NONINFECTIOUS FACTORS ASSOCIATED WITH CERVICAL INFLAMMATION ON PAP SMEAR RESULTS

A DISSERTATION

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BY

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To the Associate Vice President for Research and Dean of the Graduate School:

I am submitting herewith a dissertation written by Anne T. Thomson entitled "Noninfectious Factors Associated with Cervical Inflammation on Pap Smear Results." I have examined the final copy of this dissertation for form and content and recommend that it be accepted in partial fulfillment of the requirements for the degree of Doctor of Philosophy, with a major in Health Sciences.

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ABSTRACT

COMPLETED RESEARCH IN HEALTH SCIENCES
Texas Woman's University, Denton, Texas

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The purpose of this study was to establish if there is a relationship between degree of tampon use and cervical inflammation of women with no history of sexually transmitted disease, previous abnormal Pap smears, and no current abnormal vaginal symptoms.

This nonexperimental retrospective study was conducted using medical record review with complete confidentiality of the sample maintained at all times. The study population consisted of women who accessed a family practice clinic in the Dallas/Fort Worth area for a physical examination including a Pap smear between March 1, 1999 and February 29, 2000. Forty-four women met the study sample criteria of history of normal Pap smears, no history of sexually transmitted disease, having monthly menstrual cycles, and between 18 and 40 years of age.

The methodology consisted of reviewing medical records to collect descriptive statistics on the sample which included: (a) tobacco use, (b) last menstrual period, (c) last occurrence of intercourse, (d) last occurrence of douching, and (e) type of birth control. Self-reported data on tampon use was also obtained from the medical records and the researcher computed the percentage of tampon use per menstrual cycle. The variables of tampon use were recorded as never use, tampon use 1% to 25% of time per menstrual cycle, tampon use 26% to 50% of time per menstrual cycle, and tampon use 51% to 100% of time per menstrual cycle. Degree of inflammation reported on the Pap smear laboratory sheet was recorded as none, mild, moderate, or marked.

Using Chi-square for data analysis, a statistically significant relationship was found between tampon use and cervical inflammation based on Pap smear results. A statistically significant relationship was also found between degree of tampon use and degree of inflammation based on Pap smear results.

Study findings suggests that health care providers and patient educators should assume a more active role in explaining the appropriate use, benefits, and potential risk of tampon use.

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CHAPTER I

PROBLEM AND ITS BACKGROUND

Chronic tampon use has been clinically implicated in the occurrence of increased vaginal and cervical irritation which could result in mildly abnormal Papanicolaou smear (Pap smear) results, yet few studies have evaluated chronic tampon use and the incidence of cervical inflammation in the absence of infection. In clinical practice mild to moderate changes in Pap smear results, which may convert to normal findings with time, are often repeated in 3 to 6 months after the initial screening before more extensive testing is done. Some health care providers have recommended more extensive testing if inflammation is significant. The research identifies inflammation as a variant of normal to a marker for more significant cervical changes ranging from infection to precancerous dysplasia. Currently no management protocols for cervical inflammation is universally accepted in the clinical setting.

Cervical inflammation can be the result of normal reparative changes in cervical cells, chemical or mechanical irritation, or the result of a vaginal infection. Identifying noninfectious factors that can increase cervical inflammation should result in educating women and screening for these factors at the time of scheduling the Pap smear examination, perhaps resulting in the decreased incidence of repeat Pap smear testing for benign cervical inflammation. In a cost conscious health care environment identifying factors which could eliminate unnecessary repeat testing is beneficial.

Purpose of the Study

The purpose of this study was to establish if there was a relationship between degree of tampon use and cervical inflammation of women with no history of sexually transmitted disease, previous abnormal Pap smears, and no current abnormal vaginal symptoms.

Research Questions

The following research questions guided this study:

1. Is there a relationship between tampon use and the occurrence of cervical inflammation based on Pap smear results?

2. Is there a relationship between degree of tampon use and the degree of cervical inflammation based on Pap smear results?

Definition of Terms

The following terms were defined for the purpose of this study:

Abnormal vaginal symptoms. A self-reported or observed vaginal symptoms at time of examination characterized by vaginal or external genital discomfort, lesions, or abnormal discharge.

Degree of tampon use. A percentage of time when tampons are used during the subject's menstrual cycle. Number of hours of tampon use per cycle divided by total hours of menstrual cycle will be classified as: never use tampons, tampon use 1%-25% of menstrual cycle, tampon use 26%-50% of menstrual cycle, and tampon use 51%-100% of menstrual cycle. A classification of never used tampons will be included to compare with subjects who use tampons.

Inflammation. The presence of increased number of inflammatory cells, which may represent cervical cyclic changes, infection, or mechanical irritation.

Low risk. Subjects who report a history of normal Pap smears, have no history of sexually transmitted disease, and currently have no self-reported or observed symptoms of vaginal infection or risk for a sexually transmitted disease.

Noninfectious vaginal inflammation. The presence of increased inflammatory cells caused by nonsexually transmitted diseases.

Normal Pap (Papanicolaou) smear. Technique of obtaining exfoliated cells from the external and internal cervix which is evaluated for cellular changes, presence of bacteria, hormonal adequacy, and presence of inflammatory cells.

Reparative changes. The monthly cyclic cellular cervical changes where the squamous cells go through a maturation process from the basal level to the surface.

Sexually transmitted disease (STD). A group of infectious diseases which are transmitted through sexual contact caused by specific bacteria, viruses, or fungal agents.

Squamous cells. The most abundant type of cell present on the Pap smear. This cell exists in a variety of maturation's depending on the type and amount of hormones present.

Toxic Shock Syndrome. A syndrome characterized by high fever, vomiting, diarrhea, confusion, and skin rash that may rapidly progress to severe and intractable shock. Etiology of Toxic Shock Syndrome is Staphylococcus aureus which produces toxin-1 (TSST-1) (Hajjeh, Reingold, Weil, Shutt, Schuchat, & Perkins, (1999).

Tampon use. The use of a mechanical device placed within the vagina during the menstrual cycle to absorb menstrual secretions.

Limitations

The study was limited by the following:

1. The study was limited in scope to the clinical setting from which the sample was obtained, therefore generalizability was impacted.

