incidence of abnormal Pap smears is significantly greater in those who experienced initial intercourse during adolescence ($X^2=4.32$; $df=1$; $p=0.037$; $N=242$). Table 4 presents these results.

Table 4

Chi Square Pap Result Differences By Adolescent Onset Of Intercourse

		Non-malignant Pap Results		
Count		0	1	ROW
Row Pct		Normal	Abnormal	TOTAL
Col Pct				
Adolescent Onset Of Intercourse	Yes	154 86.0 76.6	25 14.0 61.0	179 74.0
	No	47 74.6 23.4	16 25.4 39.0	63 26.0
COLUMN TOTAL		201 83.1	41 16.9	242 100.0

	<u>Value</u>	<u>df</u>
Pearson Chi Square	4.33*	1

*p ≤ 0.05

Student t-tests of Pap by age and Pap by age at first use were calculated. The mean age of the two groups, normal and abnormal Pap results, differed significantly (t=-2.05; df=240; p=0.04). Table 5 presents the results. T-test for age at first use was non-significant.

Table 5

Students t-test Of Mean Age By Pap Result

	N	Mean	SD	t	df	p
Age						
Group 1 (Normal Pap)	201	21.9	4.3			
Group 2 (Abnormal Pap)	41	23.4	4.5	-2.05	240	0.04

When Chi square was used to determine differences in Pap results by the following variables there were no significant differences: multiple sexual contacts, ($X^2=3.67$; $df=1$; $p=NS$; $N=242$); frequency of sexual intercourse ($X^2=1.58$; $df=2$; $p=NS$); birth control method ($X^2=2.39$; $df=5$; $p=NS$); number of tampons used per day ($X^2=2.20$; $df=3$); use of pads ($X^2=2.49$; $df=3$; $p=NS$); and smoking status ($X^2=1.09$; $df=1$; $p=NS$).

CHAPTER V

DISCUSSION

This chapter will provide a brief summary of the study. Discussion and conclusions will be presented followed by recommendations for practice, education, research and policy.

Summary

Today the majority of females fifteen years and older have used tampons. Since their introduction in 1933, tampons have changed greatly in composition: more absorbent synthetic fibers have replaced natural fibers, plastic applicators have joined cardboard, and some contain a fragrance. While changes in vaginal mucosa including inflammatory changes, lacerations, and micro-ulcerations as a result of tampon use have been documented, no research examining the use of menstrual hygiene products and their effect on cervical cytology was located.

The purpose of this study was to examine the association between menstrual hygiene product use and the incidence of abnormal Pap smear results. The Pap smear result of interest was that of benign cellular inflammatory changes and/or atypical squamous cell of undetermined significance (ASCUS).

Data were collected by chart audit review of 250 women, ages 14 to 36, who sought Pap smear screening at a Midwestern family planning clinic. The data collection instrument was designed by the researcher. Data were analyzed using the Statistical Package for the Social Sciences (SPSS-X).

The association in Pap smear result by tampon applicator use, analyzed using Pearson Chi square, was found to be statistically significant ($X^2=18.53$; $df=4$; $p=0.003$). The difference in Pap smear result by type of tampon was also statistically significant ($X^2=48.06$; $df=3$; $p=0.000$).

Discussion

Review of the literature. The current literature suggests that ASCUS Pap smears occur at a frequency of 1.6 to 19% (Davis et al., 1987; DHHS, 1989; Gunn & Simpson, 1992; Kaminski et al., 1989; Pearlstone et al., 1992). The study results indicate an incidence rate of 12% and thus remain consistent with previously documented incidence rates.

While risk factors for benign cellular changes and atypia have not been extensively studied or reported in the literature, those for cervical cancer have been identified. Among factors identified as altering risk for cancer are those related to age, sexual behavior, contraceptive methods, and cigarette smoking (Berger, 1978; Brinton et

al., 1986; Celentano, Klassen, Weisman, & Rosenhein, 1987; Clarke et al., 1985; Irwin, 1988; Trevathan, 1983).

The results of this study indicate type of tampon (deodorant, non-deodorant) and type of applicator (plastic, cardboard, non-applicator) were associated with the increased possibility of an abnormal Pap result of benign cellular inflammatory changes and/or ASCUS. This finding is consistent with principles of vaginal health: contact with any chemical or foreign object on the fragile mucosa can cause irritation and inflammation (Fisher, 1973; Friedrich & Siegesmund, 1980; Larson, 1979), and inflammation stimulates cell division thereby increasing the chance for abnormal cell changes (Perez-Tamayo, 1985).

