ARE GONADOTROPIN-RELEASING HORMONE ANALOGS AND LAPAROSCOPIC ABLATION EQUALLY EFFECTIVE TREATMENTS FOR ENDOMETRIOSIS?

A Research Project by

Rachel Michelle Baker

Bachelor of Science, Friends University, 2005

Submitted to the Department of Physician Assistant and the faculty of the Graduate School of Wichita State University in partial fulfillment of the requirements for the degree of Master of Physician Assistant

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Wichita State University
College of Health Professions
Department of Physician Assistant

We hereby recommend that the research project prepared under our supervision by Rachel
Michelle Baker entitled Are gonadotropin-releasing hormone analogs and laparoscopic ablation
of endometrial implants equally effective treatments for endometriosis? be accepted as partial
fulfillment for the degree of Master of Physician Assistant.

Approved:

[Signature]
Richard D. Muma, PhD, MPH, PA-C, Chair and Associate Professor

[Signature]
Patricia A. Bunton, MS, PA-C, Research Advisor
Department of Physician Assistant

5/7/07
Date
ABSTRACT

Introduction: Endometriosis is a disease of the female reproductive system in which endometrial tissue exists outside of the uterus and is found attached to other organs. Although both laparoscopic ablation and gonadotropin-releasing hormone analogs (GnRHa) are treatments for endometriosis, there are no studies that directly compare these two treatment options.

Purpose: Through a systemic review of evidence-based literature with the purpose of making recommendations for treatment, this study compares the use of GnRHa therapy and laparoscopic ablation concerning symptom relief, recurrence of symptoms, safety, short and long-term side effects of treatment and overall improvement of quality of life in women ages 18-50 with diagnosed endometriosis. Methods: The study design is an evidence-based literature review, assessing each study for its level of evidence, research design, inclusion and exclusion criteria, treatment results, adverse affects and conclusions. Results: All but one research study showed that GnRHa are effective at improving quality of life by relieving endometriosis symptoms for varying lengths of time, lasting up to one year post treatment. Side effects were consistent with hypoestrogenemia and were non-life threatening. Surgical treatment by laparoscopic ablation was found to successfully treat endometriosis symptoms, but fertility rates were not consistently improved. Adhesion formation was a complication of surgery, but was found to correlate to the presence of adhesions prior to surgery. Conclusions: There are many factors that are necessary to consider when determining the best therapy including quality of symptoms, extent of endometriosis determined laparoscopically, age of patient and patient preference. Both GnRHa and laparoscopic ablation are safe, reduce symptoms and improve the overall quality of life, therefore more research is needed in order to determine specific parameters for each treatment.
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Thank you to my God for giving me the knowledge and endurance to follow my dreams. Secondly, to my parents - Kerry and Michelle, sisters - Jacelyn, Elizabeth and Jessica, niece - Madelyn, close family and dear friends who have encouraged and supported me and reminded me everyday where my strength truly comes from. It is because all of you that I am able to finish this journey and begin a new one. Thank you to Patricia Bunton, my research advisor, for your advice and direction. I appreciate your patience! Also, to David Day, a friend, advisor/professor and now colleague, for your moral support and guidance. I am excited to see how God will use this training in my future!
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CHAPTER 1
INTRODUCTION

Endometriosis is a disease of the female reproductive system in which endometrial tissue exists outside of the uterus and is found attached to other organs, predominantly in the peritoneal space, including the ovaries, bladder, fallopian tubes and rectum. 

Approximately 10 to 25 percent of women in the United States of reproductive age endure this disease, and the prevalence is 3 to 4 times greater in infertile women than in fertile women. Endometrial tissue implants respond to the normal hormonal stimulation of the menstrual cycle, thus cycling through thickening, shedding and bleeding phases along with uterine tissue. The shedding and internal bleeding of the endometrial implants is a source of increasing discomfort and pain in most women suffering from the disease and also results in a build-up of scar tissue on adjacent structures. The clinical manifestations of endometriosis are exacerbated with menstruation and depend on the location and size of the implants. Common symptoms include dysmenorrhea, dyspareunia, rectal bleeding, infertility, severe abdominal cramping and low back pain prior to or during menses. While the presentation of endometriosis is known, the pathological process that causes this disease is not fully understood. It is most commonly hypothesized that the endometrial implants are the result of sloughed endometrial tissue traveling through the fallopian tubes to the peritoneum via retrograde menstruation. Another possible explanation of endometrial implants maintains that peritoneal epithelial tissue when exposed to retrograde menstruation and estrogen converts into endometrial tissue. These two most common etiology theories support a multifactoral and possibly genetic etiology, since there is a familial trend. Endometriosis is sometimes diagnosed using the history and physical findings, but definitive
diagnosis requires laparoscopy to visualize the implants with subsequent histological confirmation.

Due to the number of females affected by endometriosis and the painful and progressive nature of this disease, it is essential to know and understand the treatments available and their efficacy. Surgical removal of endometrial implants through laparoscopic ablation is used to completely remove the ectopic endometrium through electrocoagulation, laser and/or scalpel to excise remaining tissue. In theory, removing and vaporizing the implants with laser therapy should terminate the symptoms, increase fertility, and prevent further growth of implants; however, research shows differing opinions by experts as to the full effectiveness of this treatment. According to Current Medical Diagnosis and Treatment, laparoscopic ablation of endometrial implants is often applied to patients with more progressed and severe stages of endometriosis and those experiencing infertility. Many women have experienced an improvement in their quality of life and reduction in the pain associated with endometriosis as a result of this treatment.

Another treatment option that is utilized and continually studied is the use of gonadotropin-releasing hormone analogs (GnRHa) in patients with endometriosis. GnRHa therapy down regulates the receptors in the anterior pituitary by decreasing their receptiveness to gonadotropin-releasing hormone (GnRH), which then reduces secretion of luteinizing hormone (LH) and follicle-stimulating hormone (FSH). As a result, estrogen and progesterone release is suppressed. The hormone response to GnRHa treatment denies endometrial tissue of the hormones necessary for the menstrual cycle to occur, inhibiting ovulation and usually prompting pseudomenopause. The three FDA approved GnRHa drugs include nafarelin nasal spray, leuprolide acetate and goserelin. Through controlled, clinical trails, this treatment has been
shown to be beneficial and effective, but has not been directly compared to surgical treatment. Conversely, there are a limited number of clinical trials available that compare laparoscopic surgery with the common medical therapies including GnRHa and oral contraceptives.

Although both laparoscopic ablation and GnRHa are treatments for endometriosis, the evidence that exists does not compare their efficacy and ability to treat the symptoms, prevent the recurrence of symptoms, fertility, short and long-term side effects of treatment and overall improvement of the patient’s quality of life. Considering the prevalence of endometriosis and the disabling pain and suffering it causes, comparing the safety and efficacy of GnRHa therapy and laparoscopic ablation therapy of endometrial implants provides the essentials necessary to properly utilize these treatment options in patients with endometriosis.

**Purpose of the Study**

Although laparoscopic ablation of endometrial implants and gonadotropin-releasing hormone analog (GnRHa) therapy are both recognized and extensively utilized treatments for endometriosis, the two treatments have not been analyzed to determine if they are equally effective. Through the evaluation and examination of evidence-based, medical literature, this study compares the efficacy and effectiveness of laparoscopic ablation of endometrial implants and GnRHa therapy regarding relief and recurrence of symptoms, fertility, side effects and complications of treatment in order to make evidence-based recommendations concerning the use of each treatment.
CHAPTER 2
METHODOLOGY

The design of this study is an evidence-based literature review. A search of published literature for randomized, clinically controlled trials that study either laparoscopic ablation or gonadotropin-releasing hormone analog therapy for endometriosis were reviewed. To ensure an unbiased evaluation of the literature, the search attempted to include all relevant research from 1985 to the present and assess each for its study quality and design, population inclusion and exclusion criteria, parameters measured and documented, reported results, and conclusions. Categorization and significance of literature is based on the level of evidence it provides. Level 1 includes randomized controlled trials. Level 2 research includes retrospective research, non-randomized clinical trials, cohort and case controlled studies. Level 3 includes literature reviews, consensus and expert opinion. Level 4 includes any form of background material. The outcomes and conclusions of each study were then used to compare the clinical effectiveness of each treatment.

Databases and Search Terms

The databases included in the search include Cambridge Scientific Abstracts, Medline (First Search and PubMed), InfoTrac Web, LexisNexis, Proquest (Nursing), and CINHAL. The keywords used include endometriosis, infertility, endometrial implants, endometriosis treatments, laparoscopic surgery and endometriosis, laparoscopic ablation, gonadotropin-releasing hormone analogs, leuprolide acetate, goserelin and nafarelin nasal spray.

Population Inclusion/Exclusion Criteria

Included in this review of literature are clinically controlled trials (Level 1) as well as retrospective and non-randomized studies (Level 2) with a female only population between the
ages of 18 and 50 with diagnosed endometriosis. The diagnosis must be made through a laparoscopic procedure to visualize the implants with histological confirmation desired. The ablative treatment for endometriosis includes implant excision, thermal ablation with carbon dioxide and/or laser electrocoagulation treatment. The subjects treated with either GnRHa or ablation must be evaluated at least one month after treatment, preferably 6 months to a year, to adequately assess the effects of treatment. The findings were then used to make recommendations regarding the use of each treatment.
CHAPTER 3
LITERATURE REVIEW

The literature reviewed was analyzed according to the inclusion and exclusion criteria and specific research outcomes including fertility after treatment, improvement in quality of life, recurrence of symptoms, complications, side effects and risks of treatment. Through modifications in hormone production and secretion, GnRHa have been found to be effective in the reduction of symptoms associated with endometriosis. The most commonly used drugs in this category include nafarelin nasal spray, goserelin and leuprolide acetate. Research of these drugs is extensive and multiple studies exist that compare different GnRHa to one another or to oral contraceptive therapy. There are studies that evaluate laparoscopic treatment including ablation and excision. Each of these studies approaches surgery for endometriosis differently, sometimes measuring different outcomes. The outcomes that are generally similar between studies include fertility, symptom relief and recurrence of endometriosis as visualized under a repeat laparoscopy. In contrast, a good percentage of studies that involve surgical treatments also include the use of GnRHa as a supplemental treatment before or after surgery. Using the treatments together is being evaluated by researchers to determine if there are any benefits in the combination of both therapies.

Gonadotropin-releasing hormone analogs (GnRHa) have been utilized for the treatment of endometriosis since approximately 1982. Because endometrial implants are responsive to hormone changes, GnRHa are useful in suppressing hormone production in the ovaries. As long as the GnRHa are in the body, they are working to cause a hypoestrogenic state. A study performed by Bergqvist and Theorell compared the use of nafarelin and medroxyprogesterone acetate in 48 patients. Although both medications were found to effectively reduce
endometriosis symptoms and improve quality of life with no statistical difference between the two groups, the nafarelin treatment group had a clinically significant increase in anxiety and depression throughout treatment, possibly due to decreased levels of estrogen. In fact, 18 women, mostly from the nafarelin group, dropped out of the study due to an increase in these symptoms. There is also an indication of bone density impairment in women treated with GnRHa because estradiol levels are decreased. Finkelstein and Arnold\textsuperscript{11} researched 51 patients diagnosed with endometriosis by beginning GnRHa therapy and monitoring bone mineral density (BMD) changes. They found that BMD decreased with GnRHa use and did not return to baseline upon completion of treatment. However, the addition of hPTH to the GnRHa illustrated an improvement in the BMD and returned it to baseline after treatment.\textsuperscript{11} According to Wellbery,\textsuperscript{3} recurrence of symptoms after GnRHa treatment is high (approx. 50\%) because it only suppresses ovarian function throughout treatment.

Another study that had an undesirable outcome and does not support the use of GnRHa in treatment of endometriosis was performed by Miller in 2000.\textsuperscript{15} This study injected leuprolide acetate versus placebo showing no statistical differences in the pain scores at two weeks, but at one month had a significant temporary increase in pain and decrease in quality of life. However, this study did not include any long-term care or follow-up after one month to determine the indications for long-term use of leuprolide acetate. Although, there are a few studies that demonstrate the side effects and possible BMD loss while on GnRHa therapy, multiple studies exhibit an improvement in pain scores and symptoms with non-life threatening side effects of the treatment. Some evidence suggests that GnRHa are beneficial for patients that desire temporary symptom reduction and transitory relief of endometriosis.\textsuperscript{5, 10}
Leuprolide acetate was studied by Dlugi et al in 1990\textsuperscript{16} comparing leuprolide acetate to placebo in the treatment of endometriosis in 52 patients who completed the study. The Leuprolide acetate treatment group showed significant improvement of endometriosis symptoms and all in the treatment group had suppression of menses compared to one participant in the non-treatment group. Similar results were detected when goserelin and Danazol were compared by Shaw in 1992 when 307 women participated to compare these treatments.\textsuperscript{14} The dropout rate in the goserelin group was 1\% compared to 9.7\% in the Danazol group, and goserelin side effects included mood and vocal changes and hot flashes. As for the relief of symptoms, both treatments were statistically equivalent at causing a resolution of endometriotic implants and decreasing associated symptoms. Amenorrhea, a measurement of accomplishing pseudomenopausal state, was accomplished in 80\% of the goserelin participants as well. In the same year, Danazol was compared to nafarelin nasal spray revealing no statistical differences between the two treatment groups; however, both groups were found to statistically improve pain, symptoms and laparoscopic endometrial implant scores.\textsuperscript{29}

Acien et al\textsuperscript{25} included 52 women with laparoscopically diagnosed endometriosis. Each patient received conservative treatment and then either received GnRH\textsubscript{a} post-operatively or had interperitoneal interferon α-2b placed in cul-de-sac at the time of surgery. Recurrence of endometriosis was 4 patients in GnRH\textsubscript{a} compared to 15 in the interferon group. It was not concluded that the recurrence of endometriosis was delayed or fertility improved with GnRH\textsubscript{a}. Venturini et al.\textsuperscript{5} looked at 32 patients diagnosed with endometriosis laparoscopically and measured their estradiol, LH and FSH levels throughout therapy with GnRH\textsubscript{a}. The levels of these hormones decreased, which represented accomplishment of a pseudomenopausal state. The patients were then observed and surveys of symptoms were taken throughout the experiment and
6 months beyond the end of treatment. At this point, 75% of patients claimed to be absent endometriosis symptoms.

Another benefit to GnRHa therapy is evidenced in Geber et al\textsuperscript{13} who studied two GnRHa (goserelin and leuprolide acetate) to determine which was more effective. They found that there was no difference in the downregulation of hormone levels between the two treatments and both similarly suppressed pituitary function and ovulation. As a result, the participants’ endometriosis symptoms were improved, but more importantly, this shows that the effects of two different GnRHa on endometriosis symptoms are similar. The distinction between different GnRHa is found in the side effects. Increased depression and anxiety\textsuperscript{10} and increased hot flashes\textsuperscript{29} were evident during nafarelin treatment.\textsuperscript{10} Treatment with leuprolide acetate produced side effects including headache (34% of participants), vaginitis, sweating, dizziness, nausea and insomnia with all 6 side effects present in 16% of participants.\textsuperscript{16} Hot flashes were experienced by 97% of participants in the goserelin treatment group with vaginal dryness, headache, decreased libido, insomnia, tiredness and mood alterations being present in approximately 21% to 38% of participants.\textsuperscript{5} The side effects are not life threatening, but may be life-altering enough to prevent the patient from completing treatment with GnRHa.

Surgical treatment of endometriosis is a non-specific term that includes everything from diagnostic laparoscopy to a total abdominal hysterectomy with bilateral salpingo-oopherectomy (TAH-BSO). Teirney\textsuperscript{2} claims the only curative treatment of endometriosis is the complete removal of cyclic hormone stimulation to the endometrial implants located throughout the peritoneum by removing the ovaries. This method is definitive, but also permanent and is not usually an option unless the patient is no longer of childbearing age, satisfied parity or has disabling disease.\textsuperscript{2} As a result, many patients interested in surgical therapy prefer more
conservative surgery. Laparoscopic ablation (LA) refers endometrial implant excision with a scalpel or ablation of through electrocoagulation or laser of the implants that are visible. Several outcomes are measured with laparoscopic ablation. One is fertility and the improvement thereof after ablation. Also measured and monitored is the relief of endometriosis related symptoms and recurrence of disease after treatment.

A study conducted by Abbott et al in 2003, 8 a prospective cohort study following 176 women up to 5 years after laparoscopic excision of implants, found that the pain associated with endometriosis improved up to 5 years after surgery and more than half of the women did not require any additional treatment for pain. However, Parazzini 23 found in a study including 101 women trying to conceive with laparoscopically diagnosed endometriosis that pregnancy rates were not statistically different between the non-treatment and LA treatment groups at 22.2% and 19.6% respectively. Several studies indicated that adhesiolysis of previous abdominal adhesions improves pregnancy rates. 21, 26 Bulletti et al 4 studied the recurrence of implants in patients who underwent LA compared to those that received diagnostic laparoscopy without treatment. The results of this study showed that 9 of the 14 women that were treated with LA had completely resolved symptoms in 3 months, whereas 3 of the 14 women who were not treated with ablation experienced significant recurrence of symptoms 3 months after the procedure. Also, no one in the ablation group showed re-growth of tissue, whereas 8 patients in the no treatment group had laparoscopically determined tissue re-growth.

Fertility and symptom reduction were two outcomes researched by Abbott et al (2004) 19 after LA was performed on 39 women with histologically diagnosed endometriosis. Through questionnaires, 67% had dysmenorrhea, non-menstrual pelvic pain, dyspareunia and sexual function with pleasure improved 2-5 years post-op, 25% had worsened symptoms and 8%
unchanged. Approximately 40% of the women had a history of infertility, of which 59% had a pregnancy and 44% had a live birth after surgery. Complications included finding too severe of disease upon entering pelvis to just perform excision or ablation. This included 15 women who received either oopherectomy or hysterectomy due to more complicated endometriosis after visualization of the pelvis. Of those women, 4% required a post-op blood transfusion. Treatment of endometriosis with ablation or excision in this study showed an improvement in endometriosis associated symptoms and fertility for the majority of patients. However, there were a few who had complications secondary to more severe disease than expected and a small percentage with unchanged or worsened symptoms.