2. The study was limited in scope due to the small sample size decreasing generalizability.

Delimitations

The study was delimited by the following:

1. The sample consisted of women between 18 and 40 years of age.

2. Indication of tampon use was for the previous 6 months from date of examination.

3. Other factors which could affect research findings, method of birth control, tobacco use, last occurrence of intercourse, and last occurrence of douching were used as descriptive statistics of the population.

4. Assessment of current risk for vaginal infection was based on subjective client history obtained at time of examination.

5. The study was limited to the inclusion of only women not at risk for a sexually transmitted disease based on subjective data reported at the time of examination and recorded on the medical record.

6. The study included only women seen at one clinic between March 1, 1999 and February 29, 2000.

Assumptions

For the purpose of this study, the following was assumed:

1. Study subjects will accurately estimate degree of tampon use.

2. Women will find it beneficial to know if tampon use increases cervical inflammation.

3. Method of birth control, monthly cyclic changes, tobacco use, episode of last intercourse, and episode of last douching will not influence study findings.

4. Other health problems/treatments will not impact cervical inflammation as revealed by Pap smear results.

5. Pap smear reports will be accurate and reliable.

Significance of the Study

Cancer of the cervix and its precancerous precursor lesions can be detected by cervical Pap smear screening. Although the United States death rate from this disease continues at approximately 5,000 per year, studies indicate that routine screening markedly reduces both morbidity and mortality of this invasive disease (Rolnick, LaFerla, Wehrle, Trygstad, & Okagaki, 1996). Yet at the present time approximately 50 million Pap smears are performed in the United States each year with only about 15,000 cases of cervical cancer and 60,000 potentially precancerous changes being discovered (Noller, 1997). With an increased awareness of health care costs some health planners are questioning the need for routine cervical screening after cost benefit analysis (Noller, 1997). It would be a tragedy if the best cancer detection test ever developed, the Pap smear, became restricted. If we can decrease the number of unnecessary pap smears that are performed throughout the United States and perhaps decrease the 50 million samples per year to 30

to 40 million, we may be able to preserve its usage far into the future (Noller, 1997).

Chronic tampon use has been clinically associated with cervical and vaginal inflammation on Pap smear results. Some health care providers suggest the elimination of tampon use before repeat testing after finding mild inflammation on initial Pap smear results. In the late 1970s and early 1980s significant research was conducted on the role of tampon use and incidence of Toxic Shock Syndrome. Research has indicated that no matter how small or thin a tampon is, it can still scratch the cervical surface during walking, sitting, or any type of body movement (Fooladi, 1998).

Although inflammation is reported in up to 25% of cervical Papanicolaou smears, the clinical implications and optimal management of this finding remain controversial (American Family Physician, 1995). Identifying factors that might influence Pap smear test results, causing unnecessary repeat testing that could potentially impact health care cost could prove to be a cost effective measure. This may also provide invaluable knowledge that could benefit and empower women to make responsible choices concerning their health. Omar (1998) reported that only 22% of physicians had discussed tampon

use with menstruating women. The majority of young women use tampons based on their own decision or maternal influence for comfort, convenience, and appearance (Omar, 1998). Healthcare providers should assume a more active role in explaining the appropriate use, benefits, and potential risks of tampon use.

CHAPTER II

REVIEW OF THE LITERATURE

This literature review includes an overview of the published literature which relates to the research topic from 1980 to 1999. Research conducted in the early 1980s on tampon associated Toxic Shock Syndrome is included since that was a period of extensive research ining tampon use and its effect on vaginal health. Due to the limited research conducted on tampon use and cervical inflammation the references are limited. The first section of the literature review discusses the history, technique, and classification of the Papanicolaou smear screening test which is the method of detecting cervical inflammation in this study. The second section discusses the vaginal and cervical environment. It provides background information on the vaginal ecosystem and factors associated with the development of inflammation. The third section identifies factors which have been implicated in causing cervical inflammation. The effect of tampon use on vaginal health is discussed in the fourth section of Chapter I. The last section of the literature

review addresses the financial impact of decreasing unnecessary Pap smears.

The Papanicolou Smear

The cervical Papanicolou smear is a widely accepted method used in the diagnosis of cervical cancer since 1943. In 1941, Drs. George Papanicolaou and Herbert Traut first described their use of a "vaginal smear technique" in assessing patients for uterine and cervical cancers (MMWR, 1997). Since the introduction of this technique, now known as the Pap smear test, the mortality rate from cervical cancer has declined by 70% (MMWR, 1997). The Pap smear is a technique to obtain exfoliated cells from the cervix using a variety of spatulas or brushes. Methods of specimen acquisition, preparation, and evaluation of the Pap smear have changed little since its introduction in the 1940s (National Institutes of Health Consensus Statement, 1998). Samples obtained from the cervix will consist of single cells or small tissue fragments. A fixation spray is applied promptly to prevent distortion of the epithelial cell from air drying. The Pap smear should have (a) adequate numbers of squamous epithelial cells present, (b) evidence that the transformation zone was sampled (i.e., the presence of

endocervicial cells on the smear), (c) thin one-layer thickness across the slide, (d) epithelial cells not obscured by blood, inflammatory cells, or foreign material such as lubricant or talc, (e) appropriately preserved specimen (Heller, 1997). Fiber contaminants are a common finding in cervical vaginal smears (Hoeven & Bertolini, 1996). Although not significant in the interpretation of the Pap smear, a potential pitfall is for these fibers to be mistaken for fungi or other pathogens. Common fibers found on smears have the microscopic features of cotton and, less commonly, of rayon (Hoeven & Bertolini, 1996). These fibers are the major content of tampons. To eliminate contaminants and artifacts in the Pap smear specimen previsit patient instructions should include nothing in the vagina for 48 hours. During this time advising women to avoid tampon use, intravaginal contraceptives, medications, sexual intercourse, or douching is recommended. Optimal time of ination is 1 to 2 weeks after menses and no current infection or active bleeding (Mashburn & Scharbo-DeHaan, 1997).