The results of this study support the findings that adolescent onset of sexual intercourse is associated with an increased likelihood of an abnormal Pap smear result (see Table 4). A Student's t-test was significant for the relationship between age and Pap smear result (see Table 5).

In this study, results indicate the differences between history of multiple sexual contacts, birth control method, and smoking status by Pap smear result are determined to be non-significant. The results do not support previously evidenced associations; however these other studies reviewed malignant findings while this study reviewed non-malignant Pap results.

A survey of the literature reveals a limited number of articles regarding tampon usage with the exception of those which are directly related to TSS. From 1938 to 1966, articles in the medical literature debated clinical and moral issues involving tampon use. Researchers concluded that tampons were a safe and effective means for the absorption of menstrual fluid (Arnold & Hegele, 1938; Barton, 1942; Dickinson, 1945; Karnaky, 1956; Rutherford et al., 1962; Thornton, 1943; Widenius, 1944). When it was discovered, in the late 1950s, that the deep vaginal mucosa lacked any specific nerve endings, the focus on tampons and its implications for morality diminished (Wheatley et al., 1965). The literature review revealed no documented studies of tampons usage in the medical literature from 1966 to 1977.

The literature of the late 1970's and early 1980s evidenced a growing concern for the incidence of tampon-induced lacerations and ulcerations. However, this concern was overshadowed in July, 1980, by the newly diagnosed, tampon-associated Toxic Shock Syndrome.

Why the dearth of information regarding such a common practice such as tampon use in menstruating females? No doubt, the low social status of women in times past, and the taboos, myths, and superstitions, which even now, surround menstruation have been important factors.

Theoretical framework. The Theory of Nursing as Human Science and Human Care as proposed by Jean Watson (1979) provided the theoretical framework for this study. In daily conversation about sexuality issues the nurse draws on scientific principles and the ability to demonstrate transpersonal care in order to communicate about these historically taboo subjects. Two of Watson's ten Carative Factors--Carative Factor 6: the systematic use of the scientific problem-solving method for decision making; and Carative Factor 7: the promotion of interpersonal teaching and learning had significance for this study. Applying the scientific problem solving method, the researcher examined the association between the use of menstrual hygiene products and incidence of abnormal Pap smear results. The process provided the opportunity to be engaged in the interpersonal teaching and learning process with professors, co-workers, and clients

Implications for practice. The nurse clinician's role in cervical cytology screening and the prevention, detection, and follow-up care of abnormal Pap smears includes the responsibilities of patient education, consultation, and consumer advocacy. The nurse's responsibilities require expertise in detection skills, quality assurance and control, the maintenance of a therapeutic environment for learning, and ongoing critical analysis of potential causal relationships that can alter Pap smear findings.

Patient education is guided in part by protocol and based on principles of vaginal health. The nurse clinician must provide an explanation of the reason for Pap screening and evaluate the learning needs of the patient regarding risk behaviors. The nurse should recognize and attempt to diminish the patient's negative emotions regarding the Pap smear result.

Consultation involves nurses in collaboration with physicians, cytopathologists, and cytotechnologists (list not exclusive) performing periodic review of patient histories and identification of high risk factors. Education on methods, materials, and considerations for reliable Pap screening are necessary. Ginsberg (1991) suggests standardized educational protocols for health care providers to encourage uniform Pap screening are warranted.

Nurses as consumer advocates for health must contribute to the establishment of standardized protocols for abnormal Pap smear management. Nurses can promote confidence in Pap smear screening by educating the community via newspaper, public service announcements, and agencies who serve women. Nurses can join with consumer groups to urge tampon manufacturers to list ingredients; the Menstrual Wealth Catalog (1993) reports incidence of dyes, waxes, surfactants, alcohols, acids, nitrogen compounds, and hydrocarbons being leached from tampons and pads. As advocates for women's health, nurses must increase self and

other awareness about the potential damage to the environment resulting from the disposal of plastic and paper menstrual hygiene products, approximated to be 11.5 billion pounds per year (Menstrual Wealth Catalog, 1993).

