DOES INCIDENTAL ENDOMETRIOSIS AT LAPAROSCOPIC TUBAL STERILIZATION INCREASE FUTURE HEALTH CARE UTILIZATION?

A THESIS SUBMITTED TO THE GRADUATE DIVISION OF THE UNIVERSITY OF HAWAI'I IN PARTIAL FULFILLMENT OF THE REQUIREMENTS FOR THE DEGREE OF

MASTER OF SCIENCE

IN

BIOMEDICAL SCIENCES

DECEMBER 2005

By

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We certify that we have read this thesis and that, in our opinion, it is satisfactory in scope and quality as a thesis for the degree of Master of Science in Biomedical Sciences.

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Acknowledgment:

This study was supported by a grant: NIH NCRR 5R25RR019321-02
Abstract:

Objectives: To identify if patients diagnosed with incidental endometriosis at the time of laparoscopic tubal sterilization experience a greater utilization of physician office visits for pelvic pain, gynecological surgeries, and/or pain medications compared to those without endometriosis.

Methods: This is a retrospective cohort study utilizing the largest third-party health insurance database in the state of Hawai‘i from 1999-2003. Patients with CPT codes consistent with laparoscopic tubal sterilization and an ICD-9 diagnosis code of endometriosis were compared to patients with the laparoscopic tubal sterilization diagnosis but without a diagnosis of endometriosis. Physician office visits for abdominal and pelvic pain, subsequent gynecologic surgeries, and the number of pain medication prescriptions were analyzed between the two groups in the years following tubal sterilization.

Results:
There were 1219 laparoscopic tubal sterilizations from 1999-2003. Seventy-four (6.07%) of these patients were diagnosed with endometriosis at the time of surgery. In the endometriosis group, there was an 80% (CI 1.06-3.03; p=0.029) higher rate of office visits for abdominal and pelvic pain and 5.6 times (CI=2.95-10.5; p=0.0001) higher rate of subsequent gynecologic surgeries over the 5 year study period. There was no difference in the rate of emergency room/hospital visits or the number of pain medications prescribed. For office visits, procedures,
and prescriptions, there were 78.5%, 95%, and 51% increases in costs respectively, as compared to the control group.

**Conclusion:**

The diagnosis of incidental endometriosis at the time of laparoscopic tubal ligation is associated with a subsequent increase in physician office visits and gynecologic surgeries.
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Chapter 1
Introduction

Chronic pelvic pain, defined as pelvic pain lasting greater than 6 months, is a common problem, affecting approximately 15% of women in the general population.[1] This debilitating condition also has a significant impact on healthcare costs. Based on the 1996 Gallop survey, the estimated direct costs for outpatient visits in the U.S. for chronic pelvic pain were estimated to be 881.5 million dollars a year.[1]

In a Gallop poll, 25% of women with chronic pelvic pain reported a diagnosis of endometriosis by their physicians.[1] While commonly identified in women with pelvic pain, it is unclear if endometriosis discovered incidentally at surgery will likely progress to pelvic pain or result in a greater utilization of healthcare resources in the future. Laparoscopic tubal sterilization provides an opportunity to investigate the relationship between incidental asymptomatic endometriosis and pelvic pain.

The incidence of asymptomatic endometriosis progressing to pelvic pain has not been well studied. In patients with pelvic pain, a concurrent diagnosis of endometriosis is often implicated as the cause of acute, as well as chronic pelvic pain.[2] Endometriosis is common with the prevalence ranging between 20-40% in the gynecological clinical setting. Of women undergoing laparoscopic sterilization, a review of the literature by Mahmood found the prevalence varies between 1-43%.[3] In some patients minimal endometriosis may result in pelvic...
pain, but in others severe endometriosis is asymptomatic. There is one study which addresses the question about of the progression of asymptomatic endometriosis. Moen (2002) found that future pelvic pain was more frequently reported by controls than by women with incidental endometriosis (28% vs. 6%) discovered at time of tubal sterilization. Moen, however, found no significant difference between the two groups for dysmenorrheal, premenstrual pain, dyspareunia, or hysterectomy rate.[4]

Understanding whether or not incidental asymptomatic endometriosis leads to an increased risk of pelvic pain, greater utilization of office visits, or pain medication is important. If asymptomatic incidental endometriosis leads to more office visits and pain medication use for pelvic pain, then this information can help focus the physician on aggressive management of endometriosis at time of diagnosis, which may include medical or surgical treatment.[5] Therefore the objective of this investigation was to identify if patients diagnosed with incidental endometriosis at time of tubal sterilization incurred a greater future utilization of physician office visits for pelvic pain, hospital/office procedures, or pain medications compared to those without endometriosis.
Chapter 2
Materials and Methods

