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Oral Contraceptives: The Risks, Benefits, and Dilemmas

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Abstract

Millions of women have chosen to use oral contraceptives for various reasons. However, the question must be raised as to the awareness level of the risks and benefits associated with the use of oral contraceptives. Numerous studies have been performed to establish the effects of oral contraceptives. This thesis examines these studies to consolidate the most current findings.

In order to present these studies effectively, this thesis will begin by briefly summarizing the menstrual cycle and how the use of oral contraceptives affects menstruation. Following this, a review of the risks, benefits, and ethical dilemmas will be presented. Utilizing the above research, a self-conducted, randomized, descriptive study was performed to assess how well women are informed of these findings before beginning to use oral contraceptives. The study consisted of 41 women between the ages of 18-45 at a local health clinic in eastern Virginia. The statistical findings showed that women are not being informed about the health risks and benefits associated with the use of oral contraceptives, indicating the need for an updated knowledge base on recent research studies and a revision of the current teaching methods.

## Oral Contraceptives: The Risks, Benefits, and Dilemmas Associated with Use

The use of hormones in preventing reproduction began in 1937 when AW Makepeace showed that ovulation could be prevented by injecting progesterone into rabbits. Almost twenty years later, large-scale clinical trials testing the efficacy of oral contraceptives began. In 1959, oral contraceptives were approved in the United States for use as birth control (Tchalkovaski et al., 2006). Today, millions of women use oral contraceptives for various reasons. Since most delay pregnancy and have few children overall, the average woman has approximately 450 menstrual cycles in her lifetime (Lin, 2007). The use of oral contraceptives has allowed women to control these cycles. In order for the effects of oral contraceptives to be properly presented, an overview of menstruation and the ability of oral contraceptives to manipulate the menstrual cycle is essential.

### Reproductive System

The female reproductive system is composed of two individual components--the ovarian cycle and the menstrual cycle. The endocrine system produces hormones that control these cycles, causing the average cycle to last for twenty-eight days. Oral contraceptives alter these cycles, suppressing ovulation and reducing the likelihood of conception.

#### *Overview of Conception*

*Ovarian cycle.* The ovarian cycle consists of the follicular phase and the luteal phase. The follicular phase lasts from day one until day fourteen in a twenty-eight day cycle. Under the influence of FSH (follicle stimulating hormone), a follicle that contains the egg begins to mature. When the follicle is mature, the egg (ovum) is released from the

ovary into the fallopian tube (Davidson, 2008). The release of the ovum indicates the beginning of the luteal phase. During this phase, LH (lutening hormone) increases, allowing the corpus luteum to develop from the follicle, which is needed in pregnancy to provide progesterone until the fourth month (Davidson, 2008). The ovum itself does not reach the uterus until approximately 72 to 96 hours after it is released.

*Menstrual cycle.* Menstruation typically occurs approximately fourteen days after ovulation in females who are not pregnant. The menstrual cycle has four phases: the menstrual phase, proliferative phase, secretory phase, and ischemic phase. The menstrual phase occurs during days one to six of a twenty-eight day cycle. During this phase, estrogen levels are low and the endometrium (inner layer of the uterus) is shed (Davidson, 2008). The proliferative phase begins on day seven and lasts until day fourteen. Throughout this phase, the endometrial glands in the uterus enlarge due to an increase in estrogen levels. The blood supply to the endometrium is increased and the thickness of the endometrial layer increases by six to eight times. The cervical mucus begins to thin to allow sperm easier passage (Davidson, 2008). After ovulation occurs, the secretory phase begins. Preparation for a fertilized ovum commences as vascularization is greatly increased, glycogen stores for nourishment are increased, and the endometrium continues to thicken (Davidson, 2008). The ischemic phase only occurs if fertilization does not occur. Estrogen and progesterone levels fall, small blood vessels rupture, and the overall blood flow to the endometrium decreases.

*Fertilization.* The egg and sperm only have a brief period of time to unite. The egg is only fertile for 12 to 24 hours after ovulation and the sperm is fertile for only 48 to 72 hours after it enters the female reproductive tract (Davidson, 2008). In one

ejaculation, approximately 200 million to 500 million sperm are introduced into the female. It usually takes between five and seven hours for the sperm to reach the ovum, with only hundreds of the sperm making it the entire way to the fallopian tube. Fertilization occurs when the nuclei of the egg and sperm are united together to form a zygote (Davidson, 2008).

*Implantation.* Implantation in the uterus occurs seven to ten days after fertilization. The zygote has now gone through rapid cellular divisions to form a morula, which consists of twelve to sixteen cells. The outer layer of the morula is known as the trophoblast, and the inner part of the morula is known as the blastocyst (which will continue to develop as the embryo). The glycogen that is increased in the uterine glands during the secretory phase of the menstrual cycle nourishes the blastocyst and the trophoblast attaches to the endometrium for nourishment (Davidson, 2008). The blastocyst itself eventually moves into the endometrial lining and the lining of the uterus continues to thicken under the influence of progesterone (Davidson, 2008).

#### *How the Pill Affects Conception*

Oral contraceptive pills are synthetic steroidal pills that are made in different formulations, including monophasic, biphasic, tri-phasic, and progesterone only pills (I'Onyesom, 2008). Contraceptive pills are created to work in three different ways: the first job of oral contraceptives is to prevent ovulation. Follicle Stimulating Hormone (FSH) and Luteinizing Hormone (LH) are the hormones released by the pituitary gland each month to signal the ovaries to produce an egg. Oral contraceptives are composed of synthetic estrogen and progestin, the two hormones produced by the ovaries. Contraceptives make the body think that there is already enough of those hormones,

causing the pituitary to secrete less FSH and LH (Kahlenborn, 2000). It is important to note that this does not completely eliminate ovulation but only suppresses it, posing potential ethical considerations that will be discussed in another section of this thesis.

The pill also has two distinct effects on the uterus and cervix. In the uterus, oral contraceptives act to thin out the inner lining called the endometrium. The woman's body was created to be prepared for implantation of a zygote around the time of ovulation each month by increasing nutritional stores and blood supply to the uterus (Kahlenborn, 2000). Thinning out the endometrium will cause a decrease in both the glycogen stores and blood circulation, making the uterus less able to support and nourish a zygote should conception occur (Kahlenborn, 2000). There is also some evidence that shows thickening of cervical mucus with the use of oral contraceptives, making it more difficult for sperm to make it through the cervix into the fallopian tubes for conception.

#### Benefits Associated with the Use of Oral Contraceptives

Continuous use of oral contraceptives appears to have multiple benefits. Oral contraceptives can help manage menstruation, endometriosis, polycystic ovary syndrome, premenstrual syndrome, menstrual migraines, and seizures that occur at the time of menses (Extend the option of extended contraception, 2008).

#### *Menstrual Relief*

Menstruation causes problems across the spectrum for women of all ages, from slight inconveniences to major health concerns (Lin, 2007). Approximately 20-40% of reproductive aged women have negative menstrual related symptoms. These negative effects cause 31% to become unable to function according to their physical ability for an average of 9.6 days during the year. These problems fall under the category of

dysmenorrhea, which is pain that begins at the onset of menses, causing cramping, backache, headache, nausea, vomiting, and radiating pain (Lin, 2007).

Oral contraceptives (OCs) can be used to eliminate menstrual cycles for those who suffer from dysmenorrhea. Suppressing the menstrual cycle has the ability to reduce cycle disorders like menorrhagia, dysmenorrhea, and iron deficiency anemia (Barnhart, Lin, 2007). The use of OCs has the ability to decrease the number of bleeding days, which is beneficial for those who suffer from various types of anemia and other bleeding disorders (Barnhart, Lin, 2007). Studies show that an estimated 10% of young women have iron deficiency due to prolonged and heavy bleeding, with 2.2% being diagnosed with iron-deficiency anemia (Wiegratz, 2006). Low dose OCs improved abnormal and difficult bleeding patterns in more than 80% of perimenopausal women.

#### *Decreased Bleeding*

Recent surveys show that excessive menstrual bleeding is one of the most common gynecological problems seen during primary care visits (Fraser et al., 2008). Originally, surgical procedures such as hysterectomy or endometrial ablation in the uterus were performed for women with excessive bleeding. OCs can now be used as a way to reduce menstrual bleeding while preserving the possibility of fertility and reducing risks associated with surgery. Oral progestins found in OCs have been seen to reduce blood loss in women who have excessive bleeding during each menstrual cycle. According to recent data, combination OCs are effective in reducing blood loss by up to 40-50% in women suffering from heavy menstrual bleeding. These combination agents with oral progestins have also been seen to be effective against bleeding disturbances not related to the menstrual cycle (Fraser et al., 2008).

*Effect on Endometriosis*

Endometriosis is caused when the endometrium, the inner layer of the uterus, enters the peritoneal cavity during menstruation. Endometriosis causes pelvic pain, dysmenorrhea, and infertility (Wiegratz, 2006). According to *Fertility Weekly*, the use of oral contraceptives alters the endometrium, making it less likely to develop into endometriosis (Oral Contraceptives Prevent the Development of Endometriosis, 2008). In one study, endometrial biopsies were taken, and those biopsies treated with oral contraceptives had 43% less endometriosis-like lesions (*Fertility Weekly* “Endometriosis”, 2008). In women experiencing chronic pelvic pain due to endometriosis, those who took OCs for two years had significantly reduced pain scores (Barnhart, Lin, 2007). Another study found that when OCs were used, the risk of developing endometriosis was lower, and patients with endometriosis had a decrease in pain when placed on continuous OC therapy (Maia et al., 2008).

*Effect on Polycystic Ovarian Syndrome*

Polycystic ovarian syndrome (PCOS) has become the most common cause of anovulation in women. The common characteristics include hyperandrogenism, oligomenorrhea or amenorrhea, a heterogeneous phenotype, chronic anovulation, and polycystic ovaries (Mulders, 2005). Recent studies suggest that genetic factors with an autosomal dominant pattern are related to this disorder. OCs have been used to treat the menstrual irregularities, weight gain, insulin resistance, and the hyperandrogenism caused by PCOS. A study to test the efficacy of OCs on PCOS was conducted in the Netherlands. For this study, 101 women who had been diagnosed with chronic anovulation (failure to release an egg during menstruation) were chosen to participate

(Mulders, 2005). Eighty-one of these women had been diagnosed with PCOS. 64% were not using oral contraceptives, and 33% were using oral contraceptives. Serum concentrations of the women taking OCs had significantly decreased levels of estradiol, progesterone, testosterone, and androstenedione (Mulder, 2005). This shows that the OCs had a significant effect on the phenotype expression found in those with PCOS. Subsequently, both menstrual irregularities and hirsutism were greatly reduced in those who were taking OCs during the study. However, even those taking OCs still met the qualification for PCOS. While the adverse symptoms were eliminated, ultrasonographic evaluation showed the presence of polycystic ovaries. While the use of OCs does effectively treat the unwanted physical alterations of PCOS, it appears to be unable to cure this disorder.