Basic nursing curricula need to include content on eliciting a complete psycho/social/gynecological history. A complete history should include, but not be limited to, information regarding sexual behavior, contraception, smoking status, menstrual history, and feminine hygiene practices including use of menstrual hygiene products and douching. Furthermore, nurses should be aware of the potential risks associated with these components of the patient history.

Recommendations for Further Research

Replicating this study using a larger sample, or a continuation of this presented study, to strengthen the generalizability of the results would be useful. For ease in data collection, the data regarding menstrual hygiene product use could be incorporated into the cervical cytology lab slip submitted with the specimen.

A longitudinal study of females with ASCUS Pap results could examine the frequency in which atypia persisted or recurred over time with consideration for continued/discontinued use of a specific menstrual hygiene

product. Concurrently, the natural history of the cytological changes could be examined.

A survey could be undertaken to determine female's reasons for choosing particular menstrual hygiene products, feelings about menstruation and the need for such products, and patient identified concerns regarding use of such products. Given the prevalence of use of tampons and the rapidity with which new products are introduced, nurse clinicians should know what products are used, how often, for what purposes, and at what risks or benefits to women's health.

APPENDICES

APPENDIX A

THE BETHESDA SYSTEM FOR
REPORTING OF CERVICAL CYTOLOGICAL SMEARS

The cytopathologist's cervical smear report will include information regarding the following:

Specimen Adequacy:

satisfactory,
unsatisfactory
less than optimal, limited by;

General Categorization of specimen:

within normal limits
unsatisfactory

Descriptive Diagnosis

infection
reactive and reparative changes
epithelial abnormalities
 squamous cell
 glandular cell
non-epithelial malignant neoplasm:
hormonal evaluation (vaginal smears)
other

Recommendations

(Koss, 1990).

APPENDIX B

THE PAPANICOLAOU CLASSIFICATION SYSTEM

Class 0	few cells; white blood cells, red blood cells, dried; distorted cells broken slide
Class I	Normal, differential cells, metaplasia mild inflammation. (Normal) Histology: Normal, Squamous metaplasia
Class II or III	Less than 10% basal or undifferentiated cells Histology: Atypical Squamous cells
Class III	10-20% Basal or undifferentiated cells Histology: Moderate Dysplasia
Class IV	Greater than 30% Basal or undifferentiated cells on slide Histology: Severe dysplasia Carcinoma in situ
Class V	Malignant cells Histology: invasive cancer

(DHHS, 1989).

CHART	AGE	AO	MC	SA	BCM	APPLICATOR					TYPE				#/DAY			FIRST USE	PADS				PAP RESULT	CIG	COMMENTS			
						1	2	3	4	5	1	2	3	4	1	2	3		1	2	3	4						
TOTALS																												

KEY

AO MC SA BCM
 1 = YES 1 - 12 WEEK 1 - SMALL CENTRAL EPITELIAL
 2 = NO 2 - 12 WEEK 2 - LYMPHOMA
 3 = MD 3 - STERIODS
 4 - DIAPHRAGM
 5 - EITHER AWAY FROM
 6 - OTHER

 ABBREVIATIONS
 AO - ASCUS
 MC - MULTIPLE CENTRAL
 SA - SQUAMOUS APLASIA
 BCM - BILAYERAL CENTRAL METAPLASIA
 MD - MISSING DATA

APPLICATOR

1 = PLASTIC
 2 = CARDBOARD
 3 = EITHER
 4 = NEITHER
 5 = N/A

TYPE

1 = DEO
 2 = NON-DEO
 3 = EITHER
 4 = N/A

#/DAY

0 = N/A
 1 = 0-4
 2 = 5-8
 3 = 9-12

TYPE

1 = DEO
 2 = NON-DEO
 3 = EITHER
 4 = N/A

PAP

0 = WNL
 1 = ASCUS
 2 = LSIL
 3 = INFLAM
 4 = OTHER

CIGS

1 = SMOKER
 2 = NON SMOKER

ABBREVIATIONS

WNL = WITHIN NORMAL LIMITS
 ASCUS = ATYPICAL SQUAMOUS CELLS WITH FERMINGLY NEAR N/A
 LSIL = LOW GRADE INTRACENTRAL EPITELIAL LESION
 INFLAM = INFLAMMATION

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