This was a retrospective cohort study approved by the University of Hawai'i Institutional Review Board. (see Appendix A) Subject information was drawn from the largest third-party health insurance patient database in the state of Hawaii, which insures 55% of the private insurance population, during the years of patient enrollment from 1999-2003.[6] The state of Hawaii has a very diverse ethnic mix; 20% of the population reports two or more ancestries; 20% are whites; 42% are Asians (Chinese 4.7%, Filipino 14%, Japanese 17%, Korean 2% Vietnamese 0.6%, other Asian 3.5%); 9% Native Hawaiian or Pacific-Islander ancestry; 2% are African-American and 7% Hispanic or Latino.[7]

Patients with all primary and secondary diagnostic ICD codes consistent with endometriosis (ICD-9 2004, all endometriosis codes-617.X) and CPT Codes consistent with laparoscopic tubal-sterilization/fulguration/occlusion (CPT 2004-laparoscopic fulguration of fallopian tubes-58670, laparoscopic occlusion of fallopian tubes by device-58671) were compared to those patients who had undergone laparoscopic tubal fulguration without endometriosis identified. [8, 9] Any patient with a prior ICD code of endometriosis at the time of tubal surgery was excluded from the data set.

The outcomes measured were the number of physician office visits (see Appendix B) with the diagnosis of pelvic pain or abdominal pain (see Appendix C), other subsequent gynecologic procedures associated with the management of pelvic pain (see Appendix D), and the number of pain medication prescriptions
in these two groups in the years following tubal sterilization. The eligible costs (the amount eligible for payment from the insurance member and insurance company) for these outcomes were analyzed comparing the incidental endometriosis group and the group without endometriosis.

The predictor variable was the incidental diagnosis of endometriosis at time of tubal ligation. The outcome variables included the number of physician visits for pelvic pain, number of procedures related to pelvic pain, and the number of prescriptions for pain medications. A limitation of this investigation was that only physician visits linked to the pelvic/abdominal pain ICD code were included as the outcome. In addition the validity of our data set is dependent on accurate physician coding for the diagnosis and procedure codes.

The pain medications evaluated included, but were not limited to, ibuprofen, acetaminophen with codeine, acetaminophen with hydrocodone, and acetaminophen with oxycodone (see Appendix E for complete list). The prescriptions, procedures, emergency room visits, and hospitalizations were analyzed over the 5 year period. The log of dollar costs was compared in all outcomes to assess health care utilization costs.

For statistical analyses, the number of physician visits for pelvic pain, the number of hospital procedures, and the number of prescriptions for pain medications were analyzed employing negative binomial regression models adjusting for age. The length of time the patient was insured was included in the regression models as an offset, correcting for the various enrollment times of the women in the study. Results are expressed as the relative eligible costs of
prescriptions, emergency room visits, hospital visits, office visits, and procedures after exponentiating the regression coefficients from the negative binomial models. Statistical analysis was computed on SAS Release 8.2.

Figure 1: Methods

Female patients undergone laparoscopic tubal sterilization
N=1219

Positive (+)
Endometriosis
6.1% (N=74)

Negative (-)
Endometriosis
93.9% (N=1145)

Identify the following outcomes for pelvic pain:
- # of office visits
- # of hospital/ER visits
- # of gynecologic surgeries
- # of pain med Rx's

Compare and evaluate outcomes of office visits, procedures, and pain medication prescription between + and - groups from 1999-2003
Chapter 3

Results

A total of 1219 patients had tubal sterilizations from 1999-2003. Seventy four (6.07%) of the 1219 were diagnosed with endometriosis at the time of surgery based upon the ICD codes.

With a diagnosis of endometriosis at the time of tubal sterilization, there was an 80% higher rate of subsequent office visits for abdominal and pelvic pain (Table 1), and a 5.6 times greater likelihood of having future gynecologic surgeries performed (Table 2). Both results were statistically significant (p<0.05). Patients with an endometriosis diagnosis were also 15% more likely to have pain medications prescribed and 11% more likely to have emergency room and hospital visits, but these increases were not statistically significant (Figure 2).

When examining the eligible costs for office visits, procedures, and prescriptions, there were a 78.5%, 95%, and 51% increases in the respective costs for the group with endometriosis (Figure 3). There were no significant differences in eligible costs for ER or hospital visits between the two groups.