A classification system for reporting cervical and vaginal cytological diseases from Pap smear results was generated at the National Cancer Institute in Bethesda, Maryland in 1988. This new classification system was

developed in order to standardize the terminology and provide a description of cellular changes (Mashburn & Scharbo-DeHaan, 1997). With the Bethesda System cytopathologist also include additional findings as part of the Pap smear results including presence and degree of inflammation. Increased number of inflammatory cells is found on 5% to 25% of Pap smears (Eckert, Koutsky, Kiviat, Krone, Stevens, & Eschenbach, 1995). If inflammation is significant, the cytopathologist may experience difficulty reading the slide. As defined by the Bethesda System criteria, if inflammation obscures 50% to 75% of the epithelial cells the specimen will be read as "satisfactory for evaluation but limited by inflammation." If inflammation precludes interpretation of 75% or more of the epithelial cells, the specimen will read as "unsatisfactory for evaluation" (Nuovo, 1995). Inflammation is classified under reactive changes as noted:

Bethesda System General categorization
- Within normal limits
- Benign cellular changes: see descriptive diagnosis
- Epithelial cell abnormality: see descriptive diagnosis

Descriptive diagnosis
- Benign cellular changes
- Infection
- Trichomonas vaginallis
- Fungal organism morphologically consistent with Candida

Predominance of coccobacilli consistent with shift in vaginal flora
Bacteria morphologically consistent with Actinomyces
Cellular changes associated with Herpes simplex virus
Other

Reactive Changes
Reactive cellular changes associated with:
Inflammation (includes typical repair)
Atrophy with inflammation ("atrophic vaginitis")
Radiation
Intrauterine contraceptive device
Other

Epithelial cell abnormalities
Squamous cell
Atypical squamous cells of undetermined significance
Low-grade squamous intraepithelial lesion encompassing:
Moderate and severe dysplasia, CIS/CIN 2 and CIN 3
Squamous cell carcinoma

Glandular cell
Endometrial cells, cytologically benign in post-menopausal women
Atypical glandular cells of undetermined significance: Qualify
Endocervical adenocarcinoma
Endometrial adenocarcinoma
Extrauterine adenocarcinoma
Adenocarcinoma, other
Other malignant neoplasm: Specify

Hormonal evaluation
Hormonal pattern compatible with age and history
Hormonal pattern incompatible with age and history: Specify
Hormonal evaluation not possible due to: Specify
(Mashburn & Scharbo-DeHaan, 1997)

Although the frequency of cervical cancer screening has been extensively studied, little is known about how clinicians decide to screen or recall patients for Pap smears. Curtis, Morrell, Hendrix, Mintzerm, Resnick, & Qaqish, (1997) found variation from officebased clinicians suggesting either uncertainty or different opinions in making recall and treatment decisions for smears of limited quality even when associated with cytologic abnormalities. These differences may have relevance to outcomes, clinician workload, and costs of care in cervical cancer screening.

The Vaginal and Cervical Environment

The vagina, which connects the external and internal genitalia, is a hollow tube extending between the urethra and rectum. The vaginal and uterine cavities are potential spaces unless distended by some influence to expand the space. The uterus has two parts: the body (or corpus) and the cervix. The lower part of the uterus, the cervix, protrudes into the vaginal. A round or slit-like depression, the external of the cervix, marks the opening into the endocervical canal and uterine cavity (Seidel, Ball, Dains, & Benedict, 1999). The vagina is an organ which is regularly visualized clinically, but rarely

closely inspected, especially those parts which may be obscured by the cervix or a vaginal speculum during routine gynecological ination. The posterior aspect may be the area of the vaginal surface which is most likely to experience minor trauma from sexual intercourse, tampon use, or diaphragm use. A highly significant relationship of minor vaginal changes to current tampon use was found in this study, although no serious lesions were noted (Fraser, Lahteenmaki, Elomaa, Lacarra, Mishell, Alvarez, Brache, Weisberg, Hickey, Vallentine, & Nash, 1999).

Cervical tissue consists of two types of cells. Squamous cells line the external cervix and vaginal tissue and are thicker and tougher than the one layer columnar cells found in the endocervix. The junction between these two types of cells is known as the squamous-columnar junction and is the ideal sampling site for internal cervical sampling since it is the most common site for squamous cell abnormalities. Vaginal epithelium is similar to epithelium elsewhere on the body with the exception of having glands.

Despite the absence of glands the vagina of a healthy woman of reproductive age will make approximately 1.6 to 4.8 grams of vaginal secretions a day making the vagina

and cervix a moist environment normally (Smith, 1997). Vaginal mucous occurs from shedding of vaginal epithelium and from accessory sex glands such as the Skene's and Bartholin's glands. Cervical mucus is a significant contributor to the vaginal secretions and is primarily (92% to 98%) water (Huggins & Preti, 1981). The uterine cervix and the vagina are continually being influenced by a variety of stressors including hormonal, chemical, microbiologic, and mechanical. This system is delicately balanced and a disturbance in any element can result in discharge, irritation, odor, or discomfort (Smith, 1997). The normal vaginal ecosystem contains approximately 5 to 15 different species of bacteria (ACOG, 1996). Maintaining a normal pH level between 3.8 and 4.2 is considered vital to stabilizing the vaginal ecosystem. Normal pH levels are believed to be maintained, in part, by Lactobacillus acidophilus, which are the dominant bacteria in a healthy vaginal ecosystem (ACOG, 1996). Lactobacilli break down the glycogen present in healthy, well-estrogenized vaginal tissues, liberating hydrogen peroxide and lactic acid and giving the vagina an acidic pH (Smith, 1997). Other sources suggest the large variety of micro-organisms present in the human vagina are collectively responsible for the acidic environment.

Pure colonies of lactobacilli, streptococci, and staphylococci do not produce the acids as does a natural mixture of the vaginal flora (Huggins & Preti, 1981). Factors which disrupt the normally acidic vagina permit a rise in the pH and encourage overgrowth of organisms normally found in small amounts in the vaginal, a common finding with Bacterial vaginosis and Candida yeast vaginitis. The number of organisms found with bacterial vaginosis may reach 1000 times the normal level (Migeon, Desnick, & Elmore, 1999).

Inflammation on Papanicolaou smear has been associated with a 30% to 50% incidence of bacterial vaginosis (Kelly & Black, 1990). Other sources report no associated inflammation with bacterial vaginosis (Migeon, Desnick, & Elmore, 1999). Although often described as a sexually transmitted disease, bacterial vaginoisis is found among women who are not sexually active (Priestley, Jones, & Goodwin, 1997). Lactobacilli, through their production of lactic acid, suppress anaerobes and other pathogens. When the pH level rises, lactobacilli growth is inhibited, while pathogen growth is facilitated (acog, 1996). Yeast or Candida albicans are normal flora of the skin and vagina. Under normal circumstances, vaginal lactobacilli inhibit the growth

of these fungi. When the normal ecosystem of the vagina is disturbed, rapid fungal growth may occur, resulting in vaginal irritation and inflammation. Research has shown that inflammation is commonly found in the presence of infectious pathogens associated with sexually transmitted diseases which include Trichomonas, Neisseria gonnorrhoeae, and Chlamydia trachomatis. Eckert et al. (1995) conducted research to determine the correlation between inflammation detected on Papanicolaou smear and specific lower genital tract agents. Dense inflammation was found to be independently associated with cervical infection with Neisseria gonnorrhoeae, Chlamydia trachomatis, Herpes Simplex Virus, and Trichnomonas vaginalis. Cervical ectopy was identified by Eckert to be associated with a higher incidence of inflammation on Pap smear results in a population at risk for sexually transmitted disease and in women identified at being at low risk for sexually transmitted diseases. Cervical ectopy refers to the extension of the columnar epithelium from the endocervix outward over the ectocervix. Cervical ectopy without the presence of infection is a normal finding in most female adolescents and in women on oral contraceptive (Youngkin & Davis, 1998).

The epithelial lining of the cervix is constantly undergoing repair. Cyclic influences of estrogen and progesterone during the menstrual cycle induces proliferation (increase in number of cells) and differentiation or maturation (the development of functional and morphologic features of mature cells of the parent tissue type). This dynamic equilibrium is influenced and exists as a result of interrelationships among endogenous microflora, metabolic products of the microflora and the host, estrogen level, and pH level. Previous research studies have indicated the need to examine the incidence of inflammation present on Papanicolaou smear without apparent pathogens as an etiology (Eckert el al., 1995).

Tampon Use and Vaginal Health

Commercial tampons were first developed in 1933 (Friedrich & Siegesmund, 1980). About 70% of the 73 million women who are of menstruating age in the United States use tampons. Tampons currently sold in the United States are made of cotton, rayon, or blends of rayon and cotton (Center for Devices and Radiological Health, 1999). Rayon is made from cellulose fibers derived from wood pulp. The Federal Drug Agency (FDA) is responsible

for the regulation, the safety and effectiveness of medical devices, including tampons (Center for Devices and Radiological Health, 1999). Perfumes and fragrances in some tampons are reported to cause internal irritation, allergic reactions, and disruption of a woman's microbial balance. Vaginal dryness and ulceration may occur when women use tampons (Center for Devices and Radiological Health, 1999).

The use of super absorbent tampons during the early 1980s was found to be associated with toxic shock syndrome, a potentially lethal disorder caused by absorption of one or more toxins produced by colonized Staphylococcus aureus. Staphylococcus aureus bacteria commonly live in body areas such as the nose, skin, or vagina and usually cause no problems small numbers. Toxic Shock Syndrome had been described sporadically since the 1920s. The dramatic increase in the number of cases in 1979-1980 spurred epidemiological, clinical, and laboratory studies that resulted in better understanding of the association between high-absorbency tampons and Toxic Shock Syndrome (Center for Disease Control and Prevention, 1999). Initial studies found that significantly more women with menstrual toxic shock syndrome had used tampons and used the tampons 24 hours

per day. Several mechanisms have been implicated as links between tampon use and Toxic Shock Syndrome which include alteration in the normal vagina flora, mechanical blockage of menstrual fluids, tampon contamination with Staphylococcus aureus, absorption of bacteriostatic cervical secretions, the super absorbent or synthetic material of which tampons are made, damaged cervical and vaginal mucosa, and enhanced multiplication of the organisms in the menstrual efflux (Youngkin & Davis, 1998). Using sanitary pads instead of tampons almost entirely eliminates the risk for toxic shock syndrome (Hatcher, Trussell et al., 1994). Research conducted to evaluate entry of pathogens into the blood stream from tampon use identified that tampons, specifically high absorbant tampons can result in vaginal ulcerations. Colposcopy examination was done after insertion and removal of tampons and revealed alterations of the vaginal epithelium. The most common change seen is dryness in which areas of mucosa appear devoid of superficial moisture and exhibit a distinct change in color. Areas are slightly pale and sharp-bordered with a shiny, wrinkled surface, the superficial epithelial layers peel off from the underlying cell strata. If this process of layering continues into the deeper zones of the

epithelium a microulceration results (Friedrich & Siegesmund, 1980). Regardless of brand or type, mucosal alterations were noted in the majority of tampon users after a 5-hour exposure period, although more significant findings were associated with super absorbent (Friedrich, 1981). No matter how small or thin a tampon is, it can still scratch the cervical surface during walking, sitting, or any type of body movement. Some authorities believe these small cuts, even microscopic laceration, become ports of entry for virus and other organism (Fooladi, 1998).

Tampon use has also been identified with a higher incidence of urinary tract infections. Omar (1998) examined potential association of tampon use with sexually transmitted diseases and urinary track infections. Incidence of sexually transmitted diseases was not found to be significant. In the pad group, 12% reported urinary tract infections versus 32% in the tampon group.

Economical Impact of Decreasing Repeat Pap Smear Testing Due to Inflammation

The Pap smear has been widely used in the United States to screen for cervical cancer. Although cervical cancer can be life threatening, the majority of abnormal

Pap smear findings are caused from nonlife threatening causes. At the present time approximately 50 million Pap smears are performed in the United States each year, yet only about 15,000 cases of cervical cancer and 60,000 potentially precancerous changes are discovered (Noller, 1997). Cost per examination may vary from $160 to $200 to obtain the specimen and for laboratory examination of the Pap smear.