#### *Decreased Cancer Risk*

In 1968, a study began in the United Kingdom that included 23,000 women who were taking OCs and 23,000 who had never taken OCs (“Do women who have ever used OCs have an increased risk of cancer”, 2008). This 36 year study by 1,400 practitioners at the Royal College of General Practitioners produced data indicating that those who continuously used oral contraceptives had a 12% reduction in developing any type of cancer. Even further, it included a 29% reduction in the risk of developing cancers such as cervical, uterine, and ovarian (“Pill Use is Associated with Reductions”, 2008). In this study including 23,000 women during this 36-year time frame, the “ever-users” of OCs were found to have significantly reduced risks of cancer of the bowel, uterus, and ovaries. The ever-users were 42% less likely to develop uterine body cancer and 46% less likely to develop ovarian cancers (“Do women who have ever used OCs have an increased risk

of cancer”, 2008). The risk for ovarian cancer seemed to be reduced for almost fifteen years after the last pill dose, and uterine cancer risk was reduced for five years after the last dose. However, the researchers in this study did state that the “findings may not reflect current pill users’ experiences, given changes in preparation and protocols” and that “the likely balance of cancer risks and benefits may vary in different parts of the world” (“Pill Use is Associated with Reduction”, 2008).

A similar study including 122,000 women was performed in the United States beginning in 1976. After twenty-eight years, the results seemed parallel the previous study in Britain. This American study revealed that risks for these certain types of cancers decreased with increasing years of pill use. Women who had taken OCs for more than 10 years had a decreased risk of developing cancer (“Pill Use is Associated with Reduction”, 2008).

A study published in 2006 reported a significantly reduced risk of gynecological cancers among ever-users of oral contraceptives compared with never-users (“Use of the Pill can offer cancer protection”, 2007). Even with the high dosage of pills that were used, the findings in this study indicated that women had a 3% reduced risk of developing any type of cancer if they had taken oral contraceptives at some point in their life. A decrease in large bowel and rectal cancer, uterine cancer, and ovarian cancer were also indicated by the collected results. This research also confirmed that the odds of getting ovarian cancer for those using oral contraceptives were much lower, even up to fifteen years after the last dose (“Use of the Pill can offer cancer protection”, 2007). Deborah McBride, RN (2008), stated that another new study indicates that the use of oral contraceptives has prevented over 100,000 deaths from ovarian cancer worldwide (2008).

This study, done on women both with and without ovarian cancer, showed that 12 in 1,000 women not taking OCs are expected to get ovarian cancer, whereas only 8 in 1,000 of those using OCs are at risk (Beral et al., 2008). This study went on to show that risk of ovarian cancer decreased the longer women used OCs, and that the risk remained lower for former OC users even up to thirty years after the last dose (McBride, 2008). For this reason, women with a family history of ovarian cancer are encouraged to take OCs to decrease their risk of ovarian cancer (Use of Oral Contraceptives Reduces Risk of Ovarian Cancer, 2002).

### *Acne*

Acne is prevalent in 61% of girls at the age of twelve and increases to 83% at the age of sixteen (van Vloten, 2004). Acne can have a huge impact throughout the life of an individual. It has been shown that androgens play a large role in the development of acne. To help treat excess androgenic hormones, the use of low-dose oral contraceptives can be prescribed. Studies have found that oral contraceptives containing progestins improve acne through ethinulestradiol, which works to suppress androgen production and block androgen receptors (van Vloten, 2004).

### *Convenience*

Some women simply do not wish to deal with the inconvenience of the monthly cycle. Many see their period as an inconvenience and a nuisance. Many feel that it can affect their way of living. For instance, out of 158 women surveyed at the U.S. Military Academy, 60% stated that menstruation interfered with daily activities (Barnhart, Lin, 2007). The women stated that OCs enabled them to perform at their highest capacity without having to deal with the bothersome effects of menstruation. Female athletes may

also find benefits with taking OCs. While the number one use of OCs is to prevent conception, OCs also allow women to manipulate their period. Newer OCs even offer the option of less menstrual cycles per year (Bennel, et al., 1999). OCs help enhance performance in the female athlete by maintaining blood iron levels through a decrease in blood loss. Some studies also show that the estrogen in OCs may protect skeletal muscle from exercise-induced damage (Bennel, et al., 1999).

#### Risks Associated with the Use of Oral Contraceptives

When presented with the research, the use of oral contraceptives seems logical. Along with pregnancy prevention, oral contraceptives offer relief from menstrual discomforts, a decrease in bleeding, relief from pain associated with endometriosis and polycystic ovarian syndrome, and decreased risk from certain cancers. These are all optimistic reasons supporting the utilization of oral contraceptives. However, this tipping scale may be balanced by the risks that accompany use of oral contraceptives, including increased blood clotting, increased risk of cardiovascular problems, a decrease in bone density, and an increased risk of specific types of cancer.

#### *Side Effects*

Fifty percent of new users of oral contraceptives discontinue use within six to twelve months due to the side effects (Jarva, 2007). While women are prescribed oral contraceptives to reduce menstrual symptoms, research has shown that adverse effects of OCs are similar to menstrual pain and irritation. These adverse effects include bloating, fluid retention, breast tenderness, nausea, headache, skin reaction, break-through bleeding, alopecia, and hirsutism (Fraser et al., 2008). Mood change is one of the top

reasons for discontinuation of oral contraceptives. It appears that these changes occur most frequently in the first year (Jarva, 2007).

### *Increased Blood Clotting*

Research studies causing great concern include those that have indicated an increased incidence of venous thrombosis due to increased blood clotting related to the use of OCs. Both high and low doses of OCs have been linked with a risk of thromboembolic disease (“Should oral contraceptives be sold over the counter”, 2008). Hormonal treatments, such as oral contraceptives have been linked to an increased risk of atrial complications as well (Kluft, 2007). This increase in blood clotting is said to cause other problems, including myocardial infarction, stroke, and hypertension (Akhigbe et al, 2008). The increased risk of these events seems to be caused by an increase in the procoagulant factors needed for blood clotting, including fibrinogen and factors VII, IX, X, and XII.

According to Kluft, the use of OCs has caused an increased occurrence of venous thromboembolism during the first years of use, specifically targeting susceptible groups (2007). Kluft goes on to say that an increase in the dosage of oral estrogens clearly affects hemostasis and causes a significant increase in the risk of venous thromboembolism. The dose of estrogen in oral contraceptives is much higher than in hormonal treatment for menopausal women, thus increasing the clot risk for women on OCs (Kluft, 2007). Even at low dosages, these oral estrogens found in many OCs reduce blood levels of coagulation inhibitors, increasing the rate and speed of coagulation, thus causing an increased risk of venous thromboembolism. This unfortunately shows that even decreasing the amount of estrogen in OCs will not have much effect on improving

the risk ratio (Kluft, 2007). While combining progestins with estrogen can counteract some of the effects of estrogen only use, the risks for venous thromboembolism still remain. In fact, some studies have shown that recent generations of combined OCs may have a higher risk of venous thrombosis than earlier generation combinations (Fraser et al., 2008).

To further test the hematological effects of long-term administration of OCs, a study was conducted that tested the effect oral contraceptives had when given to rats over a seven week period. Forty rats were divided into a control group and experimental group, with the experimental group receiving oral contraceptives. After seven weeks, data collection showed that blood viscosity of the OC-treated group increased greatly (Akhigbe, 2008). Blood viscosity increased to 4.421 from the initial baseline of 3.218. This shows an increase of 13% in blood viscosity from the control group. Along with the increase in blood viscosity came an increase in plasma viscosity. Serum albumin levels were increased by 29% and total plasma protein levels were increased by 19%, thus increasing blood viscosity and the risk for venous thrombosis (Akhigbe, 2008).

Another study by Mirjam Meltzer and colleagues shows the correlation in women with hypofibrinolysis (decreased ability to dissolve a blood clot) and the increased risk of a venous thrombosis imposed by the use of OCs. In this study, women with hypofibrinolysis who also used oral contraceptives had a 22% increased risk of developing a venous thrombosis, compared to the women who were not using OCs (Meltzer et al., 2008).

Regardless of the type or combination of prescribed OC, users have a three-fold higher risk of developing blood clots than non-users (Fraser et al, 2008). The new third

generation oral contraceptives even have a 1.5-2.7 time further increase in risk of venous thromboembolism, creating a 4.8-9.4 time total increase (LeBlanc, 1999). This increased risk of blood clotting is seen primarily in the first year of use and the risk is related to the dosage of hormones used in the pill. Fortunately, these blood-clotting effects can be reversed within three months after cessation of the pill (Fraser et al., 2008).

### *Increased Cancer Risk*

While many studies have published the benefits that the use of oral contraceptives can have on decreasing the risk of many types of cancers, research has shown that the use of the pill can also *increase* the risks of developing certain other types of cancer. The same study started in 1968 that was previously used to portray benefits of taking OCs simultaneously found long term risks with taking OCs, including increased risks for cancer. This study found that women who used oral contraceptives for more than eight years had an increased risk of being diagnosed with cancer, specifically cervical cancer and cancer of the central nervous system or pituitary (“Use of the pill can offer cancer protection”, 2007) (“Do women who have ever used OCs have an increased risk of cancer”, 2008). A study by the Oxford Family Planning Association correspondingly discovered an increase in mortality rates among women using oral contraceptives for greater than eight years compared to those who were considered to be never-users (Vessey et al., 2003). There has also been a correlation between the use of oral contraceptives and an increase in thyroid cancer risk (“Correlation with Cancer Risk”, 2008). This study on women with thyroid cancer showed that risk for thyroid cancer greatly increased with the use of progesterone found in OCs.

Recent data from a study at Oxford show that OCs increase the risk of breast cancer in premenopausal women. While OCs do not play a critical role in the risk of breast cancer, a small increase in this risk has been evidenced in those who have taken OCs (Casey et al., 2008). The increase was greater in women who began taking oral contraceptives before the age of twenty and before the birth of their first child. Another study conducted from 1977-1992 collected data from 3,540 women who had a first incidence of breast cancer diagnosed within the preceding year and 4,488 women who were taking oral contraceptives but had not been diagnosed with any malignant condition. The study found a relationship between an elevated risk of breast cancer and women between the ages of 25-34 who had used OCs for one year or longer (Rosenberg, 1996). Women in this age group were 1.7 times as likely to be diagnosed with breast cancer. A significantly greater risk was associated with women in this age group who had used OCs for over 10 years (Rosenberg, 1996).

#### *Increase in Blood Lipids and Glucose Levels*

A consequence of most hormone replacement therapies is an increase in plasma triglycerides and other lipid levels. This has been shown to be associated with elevation of plasma viscosity, which could cause many other health problems (Akhigbe, 2008). Recently, a study performed in Nigeria found that oral contraceptive pills cause an increase in blood lipids and glucose levels. A selected group of 129 women taking oral contraceptives were followed for 18 months and given blood tests throughout the research period. After 18 months on oral contraceptives, studies showed an increase in triacylycerol and glucose levels, increased body weight, increased VLDL-cholesterol and LDL- cholesterol, and a decrease in HDL- cholesterol levels (I'Onyesom, 2008).

The increase in glucose and lipid levels has been linked to insulin resistance, thromboembolism, coronary heart disease, and stroke (I'Onyesom, 2008). The use of OCs apparently causes interference with the metabolism of lipids, increasing the risk for cardiovascular diseases including myocardial infarction and other vascular disorders. The data in this study showed that LDL-cholesterol, or the "bad" cholesterol, increased by 5.6-13.7% after one year of use. On the other hand, HDL-cholesterol, the "good" cholesterol, was reduced by 4.1-5.0% by the end of the first year of use (I'Onyesom, 2008). Glucose levels and body weight had also increased in those who had been taking OCs for over a year, causing a reduction of insulin sensitivity and an increase in glucose intolerance. While the researchers state that further study needs to be completed to solidify these claims, the conclusion of this study seems to indicate that OCs have an effect on the entire body.

#### *Cardiovascular Problems*

The risk of thromboemboli caused by the use of OCs causes an increase in other cardiovascular events such as strokes and myocardial infarctions. For this reason, women at risk or with a history of coronary artery disease, hypertension, and current smokers should not take oral contraceptives. It is the increased androgen activity that has been associated with increased hypertension, diabetes, and cardiovascular mortality (LeBlanc, 1999). According to one study, users of second-generation oral contraceptive had an increased risk of myocardial infarction (LeBlanc, 1999). Women with a history of migraines have an increased risk of ischemic stroke, with the odds ratio increasing from 6.2 to 13.9 (Casey et al, 2008). According to Dr. Alfonse Masi, numerous clinical reports suggest that using oral contraceptives may result in neurologic complications- including

those of the retinal arteries, vascular headaches, and other cerebrovascular disorders (Masi et al, 1970). Studies on the third-generation contraceptives are still inconclusive as to whether or not they have an increased risk of causing strokes. However, all studies, regardless of the generation of oral contraceptive used, have concluded that women who smoke and use oral contraceptives have a greater risk of developing cardiovascular problems (LeBlanc, 1999).

#### *Smoking While Using Oral Contraceptives*

Cigarette smoking alone is a huge risk factor for hypertension, atherosclerosis, and developing coronary heart disease. Combining the use of oral contraceptives with a smoking habit has been seen to compound the risk factors. It appears that estrogen-containing oral contraceptives dramatically increase the risk of myocardial infarction and subarachnoid hemorrhage in women who also smoke (Webber et al, 1982). An exacerbated reduction in HDL cholesterol is seen as well. For example, a study including 1000 women in the Netherlands showed a reduced serum level of HDL cholesterol in women ages 40-41 that both smoked and used oral contraceptives. The Framingham Offspring Study provided similar data, showing that there was a significant negative association between a decreased level of HDL cholesterol and the number of cigarettes smoked while taking oral contraceptives (Weber et al, 1982). Dr. Larry Weber performed a study on adolescents who currently smoked. Included in this study were thirty-five girls who also used oral contraceptives. The results of this study showed that the oral contraceptives added to an increase in total cholesterol and triglycerides compared to those who were not using oral contraceptives (Weber et al, 1982).

A study from the Oxford Family Planning Association set out in 1974 to test for a correlation between oral contraceptives, smoking, and mortality rate. The researchers enlisted 17,032 women between the ages of 25-39 years in 1974 and followed these women until 2000. At the age of 45, each woman was placed into one of two categories: those who never used oral contraceptives and those who had used oral contraceptives for greater than eight years. Those who used oral contraceptives for less than eight years were not included in the remainder of the study. In 2000, researchers began analyzing the deaths of 889 participants that occurred during this twenty-six year study. The findings related to smoking were quite substantial. Women who smoked fifteen or more cigarettes a day while taking oral contraceptives had an increased mortality risk from hemorrhagic strokes and thrombotic strokes. The participants who were considered heavy smokers (fifteen or more cigarettes per day) were shown to have a mortality rate more than doubled that of those who used oral contraceptives alone, with a 2:14 ratio (Vessey et al., 2003).

### *Bone Density*

Decreased bone mineral density early in life can be a contributing factor for osteoporosis. Recent experimental studies have shown that progestins have an effect on bone quality. Young women who start using progesterone-based oral contraceptives have a significant decrease in bone quality (Thijssen, 2007). These experiments show that adolescents and young women who use a low dose OCs right after puberty did not gain as much bone mineral density as those who did not use oral contraceptives. In fact, the Department of Reproductive Health and Research of the World Health Organization concluded that the use of OCs might indeed have a negative effect on bone density

(Thijssen, 2007). It appears that the loss occurs during the first two years of use due to an increased bone turnover rate.

### *Low-Birth Weight*

Many studies have been conducted on the effects of periconceptional exposure (4 weeks prior to and 4 weeks after conception) to OCs has on newborns. A study conducted from March 2001 to June 2006 compared an exposed group of 136 pregnant women to another group of women who had been exposed to other non-teratogenic drugs during the periconceptional period (Ahn et al., 2008). While this study did not show an increase in birth defects, it did show an increase in babies born with low birth weights. In this study, 7.1% of the babies exposed to OCs during the periconceptional period had low birth weights, compared to the 2.6% that were born with low birth weights in the non-exposed group. Since the women were relatively comparable in other respects, it seems likely that the OCs were the sole reason for the difference in birth weight. Another study by Dr. Ahn had similar results, in which high-dose exposure of hormones in-utero had a direct influence on fetal growth (Ahn et al., 2008).

### Ethical Dilemma Associated with Oral Contraceptive Use

After identifying both the risks and benefits of oral contraceptive use, it may seem that a stalemate has been reached. It appears that it is as beneficial as it is potentially dangerous to use this form of contraception. However, there remains a final issue that has the potential to tip the scale for women considering the use of OCs.

### *Contraceptive Pills as Abortifacials*

Perhaps the biggest controversy in regards to oral contraceptives is the question of whether or not the use of OCs can cause spontaneous abortions to occur. This would

not create a dilemma, should one suppose that life does not begin at conception. On the other hand, if one believes life *does* begin at conception, anything that has the potential to cause an abortion should be avoided.

As discussed at the outset, oral contraceptives act to suppress ovulation, thin the endometrium of the uterus, and thicken cervical mucus. Each of these is an attempt at preventing conception from occurring. Ovulation suppression and cervical mucus thickening occur before conception takes place, thus preventing pregnancy from occurring. However, the thinning of the endometrial lining that has the potential to inhibit an unborn fetus from implanting after conception has already occurred (Kahlenborn, 2000).

*Ovulation suppression.* As Kahlenborn notes, suppressing ovulation is not synonymous with eliminating it. Since there is sufficient evidence of women conceiving while on birth control- as seen with full-term pregnancies, miscarriages, and ectopic pregnancies- to state that oral contraceptives *usually* suppress ovulation. According to the *Physicians Desk Reference*, each listing under oral contraceptives has a failure rate of 3% (Alcorn, 2008). This implies that couples who used oral contraceptives consistently and correctly for an entire year would still have a pregnancy rate of 3% (Kahlenborn, 2000). Another study states that the lower dose OCs used today allow more breakthrough ovulations to occur, with a pregnancy rate during use of OCs at 7% (Potter, 1996).

*Effects on the endometrium.* The effect that oral contraceptives have on the inner lining of the uterus raises debates even among pro-life physicians. For instance, James Johnston (2005) argues that were a woman to ovulate while taking OC, the fertilized egg would still initiate enough hormone response to prepare the uterus before the zygote

traveled the seven days through the fallopian tubes to the uterus. On the other hand, Randy Alcorn (2008) repudiates this, claiming that there is not enough time for the uterus to properly prepare itself should conception take place. However, as discussed below, most research leads to the conclusion that OCs do in fact alter the endometrium lining, lessening the chance for a zygote to successfully implant.

Oral contraceptives are comprised of synthetic estrogen and progesterone that signal the body to decrease its own production of these hormones. Evidence of the thinning effect that oral contraceptives have on the uterine lining can be seen in the substantial decrease in the volume of menstrual contents that a woman on birth control has during a monthly cycle (Kalenborn, 2000). This indicates that the endometrium has indeed become thinner due to the use of the OCs. When the endometrium thins, blood supply and nutrient supply to the uterus is also decreased. Kalenborn (2000) presents research that shows a decrease in the size of the blood vessels and a decrease in the rate of cell division at the microscopic level.

The use of technology further supports the claim that oral contraceptives cause the uterus to become a hostile environment for implantation. Magnetic Resonance Imaging shows that the endometrial lining in a woman taking oral contraceptives is up to 58% thinner than in a non-user (Brown, 1991). The endometrium lining for a successful pregnancy must have a minimal thickness of 5 to 13 mm (Alcorn, 2008). Research has shown that even a change of 1 millimeter in the thickness of the uterus causes a substantial decrease in the ability of implantation to occur (Dickey, 1993). The average thickness of the endometrium in a woman taking oral contraceptives is only 1.1mm (Alcorn, 2008).

Just as OCs have failure rates for not suppressing ovulation and not thickening the cervical mucus enough to prevent the sperm from reaching the egg, they can also fail to thin out the endometrium. This is how implantation can occur, the life of the child can be sustained, and the woman taking birth control pills can find herself pregnant. Randy Alcorn plainly states that for something to be considered an abortifacient does not mean that it always causes an abortion. It can be qualified as an abortifacient even if it only sometimes causes an abortion (2008). A woman who is sexually active and taking OCs puts a zygote at greater risk of being aborted than does a woman who is not taking OCs (Alcorn, 2008). Further evidence shows that once a woman stops taking OCs, it takes several menstrual cycles for the volume of her menstrual contents to increase to that of a woman not using OCs (Stanford, 1995). This would indicate that it takes more than a few days for the endometrium to regain the optimal thickness needed to support a pregnancy, thus refuting those who believe that a woman's endometrium will be adequately restored should she happen to conceive while taking contraceptives.

It is here, as Randy Alcorn (2008) states, that one must consider a critical question. The question is not if OCs *always* prevents implantation, but rather if it could *sometimes* prevent implantation. The *Physicians Desk Reference* states that there are three mechanisms of action to birth control. The primary mechanism of this action is inhibition of ovulation, followed by changes in the cervical mucus to increase the difficulty of sperm entry into the uterus. However, the third mechanism to prevent conception is the thinning and shriveling of the uterus to the point that it is unable or less able to facilitate the implantation of the egg (Alcorn, 2008). Since implantation requires

conception to have already taken place, oral contraceptives must have the word “abortifacient” printed on their label.

Those who do not believe that life begins at conception face no difficulty using birth control pills that are considered abortifacients. However, those who believe that life does begin at the very moment of conception face a dilemma. It would be inconsistent for someone who claims to value life to justify the use of a medication that is classified as an abortifacient. Yet it would be difficult to ignore the research that has been done to show the effectiveness that oral contraceptives have on treating various diseases. Balancing the use of OCs in treating chronic problems with the risk of causing an abortion is a challenging task. Because of dilemmas like this, it is imperative that each woman be made aware of the risks and benefits of being placed on OCs to allow them to make a fully informed decision. The following self-directed survey will address the adequacy with which health personnel inform women of these considerations before they begin taking OCs.