Patients with a diagnosis of endometriosis were 23% less likely to have office visits for each advancing decade of age (p < 0.001). The opposite was true with gynecological procedures. For patients with a diagnosis of endometriosis, each decade of advancing age increased by 2.9 times the chances for subsequent gynecological surgery (p< 0.001). In addition, the eligible costs for gynecologic surgery increased by 12% for each advancing
decade of age (p=0.03), while the prescription eligible costs decreased 16% for each advancing decade (p=0.03).
Chapter 4
Discussion

The results from this retrospective cohort study suggest an association between a diagnosis of incidental endometriosis and increased future utilization of health care for office visits and surgical procedures for pelvic pain. This is in contrast with Moen’s study[4] who found that future pelvic pain was more frequently reported by controls than by women with incidental endometriosis (28% controls vs. 6% endometriosis) without any differences in dysmenorrhea, premenstrual pain, dyspareunia, or hysterectomy rate between groups. Moen’s investigation was a prospective, long-term study of 39 women with minimal and asymptomatic endometriosis. Moen’s results suggest a lack of an obvious association and natural progression of incidental endometriosis to symptomatic endometriosis. Our data suggests otherwise.

The strength of our study is the large number in our data set, which includes a substantial cross-section of the population of the state of Hawai‘i. Although our study does not definitively answer the question of whether more pelvic pain occurs in subjects previously diagnosed with subclinical endometriosis, our data suggests a positive association between incidental endometriosis and the increased observed health care utilization for pelvic pain, office visits, and related procedures. In contrast, Moen’s study addressed physician consultations for pelvic pain, laparoscopy for pain, and hysterectomies as outcomes of future health care utilization, but his cohort was likely
underpowered to reach any definitive conclusions or to detect any significant
differences.

In our study, we found patients with incidental endometriosis had greater
utilization of office visits for pelvic pain and more gynecologic surgeries.
Associated with these results were greater costs for office visits and surgeries, as
measured by the eligible costs. Although more pain medications were prescribed
and more emergency room and hospital visits were documented in the
endometriosis group, these results were not statistically significant. The costs for
the prescriptions were increased, but this investigation was not powered to
detect a significant difference.

In the endometriosis group, gynecologic surgeries increased by a factor of
2.9 and costs for those surgeries increased by 12% for each advancing decade
of age. We speculate that this may be a result of women deciding on more
definitive surgical treatments, such as bilateral oophorectomy with or without
hysterectomy, once their childbearing years have ended. Since surgeries such
as oophorectomy may reduce pelvic pain associated with endometriosis, this
could also explain the decrease in prescription cost of 16% for each advancing
decade of age.[10]

There are several limitations to this study. Indeed, it is unknown whether
endometriosis has a causal relationship with these reported outcomes, or if there
was a selection bias in our dataset which led to an increased detection of the
reported outcomes, once subjects were identified as having endometriosis. To
be sure, it is possible that the association between incidental endometriosis and
increased office visits and surgeries may be the result of subjects seeing their physicians more frequently or their physicians doing more procedures, based on the diagnosis alone, irrespective of other associated issues.
Chapter 5

Conclusion

Within the limitations of this study, we conclude that our data suggests a positive association between the diagnosis of incidental endometriosis and future increased utilization of health care including office visits and surgical procedures for pelvic pain. Understanding the natural history of incidental endometriosis in relation to signs and symptoms, and health care utilization is important because many women are affected by chronic pelvic pain. If it can be shown that pelvic pain and health care utilization are related to early incidental endometriosis, then aggressive medical or surgical management at the time of diagnosis may alter the natural history and avoid significant morbidity for those affected individuals. A randomized controlled trial of medical or surgical treatment of incidental endometriosis at the time of tubal sterilization may be indicated to definitively answer this question.
Table 1: Relative Rates of Office Visits over the 5 Year Study Period in Patients with Incidental Endometriosis vs. No Endometriosis found at Tubal Sterilization

<table>
<thead>
<tr>
<th>Number of Office Visits</th>
<th>Negative for Endometriosis</th>
<th>Positive for Endometriosis</th>
<th>Relative Rates of Office Visits</th>
<th>Confidence Interval</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>862 (75.3%)</td>
<td>48 (61.5%)</td>
<td>1.79</td>
<td>1.06-3.03</td>
<td>0.03</td>
</tr>
<tr>
<td>1-15</td>
<td>283 (24.7%)</td>
<td>26 (35.1%)</td>
<td>1.00</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>1145</td>
<td>74</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Table 2: Relative Rates of Subsequent Gynecologic Surgeries over the 5 Year Study Period in Patients with Incidental Endometriosis vs. No Endometriosis found at Tubal Sterilization