Practice protocols for the clinical management of cervical inflammation and mildly abnormal Pap smear results is not universally accepted. It is more difficult to accurately read a Pap smear in which the cervical cells under scrutiny are mixed with inflammatory cells, abnormal vaginal cells, or bacteria (Sweet, 1997). Cervical specimens in which the cells are obscured by inflammation are rejected for interpretation by the cytopathologist and require repeat testing.

Clinical practice for mildly abnormal Pap smears may include repeat cervical Pap smear screening and may eventually lead to more extensive colposcopic examination, a more extensive and costly procedure used to detect cervical pathology. With an increased awareness on health care spending decreasing the number of unnecessary Pap

smears that are performed throughout the United States can provide a substantial savings in health care cost.

As has been widely publicized, the United States spends a large fraction of its gross national product on health care. Our expenditures far exceed those of many other developed countries. Other nations which spend less have greater longevity, lower infant morbidity, and lower mortality. Although cost savings from unnecessary repeat Pap smears is relatively small in comparison to the billions of dollars spent on health care in the United States, it is still a worthwhile effort. If we can decrease the number of unnecessary Pap smears that are performed throughout the United States, and perhaps decrease the 50 million samples per year to 30 to 40 million, we may be able to preserve its usage far into the future (Noller, 1997).

Summary

The literature review describes the Papanicolaou smear as an effective method of screening for cervical cancer and as a method of evaluation for the presence of cervical inflammation. Concurrently, the review reports that specimens obscured by inflammation may result in repeat cervical screening and may ultimately lead to

more invasion colposcopy cervical examination to rule out cervical pathology.

The literature review describes factors which influence inflammation on Pap smear results. The bacterial inhabitants of the vagina, dominated by lactobacilli, provides an acidic environment which discourages the overgrowth of more pathogenic organisms. Factors which disrupt the predominance of lactobacilli may indirectly influence the development of bacterial vaginoisis or provide an environment conducive to overgrowth of yeast. Both conditions have been shown to increase cervical and vaginal inflammation. The literature review supports the role of sexually transmitted diseases resulting in inflammation on Pap smear results. Therefore, a history of sexually transmitted disease or current vaginal symptoms of irritation itching or abnormal discharge excluded subjects from the sample.

The literature review supports that cervical inflammation may result in repeat Pap smear screening and that identifying factors which increase inflammation could impact health care cost by decreasing unnecessary repeat screening. Therefore, the literature review supports the value of evaluating if cervical inflammation is influenced by the use of vaginal tampons.

CHAPTER III

METHODOLOGY

The purpose of this study was to establish if there was a relationship between degree of tampon use and cervical inflammation of women with no history of sexualy transmitted disease, previous abnormal Pap smears, and no current abnormal vaginal symptoms. A retrospective, nonexperimental design was used to answer the study questions.

The methodology chapter of this retrospective, nonexperimental design study includes a description of the procedures followed in the development of the study under the following headings: (a) Preliminary Procedures, (b) Setting, (c) Population and Sample, (d) Protection of Human Subjects, (e) Instrumentation, (f) Data Collection Procedures, and (g) Treatment of the Data.

Preliminary Procedures

Prior to beginning the study, the researcher completed several preliminary steps. A review of the related literature was conducted to aid in the development

of the prospectus which was presented to the dissertation committee for suggestions and corrections. The outline was revised as suggested by committee members. Permission to conduct the study was obtained from the Texas Woman's University Human Subjects Review Committee (see Appendix A). Finally, the prospectus was filed and approved with the Graduate School at Texas Woman's University (see Appendix B).

Setting

Data for this study were obtained from medical record review completed by the researcher at a family practice clinic in the Dallas/Fort Worth area that provided services to approximately 380 clients for Pap smear screening over a 1-year period. The clinic served a predominantly middle- to upper-middle income, and medically insured Caucasian population. Data needed for the study were a part of the medical history inventory, which was completed at a well woman examination when the Pap smear was performed. Additionally, the medical record review included data collection from the Pap smear laboratory report to record degree of inflammation.

Population and Sample

The population for this study was women who accessed the clinic for yearly examinations including a Pap smear from March 1, 1999 through February 29, 2000. Participants were women between 18 and 40 years of age. For purposes of the study the population was further delimited to women who met the following criteria: (a) had a history of normal Pap smears, (b) had no history of any sexually transmitted disease, (c) were currently having monthly menstrual cycles, and (d) currently had no vaginal symptoms of abnormal vaginal discharge, vaginal itching, or irritation.

Protection of Human Subjects

The study was designed to be in compliance with all the rules and regulations enforced by the Human Subjects Review Committee. Subsequently, approval was obtained from the family practice clinic where data were collected. A sample letter for the consent to conduct the medical record review and obtain the data at the clinic is included in Appendix C. For purposes of confidentiality identifying information is omitted from the consent letter. The research involved only the review of medical records and did not involve the identification

of human subjects. All data was presented as group data to ensure anonymity and confidentiality.

Procedures

Data for this study were obtained from chart review completed by the researcher at a Family Practice Clinic in the Dallas/Fort Worth area. Data needed for the study was a part of the medical history inventory which was completed at the well woman examination when the Pap smear was performed.

The sample for this study was chosen from a total population of approximately 380 women who accessed the clinic for a well woman examination conducted by the researcher from March 1, 1999 to February 29, 2000. A data collection form (see Appendix D) was developed by the researcher to record pertinent data. Data collection forms were assigned a number (identified by consecutive numbers) with no patient identification recorded. A computer list which contained the date of examination and age of all women seen for the well woman examinations from March 1, 1999 to February 29, 2000 was reviewed. Participants who did not fit the age parameters were then deleted from the list of eligible participants. From the approximately 380 medical records reviewed,

approximately 146 were eligible for the study according to time of examination and age parameter. Medical records were then reviewed by the researcher with the final sample being 44 women who met the study sample criteria of history of normal Pap smears, no history of sexually transmitted disease, currently having monthly menstrual cycles, no current vaginal irritation itching, or abnormal discharge at the time of examination. The data collection form, developed by the researcher (see Appendix D), was used to record participant information.

Instrumentation

The data collection form (see Appendix D) was developed by the researcher for this study. The purpose of the form was to collect descriptive statistics and research data variables from the medical record review. The form contained no identifying patient information. The date of last menses and date of examination was recorded to allow the researcher to determine the phase of the menstrual cycle in which the screening was performed. The recorded date of examination also allowed the researcher to ensure that the examination was conducted between March 1, 1999 through

February 29, 2000. History of normal Pap smears and no history of sexually transmitted disease were included on the collection form to screen for the sample criteria set by the researcher for the study. Tobacco use, date of last menses, last occurrence of intercourse, last occurrence of douching, type of birth control, and average days of menses were used for the descriptive characteristics of the study sample. Average days of menses and number of hours tampons were used during menses was recorded to enable the researcher to determine the degree of tampon use. The degree of tampon use was recorded as: (a) never use, (b) tampon use 1% to 25% per menstrual cycle, (c) tampon use 26% to 50% per menstrual cycle, (d) tampon use 51% to 100% per menstrual cycle. Degree of inflammation was categorized as none, mild, moderate, or marked consistent with the reporting of inflammation on the Pap smear laboratory reports.

Data Collection

Data for this research study were obtained by medical record review and recorded on the data collection form (see Appendix D). The data collection form was completed on 44 women who presented for a physical examination including a Pap smear from March 1, 1999 to

February 29, 2000 at a Dallas/Fort Worth family practice clinic. Complete confidentiality was maintained at all times during medical record review. Each participant met the study screening criteria of history of normal Pap smears and no history of sexually transmitted disease. These participants were having monthly menstrual cycles and had no current vaginal symptoms of itching, irritation, or discharge.

Tampon use, a research variable, was obtained from chart review, self-reported from the client at the time of the screening examination and recorded as a number of hours of tampuse use per cycle. The researcher computed tampon use for each participant as a ratio and reported tampon use as a percentage of tampon use per menstrual cycle. The following categories were used in Chi-square data analysis to measure tampon use: (a) never use, (b) tampon use 1% to 25% of time per menstrual cycle, (c) tampon use 26% to 50% of time per menstrual cycle, and (d) tampon use 51% to 100% of time per menstrual cycle. The research variable degree of inflammation was collected from the laboratory Pap smear and recorded as none, mild, moderate, or marked.

The researcher also collected from the medical record descriptive variables of the sample including: (a) tobacco

use, (b) date of last menses, (c) last occurrence of intercourse, (d) last occurrence of douching, and (e) type of birth control. The researcher was able to determine each participant's phase of menstrual cycle at the time of the well woman examination by comparing the date of last menses with the date of the examination.

Data Analysis

Chi-square with a Yates Correction (alpha level of .05) was used for analysis to determine the relationship between the independent and dependent variables. Inflammation was coded as 0 for no inflammation, 1 for mild, 2 for moderate, and 3 for marked inflammation. Occurrence of tampon use was coded 0 for never use, coded 1 for tampon use 1% to 25% of time per menstrual cycle, coded 2 for tampon use 26% to 50% of time per menstrual cycle, and coded 3 for 51% to 100% of time per menstrual cycle. The descriptive variables of the population, use of tobacco, last incidence of intercourse, and last occurrence of douching were entered as variables to be calculated as percentages for a frequency table to further describe the sample. Tobacco use was coded 0 for no use and 1 for smokers. Information on menses was coded for each phase of the menstrual

cycle that the Pap smear was obtained, day 1 through 7 of the menstrual cycle was coded as 1, days 7 through 14 were coded as 2, and day 14 to onset of next menses was coded as 3. Last occurrence of intercourse was coded 0 for no history of intercourse, coded 1 for intercourse in the last 24 hours, coded 2 for intercourse greater than 14 hours but less than 1 week, and coded 3 for intercourse greater than 1 week. Douching was coded for 0 for no history of douching, coded 1 for douching within the last 24 hours, coded 2 for greater than 24 hours but less than 7 days, and coded 3 for douching greater than 7 days previous to the examination. Type of birth control was coded 0 for no use of birth control, coded 1 for birth control pills, coded 2 for condoms, and coded 3 for depro provera injection. Any data not available from chart review were coded 9 for missing. Data from the 44 collection forms were entered into a SPSS statistical program for analysis.

The research study met the criteria for the use of Chi-square to assess differences among the grouped data from the study.

1. Both the independent and dependent variable are categorical.

2. The data consists of frequencies, not scores.

3. Each randomly selected observation can be classified into only one category for the independent variable(s) and only one category for the dependent variable. There are no repeated observations and no multiple response categories (Pett, 1997).

CHAPTER IV

FINDINGS

The purpose of this study was to establish if there was a relationship between degree of tampon use and cervical inflammation of women with no history of sexually transmitted disease, previous abnormal Pap smears, and no current abnormal vaginal symptoms. A retrospective, nonexperimental study consisting of medical record review was conducted in order to answer the research questions.

In this chapter, presentation of findings are reported in both tabular and narrative form. Specific findings of this study are the descriptive characteristics of the sample presented in frequency tables and Chi-square statistical analyses of the research variables. A summary concludes the chapter.

Descriptive Characteristics of the Participants

Forty-four records from the approximately 380 women seen from March 30, 1999 to February 29, 2000 were abstracted for this study. The sample population consisted of women 18 to 40 years of age who had accessed a family practice clinic for a physical examination including

a Pap smear. All women in the study had no history of sexually transmitted disease, had a history of normal Pap smears, and had no current history of vaginal irritation itching or abnormal vaginal discharge. The geographic area was predominantly middle to upper-middle income, medically insured Caucasian population in the Dallas/Fort Worth area.

Other variables which were collected to describe the population included tobacco use, last occurrence of intercourse, last occurrence of douching, date of last menses, and date of examination to approximate menstrual phase of the cycle the Pap smear was obtained.

Based on the 44 data collection forms, 38, or 86.4%, of the participants reported no history of smoking in the last 6 months. Five of the 44 reported a history of regular smoking in the last 6 months. One of the 44 records did not include tobacco use. Table 1 presents a summary of the descriptive characheristics of the participants. As to phase of the menstrual cycle, 9, or 20.5%, of the population had the Pap smear during days 1 through 7 of the cycle, 18, or 41%, were collected during day 8 through day 14 of the cycle, and 13, or 30%, had the Pap smear during day 14 to the onset of the next mensus. Four medical records did not include

Table 1

Frequency and Percent of Descriptive Characteristics of the Study Population

Variable	Frequency N=44	Percent %
Tobacco Use		
Smokers	5	11.4
Nonsmokers	38	86.4
Missing	1	2.2
Phase in Cycle		
Days 1-7	9	20.5
Days 8-14	18	41.0
Day 14 to next menses	13	30.0
Missing	4	9.0
Last Occurrence of Intercourse		
No history of intercourse	6	13.6
Within last 24 hours	7	15.9
>than 24 hours <7 days	14	31.8
>than 7 days	17	38.6
Last Occurrence of Douching		
No history of douching	37	84.1
Within last 24 hours	1	2.3
>24 hours <7 days	2	4.5
>than 7 days	4	9.1
Type of Birth Control		
None	17	38.6
BCP	17	38.6
Condoms	5	11.3
Depo Provera	1	2.3
Missing	4	9.1

N = 44
Percentages may vary slightly due to rounding.

exact date of last menstrual cycle and were coded as missing. With reference to last of intercourse, 7, or 15.9% had intercourse within 24 hours of the examination, 14, or 31.8%, had intercourse longer than 24 hours but less than 1 week before the examination, and 17, or 38.6%, reported not having intercourse for greater than 1 week prior to the examination. Douching was reported as 37, or 84.1%, having no history of douching, 1, or 2.3%, had douched within 24 hours of the examination, 2, or 4.5%, had douched greater than 24 hours but less than 1 week, and 4, or 9.1%, had douched greater than 1 week before the examination. The data indicated that for type of birth control 17, or 38.6%, were currently not using birth control, 17, or 38.6%, were using an oral contraceptive for birth control, 5, or 11.3%, used condoms for birth control, and 1, or 2.3%, used Depo Provera injection for birth control. Four medical records did not indicate a type of birth control and were coded as missing.

Findings by Research Questions

To answer the first research question "Is there a relationship between tampon use and the occurrence of inflammation," the data were analyzed using SPSS

statistical software. Of the 13 women who had cervical inflammation reported on their Pap smear results, 12 were tampon users and 1 was not. Using Chi-square with Yates Correction (df=1, N=44) the computed Chi-square statistic was 9.47. This result supported a statisically significant relationship (p = .002) between tampon use and the occurrence of imflammation. Table 2 presents a summary of the findings, showing the actual and expected counts in each cell of the cross-tabulations.

Table 2

Cross-tabulation of Use of Tampons and Occurrence of Inflammation

Use of Tampons	No Inflammation	Inflammation Present	Total Tampon Use
No Tampon Use			
Actual Count	18	1	19
Expected Count	13.4	5.6	
Yes for Tampon Use			
Actual Count	13	12	25
Expected Count	17.6	7.1	
Total	31	13	44

N = 44

To answer the second research question "Is there a relationship between degree of tampon use and degree of inflammation" the data were analyzed using SPSS statistical software. There is a statistically significant relationship between degree of tampon use and degree of inflammation identified as significant (p=.001) with a computed Chi-square of 27.23 (df=9, N=44). The cells of the cross-tabulation table (see Table 3) were then examined to determine where the significance occurred. Ananysis of the data showed the following to be inportant: (a) 18 of the 19 (94.7%) of those who did not use tampons had no inflammation, (b) 9 of the 18 (50.0%) who used tampons greater than 51% of their cycle had no inflammation, and (c) 7 of the 18 (38.9%) who had used tampons greater than 51% of their cycle had marked inflammation.

Table 3

Cross-tabulation Degree of Tampon Use and Degree of Inflammation

Degree of Tampon Use	Degree of Inflammation None	Mild	Moderate	Marked	Total Tampon Use
Never Use					
Actual Count	18	0	1	0	19
Expected Count	13.4	.9	1.7	3.0	
Use 1%-25%					
Actual Count	3	0	0	0	3
Expected Count	2.1	.1	.3	.5	
Use 26%-50%					
Actual Count	1	1	2	0	4
Expected Count	2.8	.2	.4	.6	
Use greater than 51%-100%					
Actual Count	9	1	1	7	18
Expected Count	12.7	.8	1.6	2.9	
Total Inflammation	31	2	4	7	44

N = 44

Summary

The descriptive characteristics of the study sample, self-reported at the time of the examination, indicated that the majority of this population were nonsmokers and did not douche by history. Additionally, the majority of the sample either used no birth control or used oral contraceptives. Last occurrence of intercourse and time of examinations during the menstrual cycle were variable.

The results of the study are summarized in the following statements:

1. There was a statistically significant relationship between tampon use and the incidence of cervical inflammation.

2. There was a statistically significant relationship between the degree of tampon use and the degree of cervical inflammation.

CHAPTER V

SUMMARY, CONCLUSIONS, DISCUSSION, AND RECOMMENDATIONS

This chapter is presented in three sections. The first section presents an overview of the entire study. The second section is a summary of the study findings. The final section contains recommendations for further research and study implications for health providers, including health educators.

Summary of the Study

The purpose of this study was to establish if there was a relationship between degree of tampon use and cervical inflammation of women with no history of sexually transmitted disease, previous abnormal Pap smears, and no current abnormal vaginal symptoms. A nonexperimental retrospective study was done through medical chart review. Women 18 to 40 years of age with a history of normal Pap smears, having monthly menstrual cycles, no history of sexually transmitted disease, and no current symptoms of abnormal vaginal discharge, itching, or irritation were included in the chart review. A data collection

form was utilized by the researcher to collect data which included demographic statistics on tobacco use, date of last menses, date of examination, last occurrence of intercourse, last occurrence of douching, and type of birth control. Tampon use per menstrual cycle was recorded as never use, tampon use 1% to 25% of time per cycle, tampon use 26% to 50% of time per cycle, and tampon use 51% to 100% of time per cycle. Degree of inflammation as reported on Pap smear laboratory report was recorded as none, mild, moderate, and marked inflammation. Data were analyzed using SPSS statistical software (Version 9, 1999). Chi-square was used to determine if there was a statistically significant relationship between tampon use and cervical inflammation.