Several studies combined the use of GnRHa with surgical treatment either as pre-op or post-op treatment. One such study by Gurgan et al\textsuperscript{26} researched infertility in 19 infertile patients. After 3 months of pre-operative GnRHa treatment, laparoscopy with adhesiolysis and ablation was performed and followed by another 3 months of GnRHa therapy. As a result, 9 of 19 women included conceived during the post-operative follow-up and only one participant had a recurrence of disease. Donnez et al\textsuperscript{12} treated 358 cycling women over the age of 30 with dysfunctional uterine bleeding with goserelin versus placebo injections 6 weeks prior to LA, of which 337 patient could be evaluated at the 1-year follow up. Amenorrhea was observed in 21% versus 14% in the goserelin and placebo groups respectively. The goserelin treated group saw a longer mean time to hysterectomy at 664 days compared to 571 days in the placebo treated group. While goserelin prior to LA did not prevent endometriosis related pain and bleeding, it did lengthen amenorrhea and prolong the need for a hysterectomy. Another study that evaluated goserelin injections for 5 to 6 months post-laparoscopic ablation was accomplished by Rickes et al\textsuperscript{28} who found the use of GnRHa post-operatively increased pregnancy rates. This is
demonstrated by an 89% versus 61% of pregnancy rates in GnRHa treated post-operatively and LA treated only group respectively.

Results

Figure 1 - Literature Review Diagram

Out of the 15 clinical trials for GnRHa included in this research, 12 show Nafarelin, leuprolide acetate and goserelin are effective at minimizing symptoms of endometriosis from six months to one year after completion of treatment. One study found that there was a temporary increase in pain and decrease in quality of life for the first month when treated with leuprolide acetate. In a study comparing fertility one year after treatment, live pregnancies were 50% in the leuprolide acetate treatment group in previously infertile women, demonstrating an improvement in fertility. Side effects with GnRHa use were non-life threatening. Research evidenced that GnRHa have the potential of causing bone mineral density (BMD) loss, which did not return to baseline after the completion of treatment.
Laparoscopic ablation (LA) did not show a significant improvement in pregnancy rates when compared to no treatment in two separate studies; however, symptoms improved up to one year post surgery.\textsuperscript{20, 23} In opposition to their findings were 3 other research studies that observed an increase in fertility rates.\textsuperscript{8, 19, 21} As for symptom and disease recurrence, one study indicated 12 of 14 patients experienced significant reduction or disappearance of symptoms and repeat laparoscopy showed no re-implantation of endometrial tissue post LA.\textsuperscript{9} Three studies were excluded because the surgical procedure performed was unclear and did not match the inclusion criteria or referred to chocolate cysts instead of endometrial implants.\textsuperscript{30-32} Low-incidence complications of laparoscopic surgery included adhesion formation, bowel or ureteral injury, infection and death. While these complications are not reported in the individual literature reviewed for this study, a previous evidenced-based study concerning endometriosis found that they do, in fact, occur on rare occasions.\textsuperscript{12} A study by Abbott et al in 2003\textsuperscript{8} showed LA complications to include finding too severe of disease upon entering pelvis to just perform excision or ablation. This included 15 women who received either oopherectomy or hysterectomy. Post-operative blood transfusion occurred in 4\% of women secondary to post-operative anemia.\textsuperscript{8}

Combination therapy with GnRHa pre- or post-operatively with LA has been found to improve pregnancy rates and reduce the re-growth of endometriosis after treatment. The medical side effects are the same as if the GnRHa are utilized as monotherapy. The same is found with LA complications when GnRHa therapy is added. Of the 4 studies addressing the combination of these two treatments included in this review, 3 studies found the combination of GnRHa and LA to be beneficial and decrease symptoms, disease recurrence and improve fertility.\textsuperscript{12, 25-27} The
other study found there to be no significant difference in combination therapy when compared to the use of each treatment as a monotherapy.¹¹
CHAPTER 4
DISCUSSION

Evidence in the Literature

Although the combination of GnRHa use and LA were not originally going to be included in this review, the availability of evidence and multiple studies performed concerning the combination of the two showed the recent development of combination therapy. Therefore, these studies were included to clarify the combination or separate use of these treatments.

Weaknesses in the Literature

Due to the disease process of endometriosis, it is difficult to objectively determine the effectiveness of a treatment. Instead, the researcher relies on the subjective evaluation from the patients’ symptoms, which is difficult to compare between individual patients. Each person has a different perception and manifestation of endometriosis pain as well as sensitivity to side effects of medical therapy. Literature concerning endometriosis treatments is difficult to compare to one another because no two research studies compare the same outcomes or have comparable methods. To completely and accurately evaluate and compare these two treatments would require that the disease presented the same in each person at every stage of the disease. Since the opposite is true and many people have severe evidence of endometriosis without symptoms and vice versa, making a definitive treatment recommendation based on evidence that is strongly subjective is not suggested. An additional limitation is the lack of clinical studies that address either GnRHa therapy or laparoscopic ablation using similar criterion and measured parameters. For example, fertility is rarely addressed in GnRHa research because it produces a pseudo-menopausal state, and therefore prevents pregnancy until after the completion of treatment. Laparoscopic ablation is rarely addressed in research alone as a treatment but is
commonly combined with surgical excision of endometriosis and/or medical management.