<table>
<thead>
<tr>
<th>Number of Subsequent Gynecologic Surgeries</th>
<th>Negative for Endometriosis</th>
<th>Positive for Endometriosis</th>
<th>Relative Rates of Gynecologic Surgeries</th>
<th>Confidence Interval</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>1126 (98.3%)</td>
<td>69 (93.2%)</td>
<td>5.57</td>
<td>2.95-10.5</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>1-2</td>
<td>19 (1.7%)</td>
<td>8 (10.8%)</td>
<td>1.00</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>1145</td>
<td>74</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Table 3: Relative Rates of Hospital and Emergency Room Visits over the 5 Year Study Period in Patients with Incidental Endometriosis vs. No Endometriosis found at Tubal Sterilization

<table>
<thead>
<tr>
<th>Number of Hosp &amp; ER Visits</th>
<th>Negative for Endometriosis</th>
<th>Positive for Endometriosis</th>
<th>Relative Rates of Hosp &amp; ER Visits</th>
<th>Confidence Interval</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>1090 (95.2%)</td>
<td>69 (93.2%)</td>
<td>1.12</td>
<td>0.45-2.78</td>
<td>0.08</td>
</tr>
<tr>
<td>1-3</td>
<td>55 (4.8%)</td>
<td>5 (6.8%)</td>
<td>1.00</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>1145</td>
<td>74</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Table 4: Relative Rates of Pain Medication Prescriptions over the 5 Year Study Period in Patients with Incidental Endometriosis vs. No Endometriosis found at Tubal Sterilization

<table>
<thead>
<tr>
<th>Number of Pain Medication Prescriptions</th>
<th>Negative for Endometriosis</th>
<th>Positive for Endometriosis</th>
<th>Relative Rates of Pain Medications Prescribed</th>
<th>Confidence Interval</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>902 (78.8%)</td>
<td>51 (69%)</td>
<td>1.15</td>
<td>.54-2.44</td>
<td>0.38</td>
</tr>
<tr>
<td>1-58</td>
<td>243 (21.2%)</td>
<td>23 (31%)</td>
<td>1.00</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>1145</td>
<td>74</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Figure 2: Relative Rates of Office Visits, Procedures, Prescriptions, and Emergency Room or Hospital Visits for Patients with a Diagnosis of Endometriosis vs. No Endometriosis at Laparoscopic Tubal Sterilization
Figure 3: Relative Costs of Office Visits, Procedures, Prescriptions, and Emergency Room or Hospital Visits for Patients with a Diagnosis of Endometriosis vs. No Endometriosis at Laparoscopic Tubal Sterilization
Appendix A: IRB Approval

Protection of Human Subjects
Assurance Identification/IRB Certification/Declaration of Exemption
(Common Rule)

Policy: Research activities involving human subjects may not be conducted or supported by the Departments and Agencies adopting the Common Rule (56FR28303, June 16, 1991) unless the activities are exempt from or approved in accordance with the Common Rule. See section 101(b) of the Common Rule for exemptions. Institutions submitting applications or proposals for support must submit certification of appropriate Institutional Review Board (IRB) review and approval to the Department or Agency in accordance with the Common Rule.

1. Request Type
   [ ] ORIGINAL
   [ ] CONTINUATION
   [X] EXEMPTION

2. Type of Mechanism
   [ ] ORIGINAL
   [ ] GRANT
   [ ] CONTRACT
   [ ] FELLOWSHIP
   [ ] COOPERATIVE AGREEMENT
   [ ] OTHER:

3. Name of Federal Department or Agency and, if known, Application or Proposal Identification No.

4. Title of Application of Activity
   "Does Inflammatory Bowel Disease Diagnosed During Laparoscopic Tubal Sterilization Result in Greater Health Care Utilization for Pelvic Pain in the Future?"

5. Name of Principal Investigator, Program Director, Fellow, or Other
   David Seil Kim, M.D.

6. Assurance Status of this Project (Respond to one of the following)
   [X] This Assurance, on file with Department of Health and Human Services, covers this activity:

   [ ] This Assurance, on file with [agency/office], Assurance No. [number], expiration date [date], IRB Registration Identification No. [number] (if applicable).