Conclusions of the Study

The research findings indicated there was a relationship between tampon use and the occurrence of inflammation and degree of tampon use and degree of inflammation. The research also indicated a relationship between inflammation based on Pap smear results.

Discussion and Implications for Health Providers and Health Educators

The literature review indicates that there is no standard of treatment for cervical inflammation on normal Pap smear results yet it is found in the literature that inflammation may indicate cervical pathology. Cervical inflammation may be related to cancer of precancerous changes, infection, normal cyclic changes, disruption in the vaginal flora, or from mechanical irritation such as with tampons. By decreasing behaviors which increase benign cervical inflammation, the appearance of significant inflammation may be more significant when it is present. As the literature review revealed, cervical inflammation can obscure cervical cells from being viewed, decreasing inflammation on Pap smear slides may increase accuracy and decrease unnecessary repeat testing due to poor slide quality due to inflammation.

If health care providers continue to evaluate health care spending, all measures to decrease unnecessary laboratory/clinical testing needs to be evaluated. If there is a relationship between tampon use and cervical inflammation, as this research suggest, then not using tampons for a specific time frame before Pap smear

screening could potentially decrease the need for repeat testing for benign cervical inflammation.

For the health educator understanding factors that increase cervical inflammation and may increase unnecessary repeat testing is useful when serving as a resource person on cost-effective health care issues. Health educators associated with breast and cervical screening programs can provide education on behaviors which might influence the quality of the laboratory screening of the cervical cells and increase repeat testing, therefore increasing the cost of the screening. The patient/health educator who provides education to women directly can help empower women to make knowledgeable decisions in regard to tampon use and cervical screening.

Recommendations

Based on the results of this study, the following recommendations are presented for further research:

1. Replicate the study using a larger sample.

2. Conduct research to evaluate the role of tampons on altered vaginal flora and occurrence of bacterial vaginosis and yeast overgrowth.

3. Conduct further research on types of tampons and cervical inflammation.

4. Conduct research on the occurrence of sexually transmitted diseases and the use of tampons due to vaginal microlacerations.

5. Conduct research on current tampon use among women and what factors determine tampon use.

6. Conduct research on the impact of patient education on tampon use and cervical inflammation on patient behavior.

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APPENDICES

APPENDIX A

Human Subjects Review Committee Approval

TEXAS WOMAN'S
UNIVERSITY
DENTON / DALLAS / HOUSTON

HUMAN SUBJECTS
REVIEW COMMITTEE
P.O. Box 425619
Denton, TX 76204-5619
Phone: 940/898-3377
Fax: 940/898-3416

December 7, 1999

Ms. Anne Thomson
1917 Dexter Court
Flower Mound, TX 75028

Dear Ms. Thomson:

Re: Noninfectous Factors Influencing Inflammation on Pap Smear Results

The above referenced study has been reviewed by a committee of the Human Subjects Review Committee and appears to meet our requirements in regard to protection of individuals' rights.

Be reminded that both the University and the Department of Health and Human Services (HHS) regulations typically require that agency approval letters and signatures indicating informed consent be obtained from all human subjects in your study. As applicable to your study, these consent forms and agency approval letters are to be filed with the Human Subjects Review Committee at the completion of the study. However, because you do not utilize a signed consent form for your study, the filing of signatures of subjects with the HSRC is not required.

Your study was determined to be exempt from further TWU HSRC review. However, another review by the Committee is required if your project changes. If you have any questions, please feel free to call the Human Subjects Review Committee at the phone number listed above.

Sincerely,

Dr. Linda Rubin, Chair
Human Subjects Review Committee - Denton

cc. Dr. Susan Ward, Department of Health Studies
Dr. Mary Walker Shaw, Department of Health Studies
Graduate School

APPENDIX B

Prospectus Approval from Graduate School

TEXAS WOMAN'S
UNIVERSITY
DENTON/DALLAS/HOUSTON

THE GRADUATE SCHOOL
P.O. Box 425649
Denton, TX 76204-5649
Phone: 940/898-3400
Fax: 940/898-3412

January 18, 2000

Ms. Anne T. Thomson
1917 Dexter Court
Flower Mound, Tx 75028

Dear Ms. Thomson:

Thank you for providing the materials necessary for the final approval of your Dissertation prospectus in the Graduate School. I am pleased to approve the prospectus entitled **"Noninfectious Factors Associated with Inflammation on Pap Smear Results"**, and I look forward to seeing the results of your study.

If I can be of further assistance, please let me know.

Sincerely yours,

Leslie M Thompson

Leslie M. Thompson
Associate Vice President for Research and
Dean of the Graduate School

LMT/sgm

cc Dr. Mary Walker-Shaw, Health Studies
Dr. Susan Ward, Health Studies

APPENDIX C

Agency Approval

Committee Members:

This is to inform you that I have knowledge that Anne Thomson will be conducting a chart review of clients seen at [clinical name omitted] from March 1, 1999 to February 29, 2000. The information obtained will remain confidential and client anonymity will be maintained at all times. Data will be collected and analyzed as group data only and used only for the dissertation "NONINFECTIOUS FACTORS INFLUENCING INFLAMMATION ON PAP SMEAR RESULTS."

_____ _____

Signature Date

APPENDIX D

Data Collection Form

Data Collection

ID #:_____

DATE:_____

HISTORY OF NORMAL PAPS? YES NO

HISTORY OF ANY STD? YES NO

SMOKER: YES AMOUNT_____ NO

DATE OF LAST MENSES:_____

LAST OCCURRENCE OF INTERCOURSE?_____

LAST OCCURRENCE OF DOUCHING?_____

TYPE OF BIRTH CONTROL:_____

Average days of menses:_____

Number of hours tampons used during menses:_____

DEGREE OF TAMPON USE:

NEVER USE TAMPONS: _____

TAMPON USE 1-25% OF TIME PER MENSTRUAL CYCLE: _____

TAMPON USE 26-50% OF TIME PER MENSTRUAL CYCLE: _____

TAMPON USE 51%-100% OF TIME PER MENSTRUAL CYCLE: _____

DEGREE OF INFLAMMATION: NONE MILD MODERATE MARKED