## Research

Before patients begin a drug regimen of any type, it is imperative that they are fully informed about the risks and benefits. As seen above, oral contraceptives can have both positive and negative effects. OCs have positive effects by decreasing risks for certain types of cancer, reducing the pain and symptoms associated with menstrual cycles, and by treating health problems such as polycystic ovarian syndrome and endometriosis. On the other hand, oral contraceptives can also increase the risk for certain cancers, cause an elevation in blood clotting, and increase cardiovascular problems. In an effort to see how well informed oral contraceptive users are of these risk and benefits, the following quantitative survey was conducted.

This descriptive survey includes women between ages 18-45 who have previously used or are currently using oral contraceptives. A pilot study using a convenience sample was first conducted to test the soundness of the survey before sending out the official surveys. The results of this pilot study showed internal consistency, and there was no indication that the participants had any difficulty understanding the questions posed by the survey. The majority of participants in the pilot study were white females between the ages of 18-25 attending a Christian university that may have altered some of the final data.

For the official study, women who met the above criteria were randomly selected for the official research from a local health clinic in eastern Virginia. The main objective of this survey was to assess if women who have or are taking oral contraceptives were fully informed on important factors that could influence their health. The survey and consent form that was distributed is provided below:

Consent Form  
Risks and Benefits of Oral Contraceptives  
Principal Researcher: Courtney West  
Liberty University  
Nursing Department

Dear Participant,

I am a senior nursing student at Liberty University. I am working on my Honors Thesis requirement for graduation. For this paper, I am researching the risks and benefits associated with the use of oral contraceptives. Below is a list of questions based on the most recent studies that I have been researching over the past few months. This study is designed to determine how well doctors/health care providers are telling their patients about the risks and benefits that are associated with the use of oral contraceptives.

Completing this survey indicates your consent/permission for the information to be used in the final research. Your name will not be asked, and the surveys will only be used as previously indicated. Any reporting of data will be of the combined group and will not be directly related to you as an individual. Each survey will be shredded after the data is collected and it will not become a part of your permanent medical record. Your participation is completely voluntary, but would be greatly appreciated, as this would strengthen my research. However, you may change your mind about completing the survey at any time. Thank you in advance for taking the time to answer the following questions.

Please feel free to contact myself, Courtney West, with any questions you have concerning this survey at phone number 813-956-8439 or through email at [cswest@liberty.edu](mailto:cswest@liberty.edu). You are also encouraged to contact my faculty sponsor, Dr. Cynthia



**6. How many years have you used oral contraceptives? Check one.**

- <1 year                       4-6 years                       >10 years  
 1-3 years                       7-10 years

**7. What was your main reason for the use of oral contraceptives?**

- Birth Control                       Endometriosis  
 Menstrual Regulation                       Polycystic Ovarian Syndrome  
 Painful periods                       Fewer Cycles  
 Other (please specify) \_\_\_\_\_

**8. Are you currently using oral contraceptives?**                       YES                       NO

**9. Have you ever smoked while using oral contraceptives?**                       YES                       NO

If yes, how many cigarettes a day? \_\_\_\_\_

**10. Have you consumed alcohol while using oral contraceptives?**  YES                       NO

If yes, how often?                       Daily                       Weekly                       Monthly

**11. Did you receive any information or teaching on the risks and benefits of oral contraceptives?**

- YES                       NO

**If yes, which best describes the source of teaching and information?**

- Primary caregiver (Doctor, Nurse Practitioner, Certified Midwife)  
 Nurse  
 Brochure  
 Website  
 Other (please specify) \_\_\_\_\_

**12. Have you been diagnosed with any of the following health concerns? Check all that apply.**

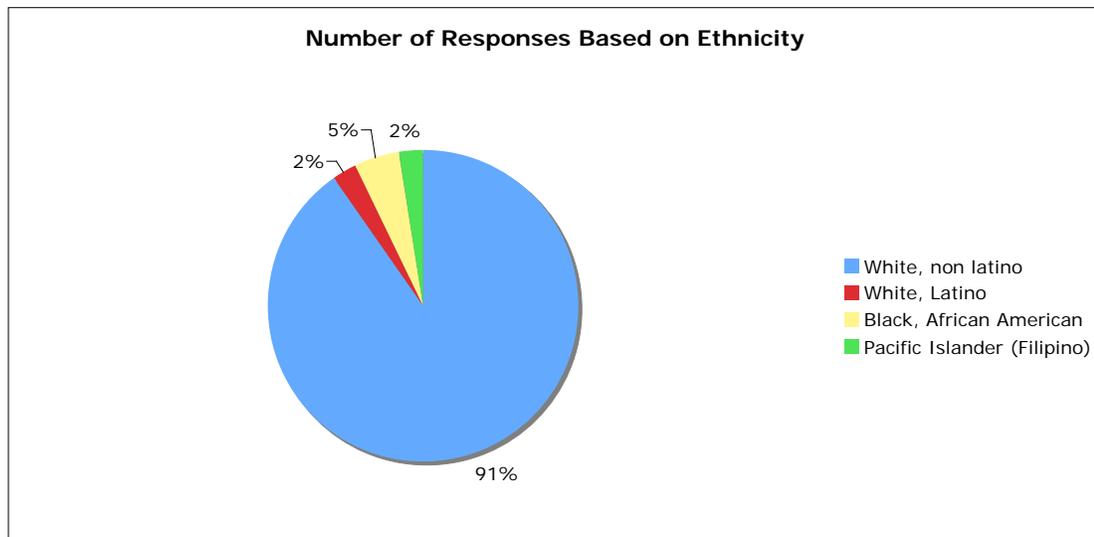
- |   |   |
|---|---|
| <input type="checkbox"/> Hypertension     | <input type="checkbox"/> Ovarian Cancer                                       |
| <input type="checkbox"/> High Cholesterol | <input type="checkbox"/> Blood clots  |
| <input type="checkbox"/> Diabetes         | <input type="checkbox"/> Endometriosis  |
| <input type="checkbox"/> Breast Cancer    | <input type="checkbox"/> Polycystic Ovarian Syndrome                          |
| <input type="checkbox"/> Uterine Cancer   | <input type="checkbox"/> Osteoporosis   |
| <input type="checkbox"/> Cervical Cancer  | <input type="checkbox"/> Cardiovascular Disorders (stroke, heart attack, etc) |
|   | <input type="checkbox"/> Other: _____   |

**The following questions are based on the most recent research and published studies. Please answer all the questions to the best of your knowledge. Circle only one answer for each question. (Note: OCs= oral contraceptives)**

- |   |       |          |        |
|---|-------|----------|--------|
| 1. OCs increase the risks of blood clotting.                        | Agree | Disagree | Unsure |
| 2. OCs decrease the risk of strokes.                                | Agree | Disagree | Unsure |
| 3. OCs decrease the risk of uterine cancer.                         | Agree | Disagree | Unsure |
| 4. OCs increase the risk of ovarian cancer.                         | Agree | Disagree | Unsure |
| 5. OCs decrease the risk of cervical cancer.                        | Agree | Disagree | Unsure |
| 6. OCs increase the risk of heart attacks.                          | Agree | Disagree | Unsure |
| 7. OCs decrease the pain of endometriosis.                          | Agree | Disagree | Unsure |
| 8. OCs increase bone density.                                       | Agree | Disagree | Unsure |
| 9. OCs increase the rate of spontaneous abortions.                  | Agree | Disagree | Unsure |
| 10. OCs increase cholesterol levels.                                | Agree | Disagree | Unsure |
| 11. OCs decrease the risk of breast cancer.                         | Agree | Disagree | Unsure |
| 12. OCs decrease symptoms of polycystic ovarian syndrome.           | Agree | Disagree | Unsure |
| 13. Risks of OCs are increased in those who also smoke.             | Agree | Disagree | Unsure |
| 14. Exposure to OCs in utero increase the risk of low birth weight. | Agree | Disagree | Unsure |

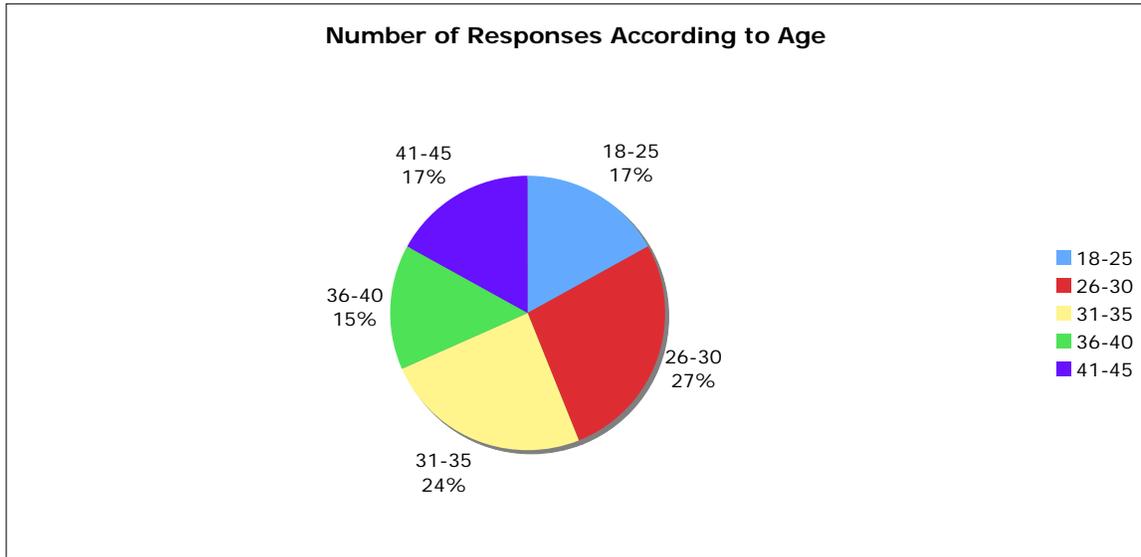
*Survey Results.*

*Ethnicity.* The general information of the 41 women who participated in this survey are displayed below in various charts. Based on the data, 91% classified themselves as white, with the remainder consisting of only 5% African American, 2% Latino, and 2 % Filipino.

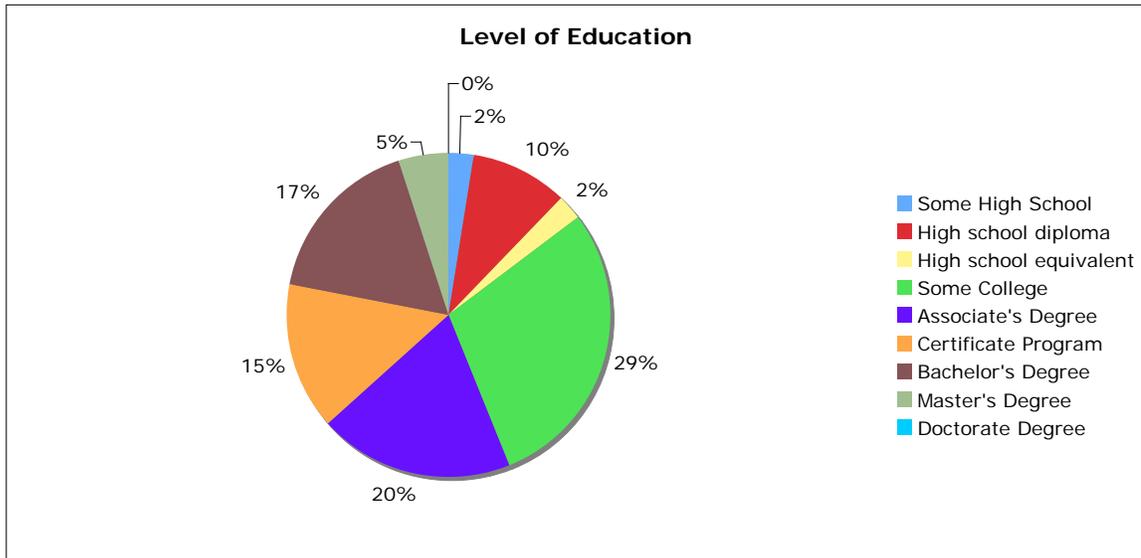


*Age distribution.* More evenly dispersed were the ages of the participants in this survey. The age range of 26-30 was the largest age group at 27%. Participants between

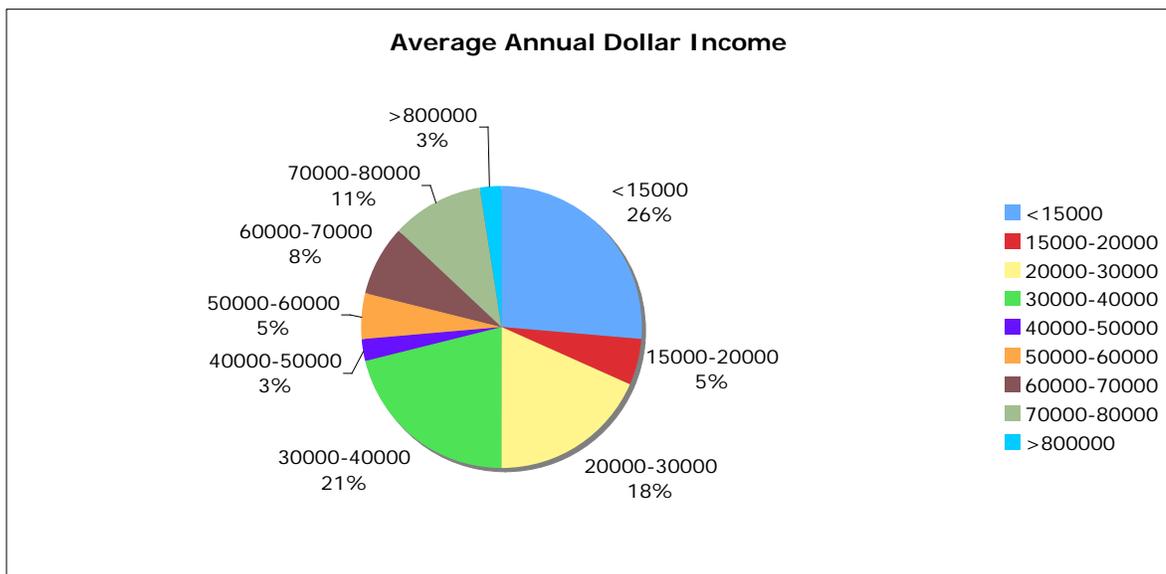
the ages of 31-35 comprised 24% of the sample population with the other three age ranges evenly dividing the remainder.



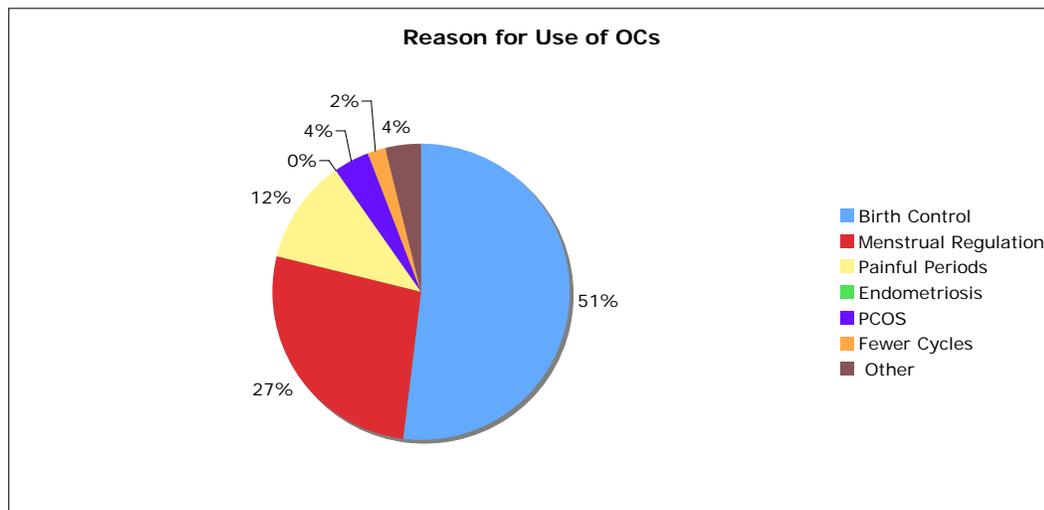
*Level of education.* Twenty-nine percent of the participants claimed to have some college education. 20% had received their Associate’s degree, and 17% have completed their Bachelor’s degree. Only one out of the 41 women surveyed did not receive a high school diploma or its equivalent.



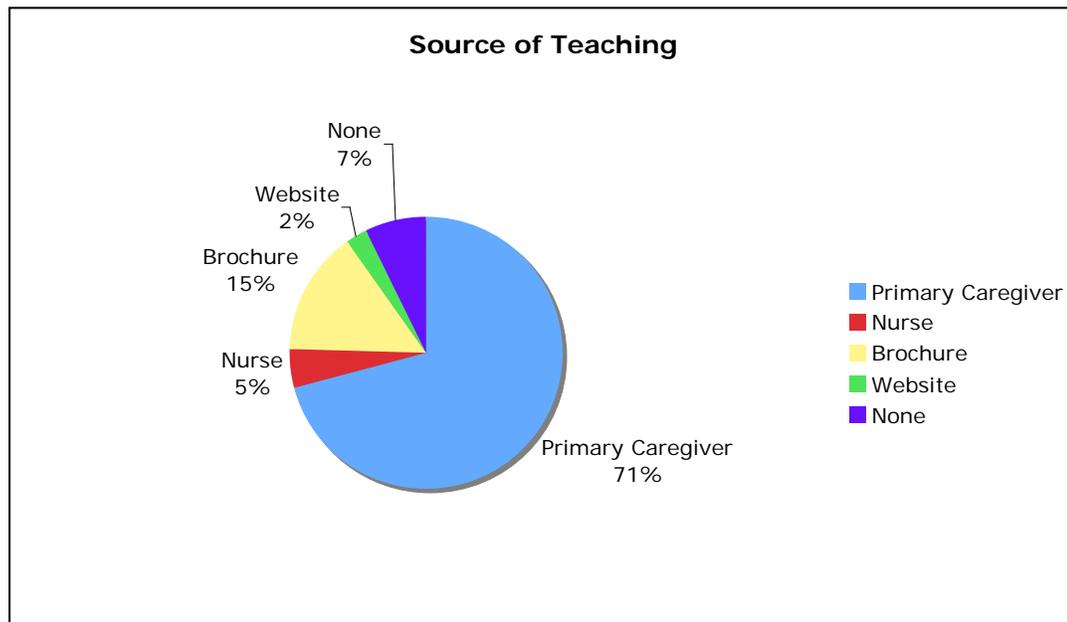
*Average income.* The annual dollar income of the participants did not have a significant effect on the number of correct responses. Of the 41 participants, the majority (26%) made less than 15,000 dollars annually and 51% make over 30,000 dollars each year. The average incomes are expressed below.



*Reasons for use.* Based on the general information gathered from this survey, birth control was the primary reason for the use of oral contraceptives at 51%. Second to birth control was menstrual regulation, which was 27%. True medical indications for the use of oral contraceptives, including polycystic ovarian syndrome and painful menstrual cycles only included 16% of the women.



*Source of teaching.* Out of the 41 women surveyed, 29 (71%) stated that they received information about oral contraceptives from their primary health caregiver. 15% received information from a brochure, with only 5% receiving any teaching from their nurse. Alarming, 7% of the participants claimed to have not received any form of teaching at all.



The information provided by the above chart is critical, as will be seen in the following data. 100% of individuals placed on an oral contraceptive regimen should have received some form of information in regards to the risks and benefits associated with use. Optimally, each participant should have received information verbally from a medical professional to allow for clarifications and questions. However, this was clearly not the findings indicated by the collected data.

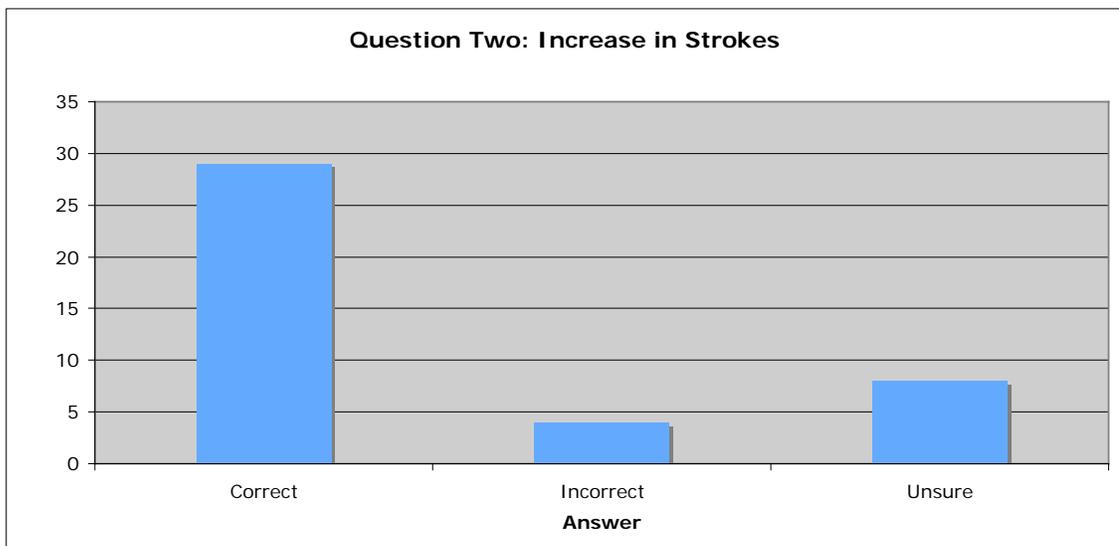
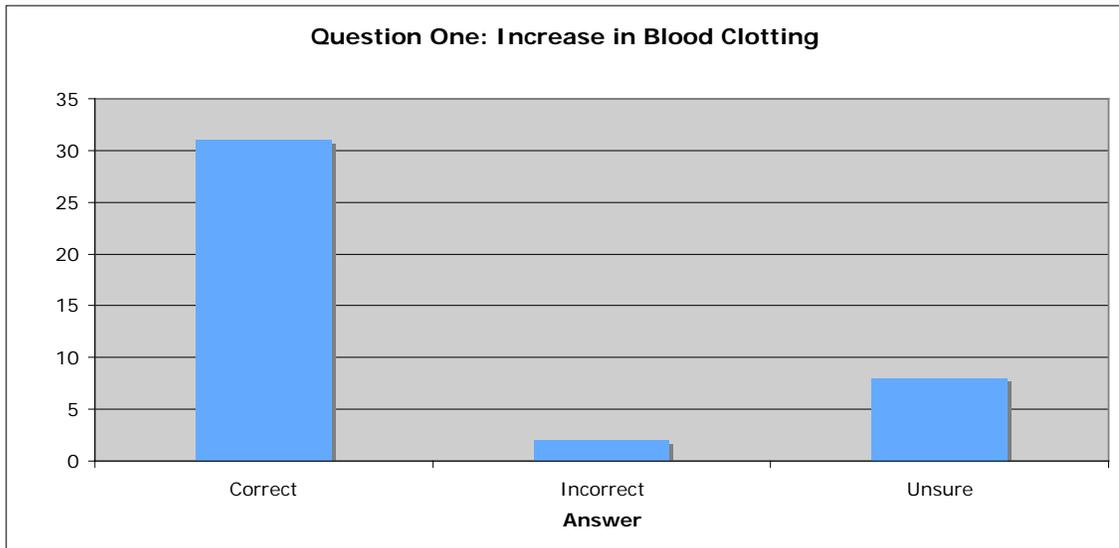
Fourteen questions were selected to assess the adequacy of teaching methods regarding the risks and benefits of oral contraceptives. In the table on the following page, each question is listed as a corrected statement, along with the correlating statistics and percentages (rounded to the nearest whole number) of the correct, incorrect, and unsure responses. The answer with the largest percentage of responses has been bolded for each question.

Statement	Correct	Incorrect	Unsure
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1. OCs increase the risk of blood clotting.	<b><u>31 (76%)</u></b>	2 (5%)	8 (20%)
2. OCs increase the risk of strokes.	<b><u>29 (71%)</u></b>	4 (10%)	8 (20%)
3. OCs decrease the risk of uterine cancer.	11 (27%)	10 (24%)	<b><u>20 (49%)</u></b>
4. OCs decrease the risk of ovarian cancer.	14 (34%)	10 (24%)	<b><u>17 (41%)</u></b>
5. OCs increase the risk of cervical cancer.	12 (29%)	8 (20%)	<b><u>21 (51%)</u></b>
6. OCs increase the risk of heart attacks.	<b><u>20 (49%)</u></b>	3 (7%)	18 (44%)
7. OCs decrease the pain of endometriosis.	<b><u>20 (49%)</u></b>	4 (10%)	17 (41%)
8. OCs decrease bone density.	15 (37%)	5 (12%)	<b><u>21 (51%)</u></b>
9. OCs increase the rate of spontaneous abortions.	10 (24%)	14 (34%)	<b><u>21 (51%)</u></b>
10. OCs increase cholesterol levels.	3 (7%)	18 (44%)	<b><u>20 (49%)</u></b>
11. OCs increase the risk of breast cancer.	14 (34%)	10 (24%)	<b><u>17 (41%)</u></b>
12. OCs decrease symptoms of polycystic ovarian syndrome.	<b><u>24 (50%)</u></b>	4 (10%)	13 (32%)
13. Risks of OCs are increased in those who smoke.	<b><u>38 (93%)</u></b>	0 (0%)	3 (7%)
14. Exposure to OCs in utero increases the risk of low birth weight.	15 (37%)	5 (12%)	<b><u>21 (51%)</u></b>

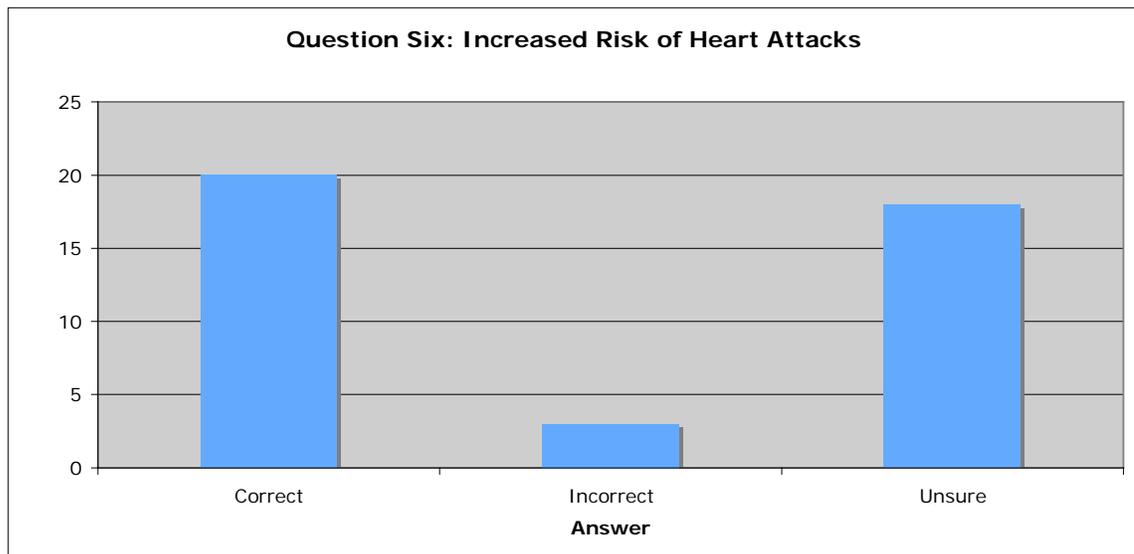
**Corrected Statements with Number and Percentage of Given Answers**

*Cardiovascular responses.* As seen in the recent research, OCs cause many changes in the cardiovascular system. According to the data, 76% of participants correctly acknowledged that the use of OCs causes an increase in blood clotting. In agreement with these statistics, 71% correctly stated that the use of OCs increases the risk of having a stroke in question two.

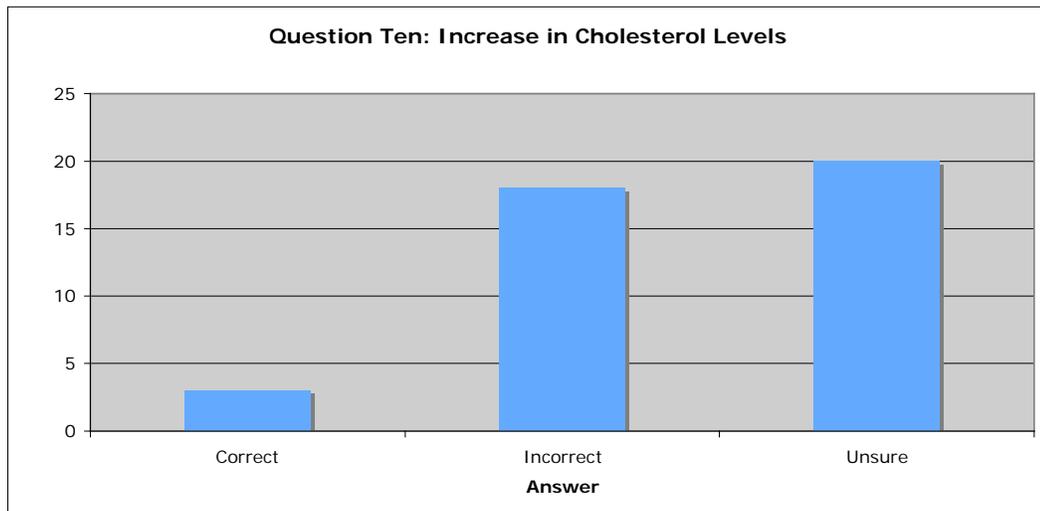


However, only 49% are aware that an increase in the viscosity of the blood and the increased risk for blood clots also increases the risk of having a heart attack.

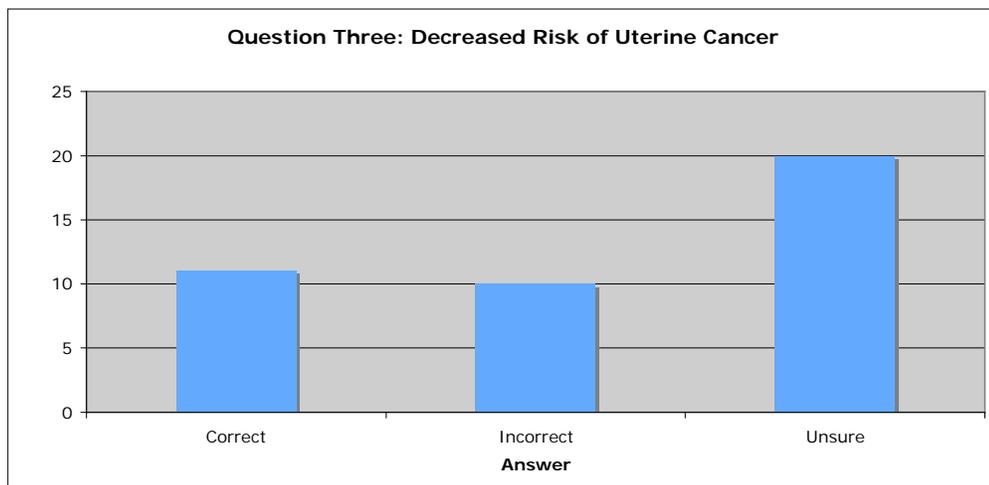
According to the data, 44% of the participants were unsure about whether or not OCs elevate the risk for a heart attack.

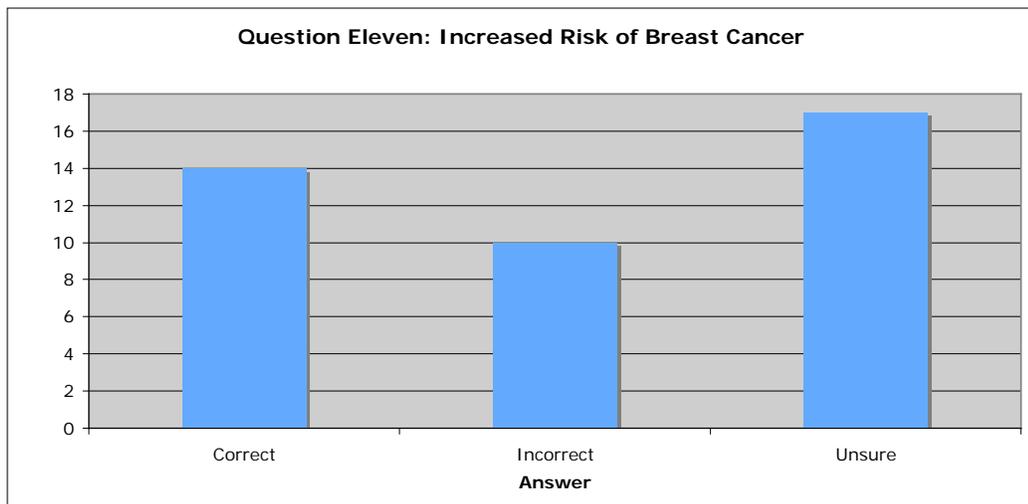
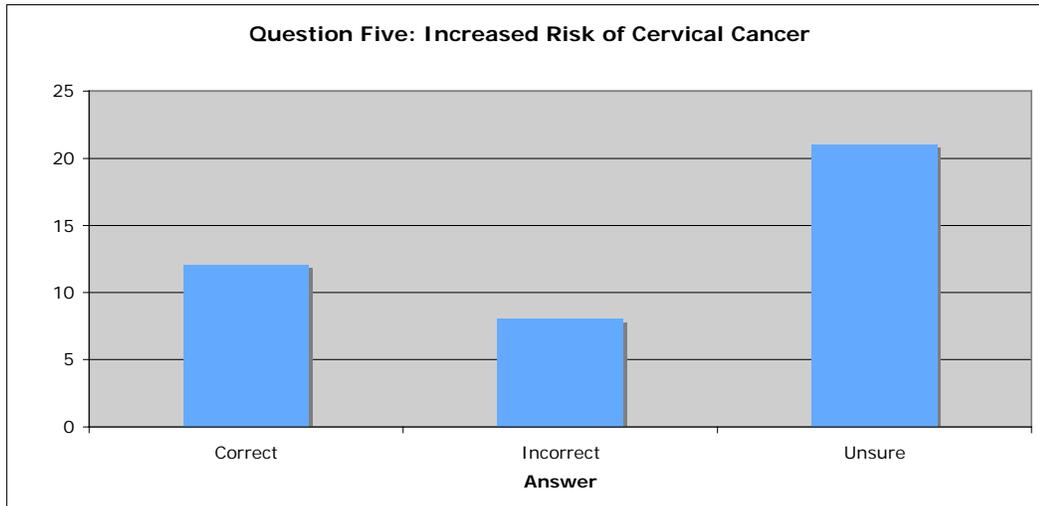
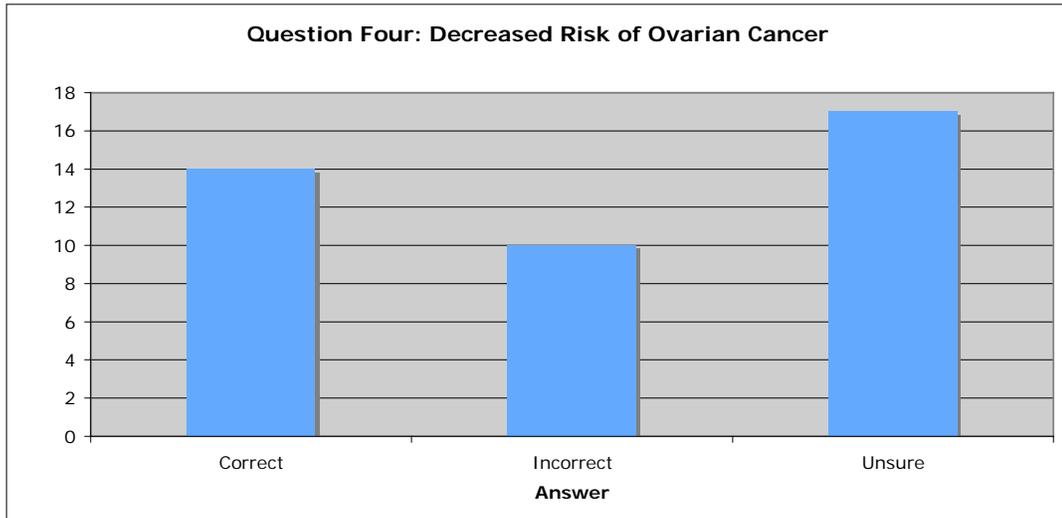


While the majority correctly identified that OCs create changes in the blood, such as increasing the risk for clotting and heart attacks, only 3% accurately stated that OCs also increase blood cholesterol levels. As seen in latest research, OCs increase the level of LDL (bad) cholesterol and decrease the levels of HDL (good) cholesterol (I'Onyesom, 2008). Yet as determined by the survey data, 49% were unsure as to the effect of OCs on cholesterol levels, while 44% incorrectly declared that OCs do not increase cholesterol levels at all.

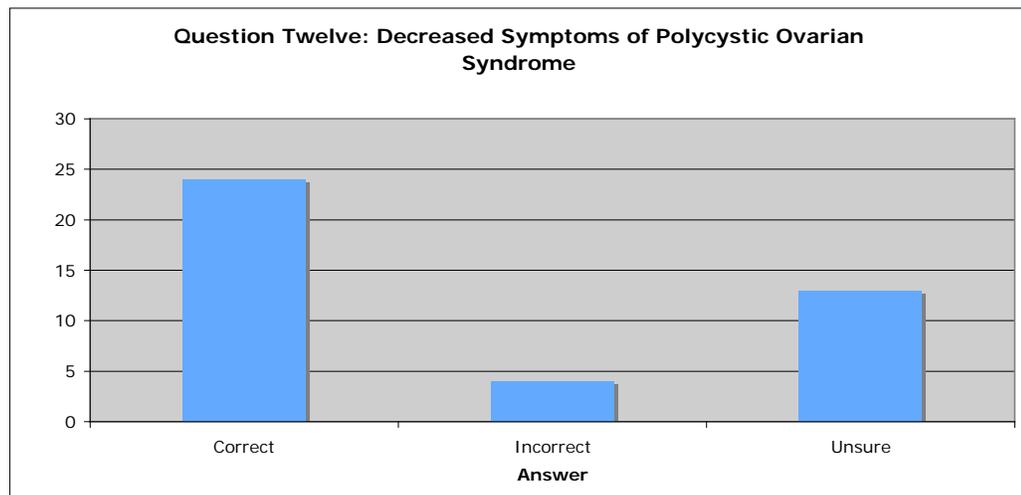
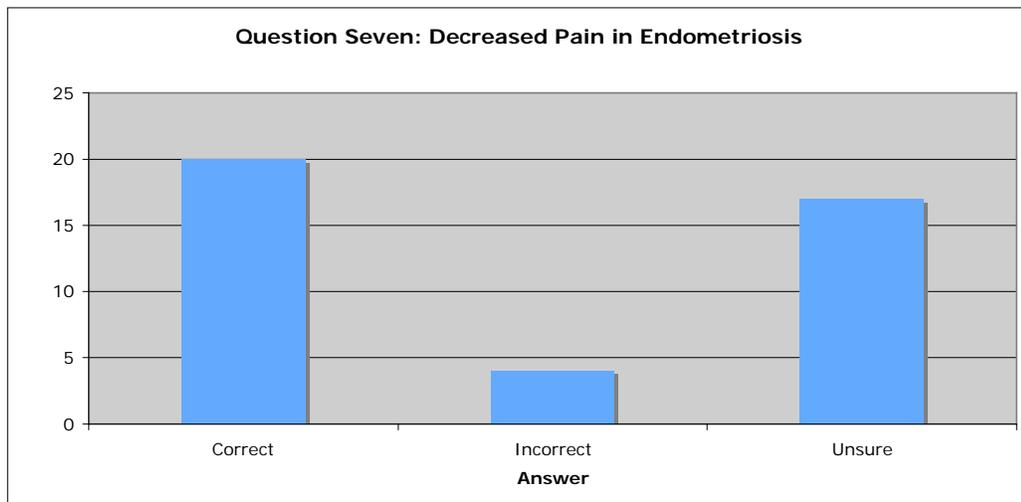


*Cancer Responses.* Recent research shows that OCs have both the potential to increase or decrease certain types of cancers. OCs decrease the risk of uterine and ovarian cancer while increasing the risk of cervical and breast cancer. The results from this study indicate that women are unsure about these risks and benefits. 49% were unsure of the effect of OCs on the risk of ovarian cancer and 41% were unsure as to the effect of OCs on ovarian cancer. Conjointly, 51% were unsure as to the result OCs play in cervical cancer, with 41% also stating that they were unsure about the role OCs play in breast cancer.

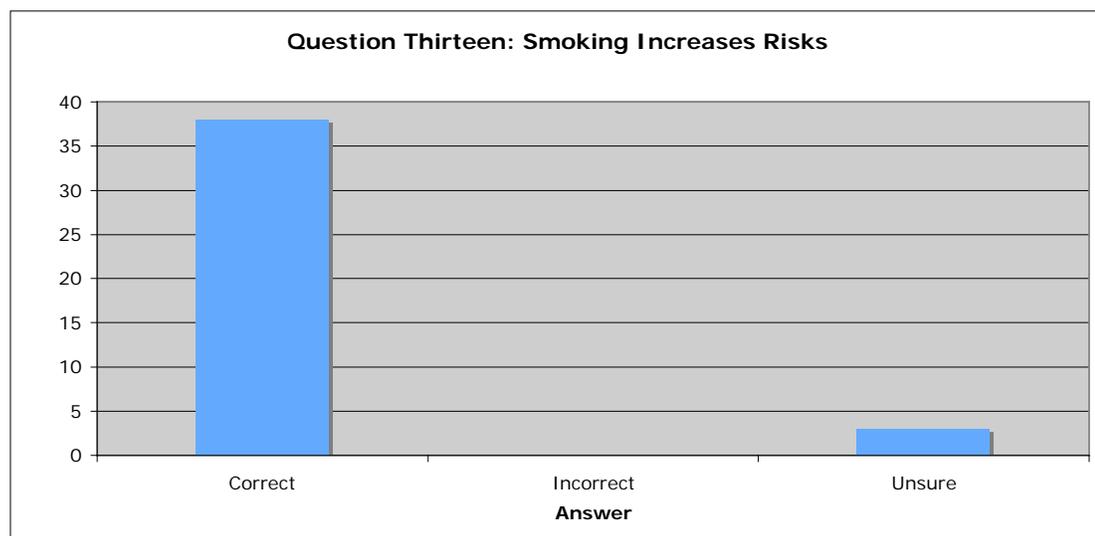




*Endometriosis and PCOS responses.* The survey showed that the majority of participants are aware of the positive effects that OCs have on decreasing the symptoms of both endometriosis and polycystic ovarian syndrome. While 50% answered correctly that OCs decrease the risk of PCOS and 40% are aware that OCs decrease the pain of endometriosis, 41% still claimed to be unsure as the role of OCs in helping endometriosis.



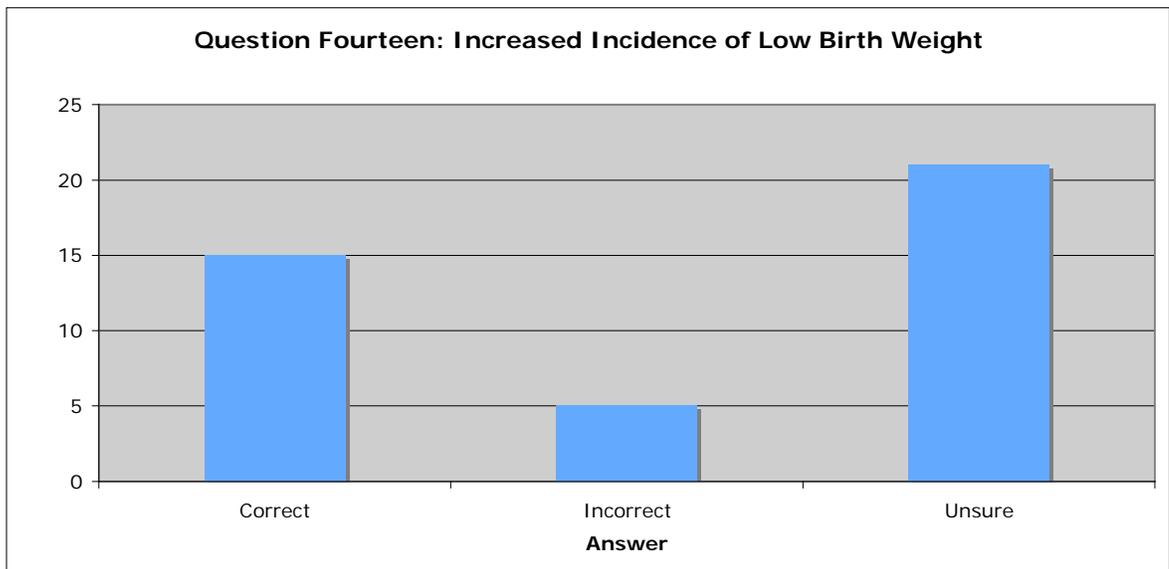
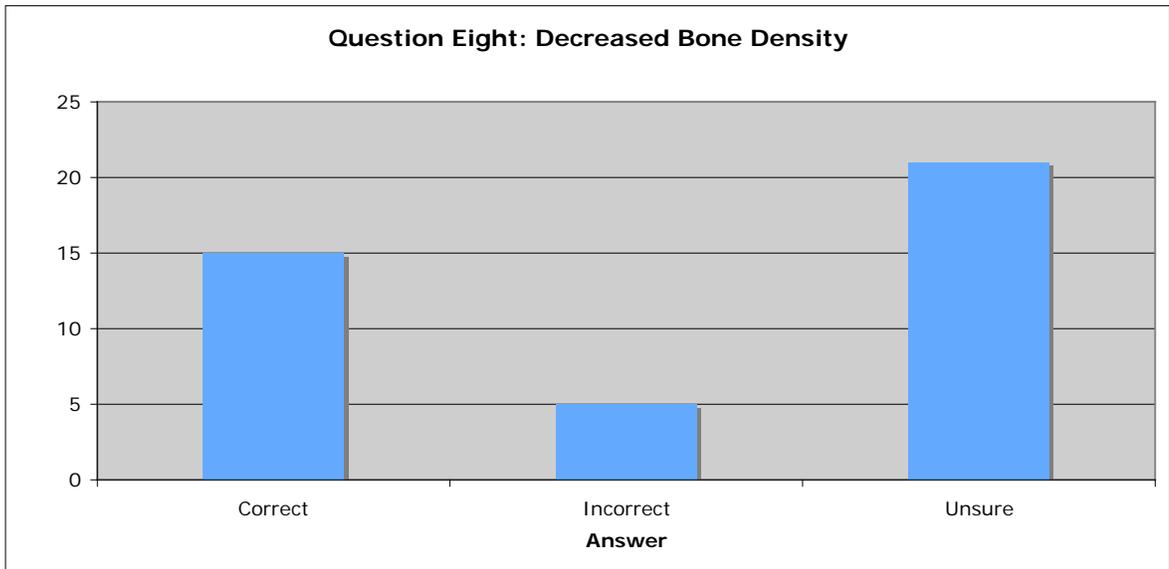
*Smoking Responses.* 93% correctly identified that smoking increases the risks associated with OCs. Current research shows that those who smoke have a mortality rate double that of those who use oral contraceptives alone (Vessey et al., 2003). Despite these statistics, 12 of the 41 participants admitted to smoking at some point during their use of OCs. This indicates that despite correct knowledge on the risks of combining smoking with the use of OCs, 29% still chose to smoke during their OC regimen. While the teaching may have been administered, this data shows that it may not have been effective in preventing the use of tobacco while taking OCs.



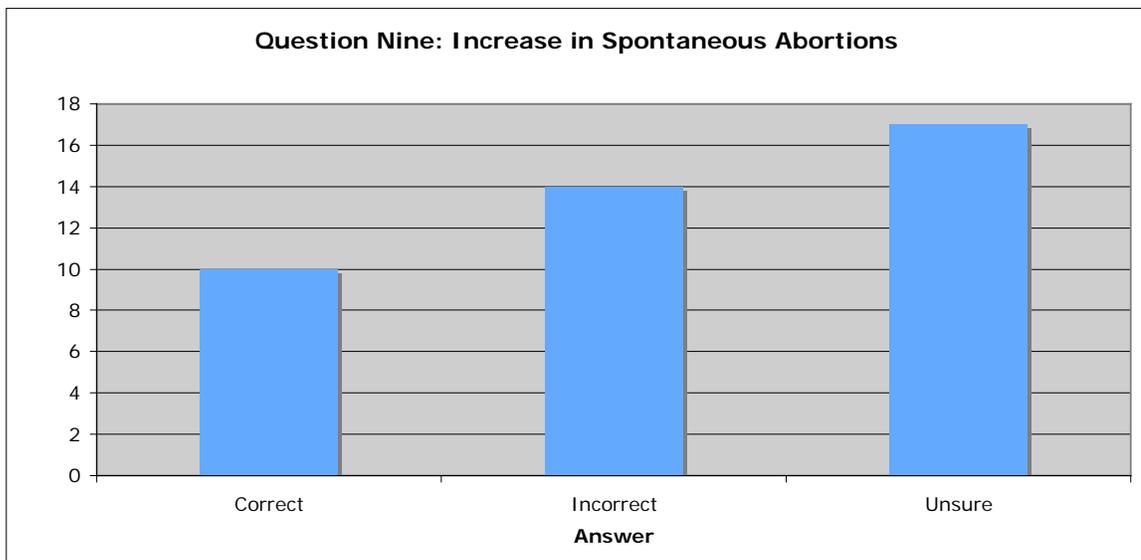
*Responses to a decrease in bone density and a decrease in birth weight.*

Responses to the questions regarding a decrease in bone density and an increase in the risk of infants born with a low birth rate were identical. In both scenarios, 51% were unsure of the effect that OCs create. Studies show that progesterone-based OCs significantly decrease bone quality especially during the first two years of use (Thijssen,

2007). Current research also shows that 7.1% of infants exposed to OCs while in utero are born with a lower weight than the infants who were unexposed (Ahn et al., 2008).



*Spontaneous abortion responses.* Regardless of personal beliefs pertaining to the moment of conception, 51% of participants stated that they were unsure as to whether or not the use of OCs increases the risk of causing spontaneous abortions. 34% answered that OCs do not cause spontaneous abortions, and only 24% were in agreement that they can cause abortions. While this is an ethical issue, scientific research demonstrates that one role of OCs is to decrease the ability for a fertilized zygote to successfully implant by thinning the inner lining of the uterus (Kalenborn, 2000). This information should be presented to women considering the use of oral contraceptives, apart from personal beliefs of either the health care personnel or the patient.



*Limitations.* Certain factors were present that could have influenced the results of this survey. First, due to time restraints, only 41 surveys of the intended 100 were completed. A larger sample group would have provided a more accurate representation of the population in eastern Virginia. As seen above, 91% of the women who completed

the surveys were White. This is not representative of the population group, and given more time, a more representative sample could have been gathered. Answers given on the survey could have been attributed to the time at which teaching was given. For instance, new research could have been discovered since the women received the teaching if they were in the upper portion of the age range. Women could have also been provided with the information, but forgotten it since they received the teaching. It is also possible that the information sources may not supply certain information due to research that is still viewed as inconclusive.

This study was only done from one sample site, making it difficult for the results to be representative of eastern Virginia. Given more time, this study could have become more than simply a descriptive survey. Analyzing the distribution of the data as related to each of the demographic factors would also have allowed correlations to be created showing the influence of education, salary, and ethnicity on the final figures. It would also have been interesting to perform further research studies to see the correlation between the methods of teaching used and the survey results. Further research would have enabled the findings of this study to be further developed for use across a wider spectrum.

*Survey conclusion.* Regardless of the presented limitations, the amount of incorrect and unsure responses indicates the inefficiency of the current teaching that is provided for women taking oral contraceptives in eastern Virginia. All patients should be informed about a prescription before beginning a medication routine. The indication that 7% did not receive any information at all is alone extremely alarming. Although some research on OCs may be inconclusive, current statistics should be provided so that

women can make a knowledge decision in regards to starting a prescription regimen of OCs. Women with a personal or familial history of certain diagnoses- hypertension, high cholesterol, strokes, heart attacks, reproductive cancers, endometriosis, polycystic ovarian syndrome, and osteoporosis- should be aware of the risks and benefits correlated with the use of OCs. Women also have the right to know that OCs cause the endometrium of the uterus to thin in order to make the uterus less likely to sustain an unintended pregnancy by increasing the risk of spontaneous abortions.

71% of the survey participants claimed to have received information from their primary health caregiver. Yet the overwhelming amount of incorrect and unsure responses indicates that current teaching methods are flawed. A variety of scenarios could be causing this dilemma—First, primary caregivers may have are not informed or updated on the recent statistics on OCs. Secondly, they may be hesitant to present information that is still under study. Thirdly, the time demands placed on primary caregivers may hinder the adequacy of the teaching given to each individual patient. Fourthly, patients could have received the appropriate information, but have since forgotten the correct answers due to the length of elapsed time since the teaching period or inattention at the time of instruction. Further research is recommended to discover the reason for the ineffective teaching discovered by this study.

Despite the factors that could have caused the tremendous amount of incorrect and unsure responses, one thing is certain: changes need to be implemented in order to ensure that patients are given the information they need to make the most educated decisions regarding their personal health. This may indicate that multiple teaching tools are needed to present and reinforce the information about the health risks and benefits

imposed by OCs. Primary caregivers need to be aware of the existing holes in patient education and make changes to alter these statistics, whether this involves increasing one-on-one teaching time between themselves and the patient, or delegating the responsibility to a nurse who is updated on the current research findings. Patients have the right to be fully informed about each decision that will influence their health, and it is the responsibility of those in the medical profession to make this information readily available.

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