Validity of the Literature

The recommendations and determination for safety and side effects of treatment were largely formulated using Level 1 and 2 evidence studies. Previous review of literature studies and background information were consulted for clarification and explanation of the treatments being studied.
CHAPTER 5

CONCLUSION

The choice of treatment for endometriosis is dependent on multiple factors including the patient’s level of pain and discomfort, improvement of symptoms with treatment, incidence of symptom recurrence, ability and desire to conceive and side effects/complications of treatment. To determine and recommend the most effective and beneficial treatment for each individual patient, all of these factors should be evaluated and considered. Therefore, being aware of the medical evidence concerning various approaches to treatment is essential to successfully treat endometriosis patients. The difficulty associated with assessing the effectiveness of endometriosis treatment is heavily dependent on the fact that researchers rely on the symptom responses of the clinical subjects. Characteristics of pain and alleviation of symptoms are purely subjective and immeasurable by the researcher. This study evidences that both GnRHa and laparoscopic ablation are shown to be safe, reduce symptoms and improve the overall quality of life; however, the quality of symptoms, extent of endometriosis determined laparoscopically, age of patient and patient preference aide the decision concerning the type of treatment utilized in an individual. More clinical research is needed in order to determine specific parameters for each treatment.
REFERENCES


## APPENDIX

### Table 1 - Matrices of Research Articles

<table>
<thead>
<tr>
<th>Author and Year</th>
<th>Level of Evidence</th>
<th>Demographics Of Research</th>
<th>Treatment Addressed</th>
<th>Results</th>
<th>Relevance to Research Question or Reason for Exclusion</th>
</tr>
</thead>
<tbody>
<tr>
<td>Abbott et al 2003</td>
<td>2</td>
<td>254 women with chronic pelvic pain; 216 had laparoscopy and 176 had diagnosed endometriosis</td>
<td>1 (Excision of endometrial implants)</td>
<td>Through questionnaires, 67% had dysmenorrhea, non-menstrual pelvic pain, dyspareunia and sexual function with pleasure improved 2-5 years post-op and 25% had worsened symptoms with 8% unchanged. 40% of the women had a history of infertility of which 59% had a pregnancy and 44% had a live birth after surgery. Complications included finding too severe of disease upon entering pelvis to just perform excision or ablation. This included 15 women who received either oopherectomy or hysterectomy. 4% of women required a post-op blood transfusion.</td>
<td>Treatment of endometriosis with ablation or excision in this study showed an improvement in endometriosis associated symptoms and fertility for the majority of patients. However there were a few who had complications and worsened symptoms.</td>
</tr>
<tr>
<td>Abbott et al 2004</td>
<td>1</td>
<td>39 women with histologically proven endometriosis randomly assigned to receive ablation at the time of diagnostic laparoscopy or at 2nd laparoscopy 2 months later</td>
<td>1 (Laparoscopic Excision of endometrial tissue)</td>
<td>The group that received ablation at the time of the diagnostic laparoscopy showed an 80% improvement of symptoms compared to 32% n the group that only received a diagnostic laparoscopy without treatment. Once the group that had previously only had a diagnostic laparoscopy received ablative surgery, they had a significant increase in patients that had an improvement of symptoms from 32% to 83%. Of the women desiring pregnancy, 50% became pregnant post-op. 1 patient received post-op blood transfusion.</td>
<td>This research project showed a unique relationship between the percentage of patients who had a significant improvement in endometriosis associated symptoms after receiving ablation versus just a diagnostic laparoscopy. Fertility was also improved.</td>
</tr>
<tr>
<td>Acien et al 2002</td>
<td>1</td>
<td>52 women with laparoscopically diagnosed endometriosis</td>
<td>Conservative surgery then post-op treatment with 2 (Decapeptyl 3.75 mg IM inj. Monthly) vs. intraperitoneal interferon α-2b placed in cul-de-sac</td>
<td>All patients underwent conservative surgery, then treated post-op with GnRHa vs. interferon. 15 patients in the interferon group had recurrence of endometriosis on return laparoscopy versus only 4 in the GnRHa group.</td>
<td>GnRHa had significantly fewer recurrences of endometriosis then the interferon group. Could not confirm that recurrence of endometriosis was delayed or fertility improved with GnRHa.</td>
</tr>
<tr>
<td>Al-Inany 2001</td>
<td>3</td>
<td>Review of literature</td>
<td>1</td>
<td>This review of literature found that women who had undergone laparoscopic ablation in minimal- mild endometriosis did not have significantly improved pregnancy rates.</td>
<td>Reviewing the literature used in this study shows that there was not an improvement in pregnancy rates post laparscopic ablation in minimal-mild cases of endometriosis</td>
</tr>
<tr>
<td>Study</td>
<td>N</td>
<td>Inclusion Criteria</td>
<td>Intervention</td>
<td>Results</td>
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<tr>
<td>Barbieri et al 2006</td>
<td>3</td>
<td>Review of literature</td>
<td>3</td>
<td>This review of literature found that laparoscopic ablation of endometriosis and adhesiolysis improves pregnancy rates when compared to diagnostic laparoscopy. Also, GnRHa do not improve fertility or fecundability.</td>
<td></td>
</tr>
<tr>
<td>Bergqvist &amp; Theorell 2001</td>
<td>1</td>
<td>48 women ages 18-46 with laparoscopically verified endometriosis - 18 dropped out leaving 30 to complete the study</td>
<td>2 (Nafarelin 200 μg IN BID plus 2 placebo tabs) vs. 2 (Medroxyprogesterone (MPA) 15 mg BID plus placebo nasal spray BID)</td>
<td>Of the 18 dropouts, 17 reported more anxiety/depression and disturbed sleep than participants. Both the Nafarelin (17) and MPA (13) treated participants reported significant reduction in dysmenorrhea, bleedings, dyspareunia and pelvic pain. Dysmenorrhea and pelvic pain significantly improved in the Nafarelin study group; whereas, only dyspareunia was significantly reduced in the MPA study group. Anxiety/depression scores increased in Nafarelin group during treatment.</td>
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<tr>
<td>Bulletti et al 2001</td>
<td>2</td>
<td>28 women ages 24-40 with at least one child with uncontrollable dysmenorrhea underwent laparoscopy to diagnose endometriosis</td>
<td>1 (Bipolar ablation or excision of implants) vs. diagnostic laparoscopy without treatment</td>
<td>9 of 14 women that had endometrial ablation had a disappearance and 3 saw a significant reduction in dysmenorrhea compared to 3 of 14 with reduction in symptoms without ablation. No retrograde bleeding was found on the follow-up laparoscopy in patients with ablation versus 9 in the no treatment group.</td>
<td></td>
</tr>
<tr>
<td>Chapron et al 1999</td>
<td>2</td>
<td>30 patients meet inclusion criteria of &gt;12 months of infertility</td>
<td>Laparoscopic treatment of deep endometriosis infiltrating the uterosacral ligament (USL)</td>
<td>47% of patients with stage 1 and 2 endometriosis and 46.1% of patients with stage 3 and 4 had intruterine pregnancy post surgery. The difference was not significant between the stages.</td>
<td></td>
</tr>
<tr>
<td>Donnez et al 2001</td>
<td>1</td>
<td>358 cycling patients over age 30 with dysfunctional uterine bleeding - assessed at 12 weeks, 6 months, 1, 3, and 5 years post-op.</td>
<td>3 – Goserelin Acetate 3.6 mg inj or placebo inj. Approximately 6 weeks prior to endometrial ablation</td>
<td>337 patients could be evaluated at three-year follow-up. Amenorrhea was observed in 21% vs. 14% in the goserelin and placebo groups respectively. The mean time to hysterectomy was longer in the goserelin group at 664 versus 571 days in the placebo group.</td>
<td></td>
</tr>
<tr>
<td>Dlugi et al 1990</td>
<td>1</td>
<td>63 patients laparoscopically diagnosed with endometriosis</td>
<td>2 (Leuprolide Acetate 3.75 mg) vs. placebo</td>
<td>52 patients completed the study (28 and 24 in LA and placebo groups respectively) LA treatment group had significant improvement in dysmenorrhea, pelvic pain and tenderness. Suppression of menses (no menses &gt;60 days) occurred in all of the LA group and 1 in the placebo group. Lab changes included mild-moderate increase in hematocrit, hemoglobin, total protein, prothrombin time, albumin, alkaline phosphotase, and calcium Increase in cholesterol, LDL and triglycerides.</td>
<td></td>
</tr>
</tbody>
</table>

Leuprolide Acetate (Lupron Depot) caused menses suppression in all treated. Participants in the LA treatment group showed a significant increase consistent with menopausal women in labs, but none were found to be clinically significant compared to placebo. Those treated with LA showed an improvement in dysmenorrhea, pelvic pain and tenderness and results lasted >6 mo. in the majority of patients. SE of LA treatment are hypoestrogenic in origin and non-life threatening.
<table>
<thead>
<tr>
<th>Study</th>
<th>N</th>
<th>Description</th>
<th>Findings</th>
</tr>
</thead>
<tbody>
<tr>
<td>Finkelstein &amp; Arnold 1999</td>
<td>51</td>
<td>51 patients ages 20-45 with symptomatic, laparoscopically proven endometriosis</td>
<td>13 women did not meet the entry requirements. Bone mineral density (BMD) decreased significantly in all skeletal sites except the proximal radius during Nafarelin treatment compared to no significant changes in the BMD in the group treated with Nafarelin plus hPTH. Post-Nafarelin treatment, cycles returned and BMD increased in the Nafarelin group alone, but did not return to baseline 1 year after treatment was discontinued.</td>
</tr>
<tr>
<td>Geber et al 2002</td>
<td>459</td>
<td>459 women ages 20-44 (292 in Goserelin and 167 in Leuprolide Acetate)</td>
<td>No difference in the downregulation achievement between the two groups.</td>
</tr>
<tr>
<td>Gurgan et al 1996</td>
<td>19</td>
<td>19 infertile women with laparoscopically diagnosed ovarian endometriomas</td>
<td>2 patients had significant bleeding and 3 had significant adhesions. 9 of 19 women conceived during post-op follow-up.</td>
</tr>
<tr>
<td>Heinrichs et al 1998</td>
<td>73</td>
<td>Review of literature</td>
<td>The relief of endometriosis symptoms was similar at 3 and 6 months after GnRHa. Retreatment as effective as initial treatment.</td>
</tr>
<tr>
<td>Hornstein &amp; Barbieri 2006</td>
<td>2</td>
<td>Review of literature</td>
<td>This literature review found that GnRHa are the most widely used medical therapy for ovarian estrogen production. Also, three GnRHa are approved by the FDA including Goserelin, Leuprolide and Nafarelin for up to 6 months of treatment due to decrease in bone mass. Steroids in conjunction with GnRHa is effective with pelvic pain, but BMD needs to be checked yearly.</td>
</tr>
<tr>
<td>Jones &amp; Sutton 2002</td>
<td></td>
<td>73 women with endometriomas 2-15 cm Study used 38 women (mean age of 33.8 years) who had tried to conceive &gt;12 months prior to surgery</td>
<td>Laparoscopic cyst fenestration with ablation of the capsule 39.5% (15/38) women became pregnant There were no major surgical complications This study found that this method is a safe method to use to improve fertility</td>
</tr>
<tr>
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<td>Study Details</td>
<td>Outcome</td>
</tr>
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<td>---------------------------</td>
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<td>-------------------------------------------------------------------------------</td>
<td>-------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Kennedy et al 2005</td>
<td>3</td>
<td>Experts in evidence-based medicine develop recommendations for diagnosis and treatment of endometriosis</td>
<td>Laparoscopy is the ‘gold-standard for direct visualization of the pelvis and endometriosis. Endometriosis-type pelvic pain prior to laparoscopy can be tested with a trial-run of GnRHa. Suppressing Ovarian function up to 6 months helps reduces pain. If infertility is present, ablation and adhesiolysis is more effective than laparoscopy alone. Treatment with Danazolor a GnRHa after surgery does not improve fertility compared with expectant management.</td>
</tr>
<tr>
<td>Ledger 1999</td>
<td>3</td>
<td>Reviewed studies involving infertility</td>
<td>Medical Tx in mod-severe Ds probably ineffective for fertility, surgical ablation was found more effective than no treatment and medical treatment at improving fertility</td>
</tr>
<tr>
<td>McPhee 2003</td>
<td>4</td>
<td>Textbook referring to disease states</td>
<td>Infertility associated with endometriosis may be secondary to endometriosis</td>
</tr>
<tr>
<td>Miller 2000</td>
<td>1</td>
<td>120 sexually active women ages 18-40 with regular menses and significant pain due to laparoscopically diagnosed endometriosis. No significant differences in age, parity, race, medical histories, and duration of symptoms between the control and treatment groups</td>
<td>There were no statistical differences in the pain scores of the two groups at baseline, but at 2 and 4 weeks, the increase in pain scores and Endometriosis Symptom Severity (ESS) had significantly increased in the Lupron treatment group and slightly improved in the control group. The mental and physical component and quality of life showed a significant decrease in both the treatment and control group.</td>
</tr>
<tr>
<td>Nafarelin European Endometriosis Trial Group 1992</td>
<td>1</td>
<td>263 women with laparoscopically diagnosed endometriosis 171 in nafarelin and 92 in danazol treatment groups Inclusion Criteria: neg. pregnancy test, normal PAP smear results, regular menses, 18-45 years old, 45-110 kg weight</td>
<td>The laparoscopic scores for endometriosis and adhesion formation decreased in both treatment groups but was not statistically different between the two groups. Severe symptoms decreased in the nafarelin nasal spray by 32% and by 40% in the danazol after 6 months of treatment. Pregnancy, further medical therapy and other medical conditions were all causes of withdrawal in this study from both treatment groups. Patients on nafarelin experienced significantly more hot flashes, and Danazol participants experienced statistically increased weight.</td>
</tr>
<tr>
<td>Parazzini 1999</td>
<td>1</td>
<td>101 women &lt; 36 yo trying to conceive ≥ 2 yrs w/ laparoscopically diagnosed mild-moderate endometriosis</td>
<td>There were no statistical nor clinical differences between the two treatment groups, however both were found to statistically improve pain scores, symptoms and laparoscopic scores.</td>
</tr>
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<td>Petta et al 2005</td>
<td>1</td>
<td>83 women ages 18-40 with histologically</td>
<td>The result of this study shows no improvement in fertility post laparoscopic ablation in mild-moderate endometriosis compared to no treatment</td>
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LNG-IUS has been approved 5 year treatment periods because it does not induce a
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<th>Intervention</th>
<th>Results</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rickes et al 2002</td>
<td>110 women ages 23-40 with stage II to IV endometriosis diagnosed with videolaparoscopy</td>
<td>Releasing intrauterine system (LNG-IUS) respectively. Although both groups showed a significant decrease in CPP and improvement in the quality of life, there was no significant difference between the two treatment groups. The GnRHa group had a lower bleeding score than the LNG-IUS group. Stages III and IV endometriosis patients had more rapid improvement than stages I and II in both treatment groups.</td>
<td>Hormone therapy increased pregnancy rates in post-op group compared to no post-op treatment.</td>
<td>Potential side effects of hormone therapy include hot flashes, depression, vaginal dryness, and bone loss.</td>
</tr>
<tr>
<td>Schlaff et al 2006</td>
<td>274 women ages 18-49 with stage II to IV endometriosis diagnosed with videolaparoscopy</td>
<td>3 (Laparoscopy with excision of endometrial implants and post-op treatment with Goserelin 3.6 mg SQ inj. Monthly 5-6 months vs. no post-op treatment)</td>
<td>Dropout rate: 48/136 in DMPA-SC 104 group and 36/138. Dropout rates due to adverse effects were equivocal between the two treatment groups at 9 patients per group. At 12 months post treatment, both treatments were statistically equivalent for improvement of dysmenorrhea, dyspareunia, pelvic pain, pelvic tenderness and induration. Bone mineral density (BMD) decline was more significant in the LA treatment group in both total hip and lumbar spine than that observed in the DMPA-SC treatment group at 12 month follow-up. The DMPA-SC treatment group did not show a significant change in either total hip or lumbar spine BMD at 12 months.</td>
<td>Statistically, LA and DMPA-SC were both found to reduce all five severe symptoms (dysmenorrhea, dyspareunia, pelvic pain, pelvic tenderness and induration) equivalently. BMD loss was more in the LA treatment group at both 6 and 12 month intervals. Hypoestrogenic SE more common in LA group and vaginal bleeding/spotting more common in DMPA-SC group.</td>
</tr>
<tr>
<td>Schriock et al 1985</td>
<td>8 women with laparoscopically diagnosed endometriosis ages 25 to 37.</td>
<td>2 (Nafarelin Nasal Spray 500 μg q 12 hrs)</td>
<td>At 6 months of treatment, of the 7 women who had completed the study, all of the women had decreased their stage of the disease compared to their staging prior to treatment. No endometrial implants were found in 5 of the 7 patients. Symptoms lessened by week 4, and improvement was maximal by week 12. All women were anovulatory. SE included hypoestrogenemia in all patients, hot flashes (some women were decreased to 250 μg TID b/c of this SE), vaginal dryness, mild HA, leucopenia (cause undetermined-this patient was withdrawn from the study at 2 months of treatment), and mild depression (2 patients).</td>
<td>This study does not include a control group and only 7 women were able to complete the study, which makes it difficult to determine the efficacy of the treatment. However, it includes evidence of symptomatic relief of endometriosis and decrease in the disease state after 6months of treatment. The SE experienced are those due to hypoestrogenemia, which is the purpose of GnRHa treatment.</td>
</tr>
<tr>
<td>Shaw 1992</td>
<td>307 women with laparoscopically</td>
<td>2 (Goserelin depot 3.6 mg SQ monthly)</td>
<td>More patients withdrew during treatment of danazol (9.7%) compared to goserelin (1.0%)</td>
<td>Both treatments were statistically equivalent at causing resolution of endometriotic implants</td>
</tr>
<tr>
<td>Tierney 2005</td>
<td>4</td>
<td>Evidence Base Medicine Review of Literature</td>
<td>3</td>
<td>Gives the different medications in the GnRHa, their names and doses.</td>
</tr>
<tr>
<td>Tulandi 2006</td>
<td>3</td>
<td>Review of Literature</td>
<td>1</td>
<td>Investigates laparoscopic surgery in infertile patients. Adhesiolysis has been found to aid in increased pregnancy rates. Stages of endometriosis still under debate. Three types of ablation/excision of endometriosis include electrocoagulation, laser and harmonic scapel. No method has been shown to be more effective than the other.</td>
</tr>
<tr>
<td>Tummon et al 1989</td>
<td>1</td>
<td>15 women with mean age of 32.1 ± 0.9 years Randomized to leuprolide (10) or danazol (5)</td>
<td>2 (intranasal leuprolide 1.6 mg/day) vs. 2 (danazol 800 mg/day)</td>
<td>Complete amenorrhea achieved in 8 of 10 in leuprolide group and 3 of 5 in danazol group, the others had minor spotting Both groups experienced symptomatic relief Leuprolide caused more significant suppression of Estradiol and Progesterone than danazol Symptoms with leuprolide included increased vag. dryness, intense vasomotor symptoms and no change in weight Danazol symptoms included acne/oily skin and tendency to gain weight Live birth rates were 50% and 40% in leuprolide and danazol groups respectively post treatment</td>
</tr>
<tr>
<td>Venturini et al 1990</td>
<td>2</td>
<td>32 women ages 21-32 with laparoscopically diagnosed endometriosis. All patients were symptomatic an 15 of 32 were infertile.</td>
<td>2 (Goserelin depot 3.6 mg IM inj.) No comparison or control group was utilized in this study.</td>
<td>All patients became ammenorrhiec after second shot and menses returned in all patients 57 to 85 days after the last injection. Symptomatic relief was as follows: Severe to very severe patients decreased in total numbers from 56.3% to 3.1% by the 2nd month of treatment and at 6 months, 75% of</td>
</tr>
<tr>
<td>Study</td>
<td>Year</td>
<td>Study Design</td>
<td>Main Findings</td>
<td>Relevant Information</td>
</tr>
<tr>
<td>-------</td>
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</tr>
<tr>
<td>Wellbery 2000</td>
<td>4</td>
<td>Background information, summarizes history and physical presentation of endometriosis. Addresses diagnostic tools and commonly used treatments.</td>
<td>Patients in the study regardless of severity claimed to have absent endometriosis symptoms. SE: hot flashes (96.9%), vaginal dryness (37.5%), headache (37.5%), decreased libido (34.4%), insomnia (28.1%), tiredness (25%), mood alterations (21.9%), breast discomfort (6.2%), and irregular bleeding (3.1%).</td>
<td>Medical treatment with OCP’s, danazol and GnRHa are all excellent options for treatment of endometriosis, however there is a recurrence rate of pain at approx. 50% of patients. Surgical treatment has a lower recurrence rate of symptoms.</td>
</tr>
<tr>
<td>Winkel et al 2001</td>
<td>3</td>
<td>Review of Literature</td>
<td>Medical treatment compares one medication to placebo with GnRHa showed 80-100% effectiveness in improvement of pelvic pain over 6 month therapy. Surgical therapy were “anecdotal” with a variety of methods with minimal literature assessing the best surgical approach.</td>
<td>This review of literature was very thorough and accurately assessed the weakness in literature. It showed how using pain as a measurement of effectiveness of treatment is inaccurate because many patients are asymptomatic. Also, it assessed available literature on both laparoscopic ablation and GnRHa therapy, but could not compare the two treatments.</td>
</tr>
<tr>
<td>Wood, et al 1996</td>
<td>1</td>
<td>Study Design</td>
<td>All treated with peritoneal excision dependant on location of dominant endometriosis site</td>
<td>This study was excluded because treatment with excision was not one of the treatments being studied. The title gives the impression that it compares excision with thermal ablation, but it only addresses excision.</td>
</tr>
</tbody>
</table>
VITA

Name: Rachel Michelle Baker

Date of Birth: October 6, 1982

Place of Birth: Wichita, Kansas

Education:

2005-2007 Master – Physician Assistant (M.P.A)  
Wichita State University, Wichita, Kansas

2001-2005 Bachelor of Science (Magna Cum Laude) – Biology: Concentration in Health Sciences – Friends University, Wichita, Kansas

Awards:

2001 Awarded Presidential Scholarship – Friends University, Wichita, Kansas

2001-2005 President’s Honor Roll – Friends University, Wichita, Kansas

2003 W.O. Mendenhall Award for Outstanding Junior Woman  
Friends University, Wichita, Kansas

2003 Alpha Chi National Honor Society Induction  
Friends University Chapter – Wichita, Kansas

2005 Genev & Cramer Reed Endowed Scholarship Recipient  
Wichita State University Physician Assistant Program
WICHITA STATE UNIVERSITY

DEPARTMENT OF PHYSICIAN ASSISTANT

Defense of Research Project and Final Approval of the Research Project

After the oral defense of the project, this form is returned to the Department of Physician Assistant. The advisor for your project verifies that all changes suggested by the Department Chair and other PA faculty (as necessary) have been incorporated in the final draft of the document.

STUDENT NAME: Rachel Baker  DATE: May 7, 2007

PROJECT TITLE: Are gonadotropin-releasing hormone analogs and laparoscopic ablation of endometrial implants equally effective treatments for endometriosis?

DEFENSE REPORT

Examination Completed: Yes or No (Circle One) Date: ________________________________

Passed:_________ Failed:_________

May the examination be Repeated? When? ________________________________

SIGNATURES:*

________________________________________________________________________

________________________________________________________________________

________________________________________________________________________

________________________________________________________________________

*To be signed by all applicable faculty members and forwarded to the Department Chair when the examination is completed and the final draft is approved. The student is responsible for meeting the submission guidelines outlined earlier in this syllabus.

Final draft approved:

________________________________________________________________________

________________________________________________________________________

DEPARTMENT USE ONLY:

______ 1 copy of the Research Project (hard copy)
_____ 1 copy of the research Project (pdf file on disk)
_____ Signed copy of Institutional Repository Access Agreement Form
Submitter’s name:  Rachel Baker

Title of work:  Are gonadotropin-releasing hormone analogs and laparoscopic ablation of endometrial implants equally effective treatments for endometriosis?

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Submitter (Printed) __ Rachel M. Baker _________________________________

Submitter (Signature) ________________________________________________

Date __ May 7, 2007 ___________________