   [ ] No assurance has been filed for this institution. This institution declares that it will provide an Assurance and Certification of IRB review and approval upon request.

   [X] Exemption Status: Human subjects are involved, but this activity qualifies for exemption under Section 101(b), paragraph 4.

7. Certification of IRB Review (Respond to one of the following if you have an Assurance on file)
   [ ] This activity has been reviewed and approved by the IRB in accordance with the Common Rule and any other governing regulations.
     by: [ ] Full IRB Review on [date of IRB meeting] or [ ] Expedited Review on [date]; [ ] if less than one year approval, provide expiration date.

   [ ] This activity contains multiple projects, some of which have not been reviewed. The IRB has granted approval on condition that all projects covered by the Common Rule will be reviewed and approved before they are initiated and that appropriate further certification will be submitted.

8. Comments

9. The official signing below certifies that the information provided above is correct and that, as required, future reviews will be performed until study closure and certification will be provided.

   William H. Dendle

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    (808) 538-3054

13. Email:
    dendle@hawaii.edu

14. Name of Official
    Compliance Officer

15. Title

16. Signature

17. Date
    June 30, 2004

CHS #13089

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Appendix B: Office, Emergency Room, and Hospital Visits CPT 2004 Codes

1. Office Visits
   a. New patient evaluation and management-99201-99205
   b. Established patient evaluation and management-99211-99215
   c. Consultations-99241-99245

2. Emergency department services-99281-99285

3. Hospital Visits
   a. Hospital Visit Initial-99221-99223
   b. Hospital Visit Subsequent-99231-99238
Appendix C: ICD 9-Pelvic and Abdominal pain:
1. Abdominal Pain-789.0x,
2. Pelvic Pain
   a. Dyspareunia-625.0
   b. Dysmenorrhea 625.3
   c. Other specified symptoms associated with female genital organs-625.8
   d. Unspecified symptom associated with female genital organs-625.9
Appendix D: Gynecologic Procedures CPT 2004

1. Total abdominal hysterectomy with or without bilateral salpingo-oophorectomy-58150
2. Total abdominal hysterectomy with colpopexy-58152
3. Supracervical hysterectomy with or without bilateral salpingo-oophorectomy-58180
4. Total vaginal hysterectomy, <250gm-58260
5. Total vaginal hysterectomy, <250 gm; with bilateral salpingo-oophorectomy-58262
6. Total vaginal hysterectomy with bilateral salpingo-oophorectomy, with enteroccele repair-58263
7. Total vaginal hysterectomy, >250 gm-58290
8. Total vaginal hysterectomy, >250 gm, with bilateral salpingo-oophorectomy-58291
9. Total vaginal hysterectomy, >250 gm, with bilateral salpingo-oophorectomy with repair of enteroccele-58292
10. Total vaginal hysterectomy, >250 gm, with colpourethrocystopexy (MMK)-58293
11. Total vaginal hysterectomy, >250 gm, with repair of enteroccele-58294
12. Laparoscopic assisted vaginal hysterectomy with or without bilateral salpingo-oophorectomy-58550
13. Laparoscopy with lysis of adhesions-58660
14. Laparoscopy surgical; with removal of adnexal structures-58661
15. Laparoscopy surgical; with fulguration or excision of lesions of ovary, pelvic viscera, or peritoneal surface-58662
16. Unlisted laparoscopy procedures of tubes or ovaries-58679
17. Ovarian cystectomy, unilateral or bilateral-58295
18. Oophorectomy, unilateral or bilateral-58940
19. Laparoscopy, abdomen, peritoneum, and omentum, diagnostic, with or without collection of specimen by brushing-49320
20. Laparoscopy, surgical; with salpingostomy-58673
21. Salpingectomy, complete or partial, unilateral or bilateral-58700
22. Lysis of adhesions-58740
Appendix E: Pain Medication Prescriptions.

1. Acetaminophen with codeine
2. Darvocet-N 50
3. Fioricet
4. Fioricet with codeine
5. Hydrocodone Bit-Ibuprofen
6. Hydrocodone with acetaminophen
7. Ibuprofen
8. Ketoprofen
9. Ketaorolac Tromethamine
10. Naproxen
11. Neurontin
12. Oxycodone with acetaminophen
13. Oxycodone/ APAP
14. Oxycontin
15. Percocet
16. Percodan
17. Tussionex
18. Tylox
19. Ultracet
20. Ultram
21. Vicodin
22. Vicodin ES
23. Vicodin HP
24. Vicoprofen
25. Vioxx
References: