Minimally Invasive Procedures: GYN
Disclaimer

This document may include demonstration of the use of surgical devices; it is not intended to be used as a surgical training guide. Other surgeons may employ different techniques. Individual surgeon preference and experience, as well as patient needs, should always dictate variation in procedure steps.

Before using any medical device, including those demonstrated or referenced in this presentation, review all relevant package inserts, with particular attention to the indications, contraindications, warnings and precautions, and steps for use of the device.
Minimally Invasive Procedures: GYN

Table of Contents

Article Abstracts 4
Value Dossier: Minimally Invasive Procedures in Hysterectomy 10
GYN Procedures: Port Placement 39
GYN Procedures: Steps 42
Comparison of Four Energy-based Vascular Sealing and Cutting Instruments: A Porcine Model

Benjamin Person • David A. Vivas • Dan Ruiz • Michael Talcott • James E. Coad • Steven D. Wexner

Received April 14, 2007. Accepted July 17, 2007.

ABSTRACT

AIM: To compare the safety and efficacy of four energy-based vascular sealing and cutting instruments.

METHODS: Blood vessels of various types and diameters were harvested from four pigs using four instruments: Harmonic ACE (Ethicon Endo-Surgery, Cincinnati, OH), LigaSure V and LigaSure Atlas (Valleylab, Inc., Boulder, CO; a division of Tyco Healthcare), and EnSeal vessel fusion system (SurgRx, Inc. Redwood City, CA). The diameters of the vessels, speed and adequacy of the cutting and sealing process, and bursting pressures were compared. An additional set of specimens was sealed and left in situ for up to 4 h after which the vessels were harvested and histopathologically analyzed for the degree of thermal injury.

RESULTS: The bursting pressures were significantly higher with EnSeal compared to all other instruments (p < 0.0001). The sealing process was significantly shorter with Harmonic ACE and significantly longer with LigaSure Atlas (p <0.0001). The mean seal width was larger with the LigaSure Atlas compared to the other instruments, and it was smaller with EnSeal and Harmonic ACE. Less radial adventitial collagen denaturation was present with EnSeal and LigaSure V than with the other two instruments; there were no significant differences in collagen denaturation although proximal thermal injury to the smooth muscle in the media of the vessel wall was less common with LigaSure Atlas than with the other instruments; however, the numbers were too small for statistical analysis.

CONCLUSIONS: The bursting pressures with EnSeal were significantly higher than with all the other instruments. Harmonic ACE was the fastest sealing instrument and LigaSure Atlas was slowest. EnSeal created less radial thermal damage to the adventitial collagen of the vessels and LigaSure Atlas created less thermal damage to the media of the vessels. The clinical significance of these findings is unknown.

For a full reprint of the article, contact your Ethicon Endo-Surgery rep.

DSL #08-1277
Open Abdominal versus Laparoscopic and Vaginal Hysterectomy: Analysis of a Large United States Payer Measuring Quality and Cost of Care

Lori Warren, MD • Joseph A. Ladapo, MD, PhD • Bijan J. Borah, PhD • Candace L. Gunnarsson, EdD

Submitted April 2, 2009. Accepted June 18, 2009.

ABSTRACT

OBJECTIVE: To compare minimally invasive procedures (MIP)—laparoscopic and vaginal hysterectomy with the traditional open abdominal hysterectomy method by evaluating clinical and economic outcomes and use.

METHODS: A retrospective analysis was performed with deidentified claims data and enrollment information from a large U.S. managed care plan. Data were collected on intraoperative and postoperative complications, length of stay, rates of readmission, and insurer and patient payment totals for inpatient and outpatient procedures. Bivariate comparisons between MIP and open abdominal procedures used t-tests for continuous variables and \( \chi^2 \) tests for proportions. The predicted generalized linear modeling regression equation evaluated the effect of procedures on expenditures.

RESULTS: Of 15 404 patients, MIP was performed in 43% of subjects, with 23% (3520) undergoing laparoscopic hysterectomy, and 20% (3130) a vaginal hysterectomy. Postoperative infection rates were higher for patients undergoing open abdominal hysterectomy: 18% as compared with 15% of laparoscopic and 14% of patients undergoing vaginal hysterectomy (P < .05). With open abdominal hysterectomy, length of stay (mean [SD]) was 3.7 (1.83) days versus 1.6 (1.5) and 2.2 (1.5) for patients undergoing MIP laparoscopic and MIP vaginal hysterectomy, respectively (P < .001 for both). Unadjusted expenditures (SD) for patients undergoing open abdominal hysterectomy averaged $12 086 ($12673), whereas MIP (laparoscopic and vaginal) patients accrued costs (SD) of $10 868 ($13 465) and $9544 ($8644), respectively (P < .05). When expenditures were adjusted for differences in patient mix, there was no difference for open abdominal hysterectomy versus MIP laparoscopic; however, there were significantly (P < .05) lower expenditures for MIP vaginal versus open abdominal hysterectomy with a mean difference of $1270 (CI $850—$1691). Adjusted expenditures associated with outpatient MIP were markedly lower than expenditures for inpatient open abdominal hysterectomy.

CONCLUSION: These clinical and economic outcomes should encourage clinicians to consider greater use of minimally invasive hysterectomy procedures in patients who have no contraindications for laparoscopic or vaginal approach to hysterectomy. Significant savings are realized when appropriate candidates receive minimally invasive procedures and are thus able to migrate from the inpatient to outpatient setting.

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DSL#11-1650
Choosing The Route Of Hysterectomy For Benign Disease

ACOG Committee Opinion No. 444


**ABSTRACT**

Hysterectomies are performed vaginally, abdominally, or with laparoscopic or robotic assistance. When choosing the route and method of hysterectomy, the physicians should take into consideration how the procedure may be performed most safely and cost-effectively to fulfill the medical needs of the patient. Evidence demonstrates that, in general, vaginal hysterectomy is associated with better outcomes and fewer complications than laparoscopic or abdominal hysterectomy. When it is not feasible to perform a vaginal hysterectomy, the surgeon must choose between laparoscopic hysterectomy, robot-assisted hysterectomy, or abdominal hysterectomy. Experience with robot-assisted hysterectomy is limited at this time; more data are necessary to determine its role in the performance of hysterectomy. The decision to electively perform a salpingoophorectomy should not be influenced by the chosen route of hysterectomy and is not a contraindication to performing a vaginal hysterectomy.
Comparing Robot-assisted With Conventional Laparoscopic Hysterectomy: Impact On Cost And Clinical Outcomes

Resad P. Pasic, MD • John A. Rizzo, PhD • Hai Fang, PhD • Susan Ross, MD • Matt Moore, MHA • Candace Gunnarsson, EdD


ABSTRACT

OBJECTIVE: To compare clinical and economic outcomes (hospital costs) in women undergoing laparoscopic hysterectomy performed with and without robotic assistance in inpatient and outpatient settings.

METHODS: Using the Premier hospital database, we identified women >18 years of age with a record of minimally invasive hysterectomy performed in 2007 to 2008. Univariable and multivariable analyses examined the association between robot-assisted hysterectomy and adverse events, hospital costs, surgery time, and length of stay.

RESULTS: Of 36,188 patient records analyzed from 358 hospitals, 95% (n = 34,527) of laparoscopic hysterectomies were performed without robotic assistance. Inpatient and outpatient settings did not differ substantively in frequency of adverse events. For cardiac, neurologic, wound, and vascular complications, frequencies were <1% for robot and non-robot procedures. In inpatient and outpatient settings alike, use of robotic assistance was consistently associated with statistically significant, higher per-patient average hospital costs. Inpatient procedures with and without robotic assistance cost $9640 (95% confidence interval [CI] = $9621, $9659) versus $6973 (95% CI = $6959, $6987), respectively. Outpatient procedures with and without robotic assistance cost $7920 (95% CI = $7898, $7942) versus $5949 (95% CI = $5932, $5966), respectively. Inpatient surgery times were significantly longer for robot-assisted procedures, 3.22 hours (95% CI = 3.21, 3.23) compared with non-robot procedures at 2.82 hours (95% CI = 2.81, 2.83). Similarly, outpatient surgery times with robot averaged 2.99 hours (95% CI = 2.98, 3.00) versus 2.46 hours (2.45, 2.47) for non-robot procedures.

CONCLUSIONS: Our findings reveal little clinical differences in perioperative and postoperative events. This, coupled with the increased per-case hospital cost of the robot, suggests that further investigation is warranted when considering this technology for routine laparoscopic hysterectomies.
Advanced Energy Systems
For Laparoscopic Gynecology Procedures

Multifunctional Technology Yields Reliable Outcomes, Enhances Patient Safety, And Increases Procedure Efficiency


ABSTRACT

A roundtable symposium of leading gynecologic surgeons was held, with the surgeons sharing their experiences in using energy devices (HARMONIC® and ENSEAL®), thoughts on the devices, their techniques and best tools for specific surgeries. The paper covers the technology behind energy devices and their proper use as well as adopting new devices, safety, tips and techniques and training on new devices.

Drs. Andrew Brill, Steven McCarus and John Bertrand are leaders in minimally invasive procedures for GYN. Their discussion provides insight into contemporary minimally invasive techniques and the adoption of new technologies into the field.

For a full reprint of the article, contact your Ethicon Endo-Surgery rep.
ABSTRACT

This paper looks at abdominal and vaginal hysterectomy, concentrating on patient outcomes, procedure time and surgeon training. Vaginal hysterectomies are explored, as well as various devices and their roles in the procedure.

The ECHELON™ 60 Endopath® Endoscopic Stapler and the ENDOLOOP® Ligature provide an effective alternative method of performing vaginal hysterectomy. Operating time is lessened, and patients experience a quicker postoperative recovery and a shortened hospital stay, compared with patients who undergo an abdominal hysterectomy.
Value Dossier
Minimally Invasive Procedures in Hysterectomy
1.0 INTRODUCTION

The purpose of this document is to provide a clinical overview of minimally invasive surgical procedures (MIP) as used in hysterectomy. In addition, a comparison of key clinical and economic outcomes with MIP vs. conventional open surgical approaches, as reported in recently published clinical trials, is presented.

1.1 HYSTERECTOMY OVERVIEW

Hysterectomy, the surgical removal of the uterus, is the second most frequently performed surgical procedure, after cesarean section\(^1\), in women of childbearing age. The prevalence of hysterectomy procedures in the U.S. is approximately 5.6 per 1000 women.\(^1\) In 2005 alone, over 533,300 hysterectomies were performed in the U.S.\(^2\) Usually the surgery is considered an elective procedure and used when less-invasive options have failed.\(^1\)
1.1.1 LEADING INDICATIONS DEFINED

The leading indications for hysterectomy include abnormal uterine bleeding (AUB), fibroids or leiomyomas, endometriosis, uterine prolapse, and gynecologic cancer. In this final category, malignant etiologies include cervical intraepithelial neoplasia (CIN II), endometrial adenocarcinoma, uterine sarcoma, leiomyosarcoma, and ovarian carcinoma. The following tables and figures display the frequencies of hysterectomies by indication, as well as the forecasted increase in numbers of procedures in future years in the U.S. and Europe.

Figure 1: Hysterectomy: Leading Indications
Table 1: Hysterectomy Leading Indications US, 2005-2011

<table>
<thead>
<tr>
<th>YEAR</th>
<th>MENORRHAGIA</th>
<th>FIBROIDS</th>
<th>UTERINE PROLAPSE</th>
<th>CHRONIC PELVIC PAIN</th>
<th>UTERINE CANCER</th>
<th>ENDOMETRIOSIS</th>
<th>TOTAL Hysterectomies</th>
<th>GROWTH</th>
</tr>
</thead>
<tbody>
<tr>
<td>2005</td>
<td>178,700</td>
<td>112,800</td>
<td>88,100</td>
<td>72,800</td>
<td>60,100</td>
<td>41,000</td>
<td>553,500</td>
<td></td>
</tr>
<tr>
<td>2006</td>
<td>162,300</td>
<td>102,400</td>
<td>90,900</td>
<td>75,300</td>
<td>62,800</td>
<td>39,600</td>
<td>533,300</td>
<td>-3.6%</td>
</tr>
<tr>
<td>2007</td>
<td>147,800</td>
<td>92,800</td>
<td>93,900</td>
<td>78,200</td>
<td>65,800</td>
<td>38,100</td>
<td>516,600</td>
<td>-3.1%</td>
</tr>
<tr>
<td>2008</td>
<td>135,000</td>
<td>84,000</td>
<td>97,100</td>
<td>81,500</td>
<td>69,100</td>
<td>36,600</td>
<td>503,300</td>
<td>-2.6%</td>
</tr>
<tr>
<td>2009</td>
<td>123,500</td>
<td>75,900</td>
<td>100,500</td>
<td>85,200</td>
<td>72,700</td>
<td>35,100</td>
<td>492,900</td>
<td>-2.1%</td>
</tr>
<tr>
<td>2010</td>
<td>113,000</td>
<td>68,500</td>
<td>104,100</td>
<td>89,300</td>
<td>76,600</td>
<td>33,600</td>
<td>485,100</td>
<td>-1.6%</td>
</tr>
<tr>
<td>2011</td>
<td>104,000</td>
<td>61,700</td>
<td>108,000</td>
<td>93,900</td>
<td>80,900</td>
<td>32,100</td>
<td>480,600</td>
<td>-1.1%</td>
</tr>
<tr>
<td>CAGR ('07-'11)</td>
<td>-8.4%</td>
<td>-9.7%</td>
<td>3.6%</td>
<td>4.7%</td>
<td>5.3%</td>
<td>-4.2%</td>
<td>-1.8%</td>
<td></td>
</tr>
</tbody>
</table>

Note: Numbers may not add to totals due to rounding.

Table 2: Hysterectomy, U.S. Procedure Volumes Forecast by Type, 2005-2014

<table>
<thead>
<tr>
<th>YEAR</th>
<th>ABDOMINAL PROCEDURES</th>
<th>ANNUAL CHANGE</th>
<th>VAGINAL PROCEDURES</th>
<th>ANNUAL CHANGE</th>
<th>LAPAROSCOPICALLY ASSISTED VAGINAL Hysterectomy PROCEDURES</th>
<th>ANNUAL CHANGE</th>
<th>TOTAL</th>
<th>ANNUAL CHANGE</th>
</tr>
</thead>
<tbody>
<tr>
<td>2005</td>
<td>404.0</td>
<td>—</td>
<td>229.5</td>
<td>—</td>
<td>101.3</td>
<td>—</td>
<td>734.8</td>
<td>—</td>
</tr>
<tr>
<td>2006</td>
<td>405.5</td>
<td>0.4%</td>
<td>223.5</td>
<td>-2.6%</td>
<td>110.9</td>
<td>9.5%</td>
<td>739.9</td>
<td>0.7%</td>
</tr>
<tr>
<td>2007</td>
<td>406.8</td>
<td>0.3%</td>
<td>217.5</td>
<td>-2.7%</td>
<td>120.3</td>
<td>8.5</td>
<td>744.6</td>
<td>0.6%</td>
</tr>
<tr>
<td>2008</td>
<td>408.0</td>
<td>0.3%</td>
<td>211.5</td>
<td>-2.8%</td>
<td>130.8</td>
<td>8.7</td>
<td>750.3</td>
<td>0.8%</td>
</tr>
<tr>
<td>2009</td>
<td>409.2</td>
<td>0.3%</td>
<td>205.8</td>
<td>-2.7%</td>
<td>141.5</td>
<td>8.2</td>
<td>756.5</td>
<td>0.8%</td>
</tr>
<tr>
<td>2010</td>
<td>410.4</td>
<td>0.3%</td>
<td>200.0</td>
<td>-2.8%</td>
<td>152.3</td>
<td>7.6</td>
<td>762.7</td>
<td>0.8%</td>
</tr>
<tr>
<td>2011</td>
<td>411.8</td>
<td>0.3%</td>
<td>194.0</td>
<td>-3.0%</td>
<td>162.6</td>
<td>6.7</td>
<td>768.4</td>
<td>0.7%</td>
</tr>
<tr>
<td>2012</td>
<td>413.0</td>
<td>0.3%</td>
<td>189.0</td>
<td>-2.6%</td>
<td>174.8</td>
<td>7.5</td>
<td>776.8</td>
<td>1.1%</td>
</tr>
<tr>
<td>2013</td>
<td>414.2</td>
<td>0.3%</td>
<td>184.0</td>
<td>-2.6%</td>
<td>187.1</td>
<td>7.0</td>
<td>785.3</td>
<td>1.1%</td>
</tr>
<tr>
<td>2014</td>
<td>415.5</td>
<td>0.3%</td>
<td>178.0</td>
<td>-3.3%</td>
<td>198.7</td>
<td>6.2</td>
<td>792.2</td>
<td>0.9%</td>
</tr>
<tr>
<td>Compound Annual Growth Rate (2005-2014)</td>
<td>0.3%</td>
<td>—</td>
<td>-2.8%</td>
<td>—</td>
<td>7.8%</td>
<td>—</td>
<td>0.8%</td>
<td>—</td>
</tr>
</tbody>
</table>

Notes: Procedure volumes are reported in thousands.
Table 3: Hysterectomy, Procedure Volumes Forecast for Select European Countries, by Country and Type, 2005-2011

<table>
<thead>
<tr>
<th></th>
<th></th>
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<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>France</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Laparoscopic</td>
<td>8,589</td>
<td>8,933</td>
<td>9,468</td>
<td>10,131</td>
<td>10,840</td>
<td>11,587</td>
<td>12,386</td>
<td>6.3%</td>
</tr>
<tr>
<td>Open</td>
<td>76,740</td>
<td>78,658</td>
<td>80,625</td>
<td>82,721</td>
<td>84,871</td>
<td>86,398</td>
<td>87,953</td>
<td>2.3%</td>
</tr>
<tr>
<td>Subtotal</td>
<td>85,329</td>
<td>87,591</td>
<td>90,093</td>
<td>92,852</td>
<td>95,711</td>
<td>97,985</td>
<td>100,339</td>
<td>2.7%</td>
</tr>
<tr>
<td>Germany</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Laparoscopic</td>
<td>14,098</td>
<td>14,803</td>
<td>15,691</td>
<td>16,633</td>
<td>17,310</td>
<td>18,365</td>
<td>19,485</td>
<td>5.5%</td>
</tr>
<tr>
<td>Open</td>
<td>127,169</td>
<td>130,221</td>
<td>133,347</td>
<td>136,800</td>
<td>140,097</td>
<td>142,478</td>
<td>144,900</td>
<td>2.2%</td>
</tr>
<tr>
<td>Subtotal</td>
<td>141,267</td>
<td>145,024</td>
<td>149,038</td>
<td>153,313</td>
<td>157,407</td>
<td>160,843</td>
<td>164,385</td>
<td>2.6%</td>
</tr>
<tr>
<td>Italy</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Laparoscopic</td>
<td>8,042</td>
<td>8,524</td>
<td>8,967</td>
<td>9,505</td>
<td>10,075</td>
<td>10,750</td>
<td>11,470</td>
<td>6.1%</td>
</tr>
<tr>
<td>Open</td>
<td>71,145</td>
<td>72,658</td>
<td>74,310</td>
<td>76,168</td>
<td>78,072</td>
<td>79,321</td>
<td>80,590</td>
<td>2.1%</td>
</tr>
<tr>
<td>Subtotal</td>
<td>79,187</td>
<td>81,182</td>
<td>83,277</td>
<td>85,673</td>
<td>88,147</td>
<td>90,071</td>
<td>92,060</td>
<td>2.5%</td>
</tr>
<tr>
<td>Spain</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Laparoscopic</td>
<td>4,544</td>
<td>4,771</td>
<td>5,058</td>
<td>5,361</td>
<td>5,682</td>
<td>6,079</td>
<td>6,504</td>
<td>6.2%</td>
</tr>
<tr>
<td>Open</td>
<td>39,081</td>
<td>39,902</td>
<td>40,780</td>
<td>41,718</td>
<td>42,677</td>
<td>43,402</td>
<td>44,139</td>
<td>2.1%</td>
</tr>
<tr>
<td>Subtotal</td>
<td>43,625</td>
<td>44,673</td>
<td>45,838</td>
<td>47,079</td>
<td>48,359</td>
<td>49,481</td>
<td>50,643</td>
<td>2.5%</td>
</tr>
<tr>
<td>United Kingdom</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Laparoscopic</td>
<td>13,778</td>
<td>14,466</td>
<td>15,334</td>
<td>16,101</td>
<td>16,906</td>
<td>17,937</td>
<td>19,031</td>
<td>5.5%</td>
</tr>
<tr>
<td>Open</td>
<td>122,141</td>
<td>124,828</td>
<td>127,699</td>
<td>130,764</td>
<td>133,902</td>
<td>136,044</td>
<td>138,220</td>
<td>2.1%</td>
</tr>
<tr>
<td>Subtotal</td>
<td>135,919</td>
<td>139,294</td>
<td>143,033</td>
<td>146,865</td>
<td>150,808</td>
<td>153,981</td>
<td>157,251</td>
<td>2.5%</td>
</tr>
<tr>
<td>Total Laparoscopic Procedures</td>
<td>49,051</td>
<td>51,497</td>
<td>54,518</td>
<td>57,731</td>
<td>60,813</td>
<td>64,718</td>
<td>68,786</td>
<td>5.8%</td>
</tr>
<tr>
<td>Total Open Procedures</td>
<td>436,276</td>
<td>446,267</td>
<td>456,761</td>
<td>468,051</td>
<td>479,619</td>
<td>487,643</td>
<td>495,802</td>
<td>2.2%</td>
</tr>
<tr>
<td>Total Procedures</td>
<td>485,327</td>
<td>497,764</td>
<td>511,279</td>
<td>525,782</td>
<td>540,432</td>
<td>552,361</td>
<td>564,588</td>
<td>2.6%</td>
</tr>
</tbody>
</table>
1.1.1.1 Abnormal uterine bleeding (AUB)

AUB is defined as excessive and/or irregular vaginal bleeding that has no specific genital tract cause. Strict definitions of abnormal uterine bleeding are difficult to reach because of the subjectiveness of categorizing bleeding amounts as "excessive," and because of the challenge of distinguishing between conditions for which no clear etiology exists, and those for which a clear etiology exists but has not yet been discovered.

There are two main types of AUB. Menorrhagia is defined as heavy or prolonged menstruation or bleeding, but at expected cycle times. Indications of menorrhagia include prolonged episodes of bleeding (more than seven days), flooding, and the passing of blood clots. Metrorrhagia is bleeding between menstrual cycles. AUB was the leading cause of hysterectomies in 2007.

Each year, up to two million women consult their physicians about menorrhagia. It is the most common gynecologic complaint. A number of conditions can cause menorrhagia or contribute to the risk, although often the cause of heavy bleeding is unknown. In fact, no abnormalities to explain the bleeding are detected in about half of hysterectomies performed because of menorrhagia. It should be pointed out, however, that while up to 30 percent of premenopausal women complain of heavy bleeding, only 10 percent experience blood loss severe enough to be defined as menorrhagia.

The etiology of abnormal uterine bleeding is usually divided into two main categories: organic and dysfunctional (or endocrinologic). Organic etiologies include submucous myomas, complications of pregnancy, adenomyosis, endometriosis, IUDs, and malignant tumors. Treatment options for AUB include drug therapies, endometrial resection, global endometrial ablation (GEA), and hysterectomy. Endometrial resection is performed as a rollerball resection, with the endometrial layer removed with a resectoscope. After resection, amenorrhea occurs in 30 percent of patients, but 90 percent experience a significant decrease in menstrual bleeding. GEA removes an even layer of the entire endometrium, in a fashion similar to the rollerball resection, except that GEA treats the entire uterus in one episode. When these measures fail, hysterectomy may be required.
Notably, the number of cases treated by hysterectomy is declining as acceptance of GEA grows and new drug therapies emerge. However, some gynecologists will continue to rely on hysterectomies because of their efficacy and reliability.\textsuperscript{4}

Improved diagnostic techniques and treatments have resulted in decreased use of hysterectomy to treat abnormal bleeding patterns. Often, patients can be treated with hormone preparations if organic causes can be excluded, there is no significant risk for cancer development, and there is no acute life-threatening hemorrhage.\textsuperscript{3}

1.1.1.2 Uterine Fibroids/Leiomyomas

Fibroids, sometimes called leiomyomas, are benign growths on the uterus, and the most common type of uterine neoplasm, arising from smooth muscle cells in the uterine wall.\textsuperscript{6} The three most common types of myomas have intramural, subserous, and submucous locations.\textsuperscript{5} Continued growth in one direction determines which myomas will be located just below the endometrium (submucosal) and which will be found just beneath the serosa (subserosal). Leiomyomas may enlarge and cause significant distortion of the uterine surface or cavity.\textsuperscript{5}

These tumors occur in 20 percent of women of reproductive age and in as many as 50 percent of women older than age 35. However, for reasons that are not well understood, leiomyomas occur two to three times more frequently in African American than in Caucasian women.\textsuperscript{5} By their fifth decade, as many as 50 percent of African American women will have leiomyomas. The Mayo Clinic states, "As many as three out of four women have uterine fibroids, but most are unaware of them because they often cause no symptoms."\textsuperscript{5}

The most common symptom associated with fibroids is heavy bleeding. Symptomatic fibroids are related to the size, location, and the number of fibroids within the uterus. Treatment options depend on the location and number of fibroids, the severity of symptoms, the woman’s age, and her childbearing plans.\textsuperscript{5} Fibroids are the most common reason for non-cancer hysterectomies and account for one third of the procedures.\textsuperscript{6} The latest CDC Hysterectomy
Surveillance Summary (2002) reported that uterine leiomyoma was the most frequent diagnosis associated with hysterectomy.\(^5\)

Often, before hysterectomy is performed, a physician will perform trials of other treatments, including hormone therapy, endometrial resection, and uterine artery embolization (UAE). Endometrial resection uses a “rollerball” and has been declining in popularity due to therapeutic competition from UAE, which is a less invasive option.\(^6\) UAE involves the internal blocking of the uterine artery with specially designed particles. It is performed by an interventional radiologist and represents a growing area of minimally invasive fibroid treatment.\(^6\)

**1.1.1.3 Endometriosis**

Endometriosis is a nonmalignant disorder in which functioning endometrial tissue is present outside the uterus, often extending onto the ovaries, fallopian tubes, or other pelvic or abdominal organs, such as bladder, intestines, bowel, colon, and rectum.\(^7\) Solitary lesions are possible, but multiple implantations are the rule. The classic symptom of endometriosis is pelvic pain, but it may present differently, and one in three women is asymptomatic.

The exact prevalence of endometriosis is unknown because surgery is required for diagnosis, but is estimated to afflict 3 to 10 percent of women of reproductive age and 25-35 percent of infertile women.\(^8\) It is seen in 1 to 2 percent of women undergoing sterilization or sterilization reversal, in 10 percent of hysterectomy surgeries, in 16-31 percent of laparoscopies, and in 53 percent of adolescents with pelvic pain severe enough to warrant surgical evaluation.\(^8\)

Currently, no cure exists for endometriosis. Treatment options include oral contraceptives, laparoscopic evaporation using electrosurgery or laser, and hysterectomy. Therapy for endometriosis depends on the patient’s age, symptoms, and reproductive desires. Because endometriosis is an unpredictable disease, with great individual variation in its natural course, many therapeutic regimens exist. Patients may undergo a diagnostic laparoscopy to establish the nature and extent of endometriosis before therapy.
Laparoscopy is employed frequently for both diagnostic and therapeutic reasons. The major advantage of treating endometriosis laparoscopically using either of two surgical instruments; the laser, or electrocautery, is that patients may be treated at the time of diagnosis. Depending on the operative technique chosen, endometriosis is coagulated, vaporized, and/or resected. The vast majority of surgical treatment for endometriosis occurs via laparoscopy rather than laparotomy because of a shorter recovery period and reduction in the extent of subsequent adhesions.

Endometriosis accounts for approximately one fifth of hysterectomies. Severe cases of endometriosis may require a partial or full hysterectomy. Although many women seek this procedure for pain relief, it does not provide a definite cure because some women in whom one or both ovaries are preserved may continue to experience problems if endometriosis tissue is left behind. Endometriosis is the single most common gynecologic diagnosis responsible for hospitalization of females 15-44 years old, being found in over 6 percent of patients. According to latest CDC Hysterectomy Surveillance Summary (2002), it was the second leading indication for hysterectomy and accounted for 17.9 percent of cases between 1994 and 1999.

1.1.1.4 Uterine Prolapse

Uterine prolapse is a condition in which the uterus descends inferiorly in the pelvic area, well below its normal position, and is the indication for hysterectomy in 16 percent of cases. Uterine prolapse occurs when weakened pelvic floor muscles, ligaments, or vaginal walls cause the uterus to descend from its original position in the pelvic cavity, into the vagina. Women may also experience vaginal prolapse or other pelvic organ prolapse. Pelvic support structures are often weakened by childbirth, other pelvic trauma, stress and strain, and the aging process. Uterine prolapse can lead to urinary incontinence, pelvic pressure, or difficulty with bowel movements. There are three grades of severity and the condition can cause urine loss or blockage and bowel movement disturbances. The uterus can descend through the vagina such that the cervix is exposed. When this occurs, the cervical tissue is often irritated by the coarse environment outside the body.
Prolapse is measured in various ways. The Baden and Walker system is the most commonly used clinical method and uses a grading system:

- Grade 0 = no prolapse
- Grade 1 = the leading edge of the prolapse is beyond the midvaginal line but above the vaginal hymen
- Grade 2 = the prolapse is no more than about 4 cm beyond the hymen
- Grade 3 = complete uterine or vaginal prolapse

Treatment options may be surgical or nonsurgical, and depend on the stage of the condition. Nonsurgical treatments are often used in early disease stages or in the setting of insignificant prolapse. These treatments include estrogen replacement therapy and Kegel exercises, i.e., pelvic floor exercises. A mild to moderate prolapse may require application of a ring pessary, a silicon device fitted firmly into the vagina to physically support the uterus.

Surgical treatments are reserved for advanced prolapse or after nonsurgical attempts have failed. There are many different surgical options to correct pelvic organ prolapse. Optimal selection requires consideration of specific anatomic defects as well as the patient’s age, health status, previous surgeries, and sexual activity. Surgery is often recommended to assist in reconstructing pelvic ligaments, and is often combined with estrogen treatment to further solidify pelvic muscles. If requested, a hysterectomy may also be performed to ensure prolapse does not recur. According to the CDC’s Hysterectomy Surveillance Summary (2002) uterine prolapse accounted for 16 percent of hysterectomies between the years of 1994 and 1999.

1.1.5 Gynecological Cancer

Specific cancers treated by hysterectomy include cervical CIN II; early invasive cervical cancer; endometrial adenocarcinoma; uterine sarcoma; leiomyosarcoma; ovarian or tubal carcinoma; gestational trophoblastic disease, if chemotherapy has failed; and colon or bladder cancer that has spread to the uterus or blocks removal of the cancer.

About 10 percent of hysterectomies are performed for treatment of malignancy. Factors that guide treatment choice include cancer stage, the woman’s age and overall health, and desire for future pregnancies.
1.1.2 SURGICAL APPROACH

1.1.2.1 Types of Hysterectomy Procedures

Hysterectomy is performed either via an open abdominal procedure or vaginally, using a laparoscope. There are four major types of hysterectomy: total (both the uterus and cervix are removed); total with bilateral salpingo-oophorectomy (similar to total hysterectomy but also involves removal of ovaries and fallopian tubes); subtotal (also known as partial or supracervical because the cervix is left intact); and radical (usually performed for cancer and includes removal of the upper part of the vagina and pelvic lymph nodes).

There are also four categories of minimally invasive approaches, which include: vaginal hysterectomy (VH); laparoscopic-assisted vaginal hysterectomy (LAVH); laparoscopic hysterectomy; and total laparoscopic hysterectomy (TLS). In LAVH, the uterine artery is not ligated, whereas it is ligated in LH.

Overall hysterectomy rates vary widely in different parts of the U.S, and about 55 percent of hysterectomies are still performed abdominally. The common factor determining the surgical approach to hysterectomy "has been found to be the comfort level of the surgeon with a particular procedure and this, nation-wide and worldwide, results in a predominance of abdominal hysterectomies."

Table 4: Surgical Approach by Indication

<table>
<thead>
<tr>
<th>Indications for Treatment</th>
<th>PROCEDURE</th>
<th>FIBROIDS</th>
<th>BLEEDING</th>
<th>PAIN</th>
<th>CANCER</th>
<th>DESCENSUS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Abdominal Hysterectomy</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X*</td>
<td></td>
</tr>
<tr>
<td>Vaginal Hysterectomy</td>
<td>X</td>
<td>X</td>
<td></td>
<td></td>
<td>X*</td>
<td>X</td>
</tr>
<tr>
<td>Laparoscopically Assisted Vaginal Hysterectomy</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X*</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Laparoscopic Supracervical Hysterectomy</td>
<td>X</td>
<td>X</td>
<td></td>
<td>X</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*with laparoscopic node dissection
The figures which follow illustrate the main surgical approaches, followed by brief text descriptions of each.

**Figure 2: Procedure: Abdominal Hysterectomy**
A. The first illustration demonstrates the Pfannenstiel’s incision being made into the abdomen to expose the uterus. B. The illustration to the right of these demonstrates the mobilization of the uterus. C. Next is the ligation of the arteries and veins and removal of the ovaries and uterus from the pelvis. D. The final illustration shows the use of sutures to close the vaginal wall.

A. A Pfannenstiel’s incision is made into the abdomen to expose the uterus.
B. The round ligaments are ligated, the bladder is reflected and the uterine arteries are clamped.
C. The arteries and veins are ligated and the uterus is incised and removed.
D. The vaginal cuff is closed with sutures.
**Figure 3:** Procedure: Vaginal versus Abdominal Hysterectomy

The trocar and laparoscope are in position for the procedure, and part of the uterus and ovary are illuminated by the laparoscope.

**Figure 4:** Procedure: Laparoscopic Hysterectomy

The trocar and laparoscope are in position for the procedure, and part of the uterus and ovary are illuminated by the laparoscope.
Figure 5: Procedure: Laparoscopic Supracervical Hysterectomy (LSH)
The laparoscopic supracervical hysterectomy procedure involves several small incisions rather than one large one.

1.2.1.1 Abdominal hysterectomy

An abdominal hysterectomy can be performed in two ways, either with a vertical incision or a bikini line cut. A vertical incision generally involves a cut from the navel to the pubic hairline. The bikini line cut (Pfannenstiel incision) is done horizontally, directly above the pubic hairline. It leaves a less obvious scar and results in a shorter recovery time.

The advantage of an abdominal procedure is that the surgeon can visualize the uterus and other organs and has more room to operate within than if the procedure is done vaginally, thus resulting in fewer urinary tract or blood vessel injuries. For this reason, surgeons may opt for the abdominal procedure if there are large tumors present or if they suspect the presence of cancer. It also allows for the concurrent repair of a prolapse. The disadvantages are that this approach is associated with more pain, a lengthier hospital stay (three to six days), and longer recovery time (up to six weeks). It is performed under general or regional anesthesia.
1.1.2.1.2 Vaginal hysterectomy

The surgeon reaches the uterus by making a circular incision around the cervix. This approach is best suited for benign conditions that lead to hysterectomy when the uterus is not too large. It’s often the ideal approach for uterine prolapse. With a vaginal hysterectomy, there is no external scarring. Recovery is more rapid, with a shortened hospital stay (one to three days) and recovery time (four weeks). However, vaginal hysterectomy affords the surgeon less room to operate and no substantive opportunity to view the pelvic organs. The procedure can be performed under general or regional anesthesia.\(^9\)

1.1.2.1.3 Laparoscopically-assisted vaginal hysterectomy (LAVH)

This approach allows the physician to view the pelvis and to remove the uterus vaginally when a large abdominal incision would otherwise be required. The surgeon makes a small incision near the navel to insert a thin device (laparoscope) that allows the surgical team to visualize the internal abdominal anatomy. Through other small incisions, the surgeon uses special surgical instruments to detach the uterus and remove it through the vagina.

Laparoscopic procedures have been promoted as being advantageous due to a shorter hospitalization and recovery time compared to abdominal hysterectomies. However, the surgeon must be experienced in the procedure before these benefits can be realized. Disadvantages include possibly longer operating times (directly related to how much of the operation is performed laparoscopically), higher costs, and an increased risk of damage to the urinary tract.

1.1.2.1.4 Laparoscopic supracervical hysterectomy (LSH)

This newer type of hysterectomy also uses laparoscopic techniques to remove the uterus, but leaves the cervix intact. Some studies have suggested that this may help reduce complications associated with total hysterectomies, such as pelvic floor prolapse and urinary incontinence. LSH is less invasive and traumatic than a total hysterectomy, and it is also associated with shorter recovery and hospitalization periods.\(^9\)
1.1.3 LITERATURE: MIP VERSUS OPEN

1.1.3.1 Search Strategy

The objective of our literature search was to identify studies that met standards of the highest level of evidence for efficacy. We searched MEDLINE and used the search terms: hysterectomy [MeSH] AND publication type. We limited our search results to manuscripts published in the English language within the past 10 years that studied human populations. The methodological quality of studies was assessed using the Oxford CEBM, which hierarchically ranks studies based on the validity of their evidence. The highest ranking evidence is systematic reviews (publication type “Meta-analysis OR Practice Guideline”), and the lowest ranking is expert opinion. Systematic reviews were screened using their entire search window, and publications that were randomized controlled trials were only considered if they were published between 2004 and 2008. Studies comparing minimally invasive surgical techniques (laparoscopic, vaginal, laparoscopic-assisted vaginal) to open surgical techniques were selected, and studies of pre- or post-operative supportive care, timing or extent of surgery (e.g. total versus subtotal), or comparisons other than minimally invasive versus open procedures (e.g. laparoscopic-assisted vaginal hysterectomy versus vaginal hysterectomy, surgical versus non-surgical treatment) were excluded.

1.1.3.2 Best Evidence for Efficacy

Our search yielded two systematic reviews of Randomized Controlled Trials (RCTs) that provide the best evidence on comparative questions (minimally invasive versus open procedures) for most clinical outcomes of interest. We also found nine randomized trials comparing minimally invasive to open procedures published since these reviews were conducted.

1.1.4 OUTCOMES

1.1.4.1 Recurrence and Overall Survival

There was no evidence of increased cancer recurrence for minimally invasive procedures versus abdominal (open) hysterectomy in endometrial cancer. In one study of 122 patients that compared laparoscopic-assisted vaginal
hysterectomy to abdominal hysterectomy, recurrence rates were 12.6 percent and 8.5 percent, respectively, at median follow-up points of 44 months (p=0.38; 1 study, 122 pts). We also found no evidence of a survival difference between minimally invasive procedures and abdominal hysterectomy in endometrial cancer. The overall survival at 44 months was 82.7 percent for patients undergoing laparoscopic-assisted vaginal hysterectomy, and 86.5 percent for patients undergoing abdominal hysterectomy (p=0.33; 1 study, 122 pts).

There have only been a few randomized studies of long-term outcomes in hysterectomy for cancer indications, and no well-powered RCTs have been published. Evidence for equivalent outcomes on recurrence risk and survival has not been definitively established.

1.1.4.2 Complications – Vaginal Hysterectomy versus Abdominal Hysterectomy

In terms of complications, there was no evidence of a difference between vaginal hysterectomy and abdominal hysterectomy in the risk of bladder or ureter injury, or wound or abdominal infection. However, patients undergoing vaginal hysterectomy were less likely to experience an infection of any type (p<0.05). They also reported returning to normal activities approximately nine and a half days sooner (p<0.05).

When complications were compared between laparoscopic hysterectomy and abdominal hysterectomy, the evidence supported a lower risk of wound and abdominal infections with laparoscopic hysterectomy, along with a lower risk of an infection of any type (p<0.05). There was also a lower risk of an operative or early post-op complication of any type, and a lower risk of a major complication (p<0.05). Major complications include bleeding and ureter injury. However, these procedures did not differ in their risk of bladder or bowel injury.

Laparoscopic hysterectomy patients also reported returning to work about 13.6 days sooner (p<0.05). Recently published trials are consistent with above results, including one large RCT not included in the Cochrane meta-analysis.
this study, the median length of stay was three days for laparoscopic hysterectomy versus four days for abdominal hysterectomy, and patients returned to work 11.1 weeks after their laparoscopic procedure, compared to 13.6 weeks after abdominal hysterectomy.\textsuperscript{34}

Compared to abdominal hysterectomy, laparoscopic hysterectomy procedures are typically lengthier by an average of 10.6 min. Laparoscopic-assisted vaginal hysterectomy, however, is shorter by an average of 7.6 min.\textsuperscript{32} Within MIP subtypes, vaginal hysterectomy is a significantly shorter procedure than laparoscopic hysterectomy (41.5 min shorter on average), and laparoscopic assisted vaginal hysterectomy is significantly shorter than laparoscopic hysterectomy with uterine artery ligation (average of 25.3 min).\textsuperscript{32}

1.1.5 CONCLUSIONS

The approach used in any given case will likely continue to depend heavily on a surgeon’s experience and expertise. However, abdominal hysterectomy should be avoided whenever possible. Few surgeons newly trained in laparoscopic approaches will have sufficient expertise and confidence to perform total laparoscopic hysterectomy, which requires the highest level of surgical skill. Physicians performing hysterectomy using a minimally invasive approach may need to convert patients to abdominal hysterectomy. Leading indications include the presence of inflammatory adhesions, inability to obtain homeostasis of the uterine vessels, and other technical difficulties.

“One vital conclusion...must be that vaginal hysterectomy remains a very good option – we have not shown any significant disadvantage of vaginal hysterectomy versus any other approach.”\textsuperscript{35}

It is also unclear whether laparoscopic hysterectomy procedures should be performed in cases where vaginal hysterectomy procedures would otherwise be suitable. ”It is uncertain whether the increased detection of unexpected pathology at laparoscopic hysterectomy versus vaginal hysterectomy affects subsequent clinical outcome.”\textsuperscript{35}
Table 5: Complications - Vaginal Hysterectomy vs Abdominal Hysterectomy

<table>
<thead>
<tr>
<th></th>
<th>NUMBER OF STUDIES</th>
<th>NUMBER OF PATIENTS</th>
<th>ODDS RATIO</th>
<th>95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bladder or ureter injury</td>
<td>2</td>
<td>239</td>
<td>3.1</td>
<td>0.3-30.9</td>
</tr>
<tr>
<td>Wound or abdominal wall infection</td>
<td>2</td>
<td>155</td>
<td>0.2</td>
<td>0.0-2.2</td>
</tr>
<tr>
<td>Infection of any type</td>
<td>4</td>
<td>295</td>
<td>0.4*</td>
<td>0.2-0.8</td>
</tr>
</tbody>
</table>

*Indicates statistical significance at the 0.05 level

Table 6: Complications - Laparoscopic Hysterectomy vs Abdominal Hysterectomy

<table>
<thead>
<tr>
<th></th>
<th>NUMBER OF STUDIES</th>
<th>NUMBER OF PATIENTS</th>
<th>ODDS RATIO</th>
<th>95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bladder or ureter injury</td>
<td>8</td>
<td>1672</td>
<td>3.0</td>
<td>1.3-6.9</td>
</tr>
<tr>
<td>Bowel injury</td>
<td>2</td>
<td>1066</td>
<td>0.2</td>
<td>0.0-1.6</td>
</tr>
<tr>
<td>Wound or Abdominal wall infection</td>
<td>5</td>
<td>449</td>
<td>0.3*</td>
<td>0.1-0.9</td>
</tr>
<tr>
<td>Infection of any type</td>
<td>12</td>
<td>1879</td>
<td>0.7*</td>
<td>0.5-0.9</td>
</tr>
</tbody>
</table>

*Indicates statistical significance at the 0.05 level

Laparoscopic

<table>
<thead>
<tr>
<th></th>
<th>NUMBER OF STUDIES</th>
<th>NUMBER OF PATIENTS</th>
<th>DIFFERENCE</th>
<th>P-VALUE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Operative and early post-op complication (any type)</td>
<td>1</td>
<td>81</td>
<td>Not reported but less frequent with LH*</td>
<td>0.05</td>
</tr>
<tr>
<td>Major complication (bleeding, ureter injury)</td>
<td>2</td>
<td>1346</td>
<td>5% less frequent with LH*</td>
<td>0.02</td>
</tr>
</tbody>
</table>

*Indicates statistical significance at the 0.05 level
Table 8: Return to normal activities

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Number of Studies</th>
<th>Number of Patients</th>
<th>Difference</th>
<th>95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vaginal Hysterectomy vs Abdominal Hysterectomy</td>
<td>3</td>
<td>176</td>
<td>9.5 days sooner*</td>
<td>6.4-12.6</td>
</tr>
<tr>
<td>Laparoscopic Hysterectomy vs Abdominal Hysterectomy</td>
<td>6</td>
<td>520</td>
<td>13.6 days sooner*</td>
<td>11.8-15.4</td>
</tr>
</tbody>
</table>

*Indicates statistical significance at the 0.05 level

Box 1: MIP viewed by Health Technology Assessment Agencies

Various laparoscopic procedures have been reviewed by HTA agencies all around the world. The scopes of these assessments are quite variable as some agencies look at clinical outcomes (applying pure EBM principles) whereas others look at cost effectiveness or even go all the way to implementation and ethical consideration.

Rather than looking at specific country clinical and economic data, this box will report the recommendations specific to laparoscopic procedures made by HTA agencies. As HTA reports are not reported into standard literature databases such as PubMed, we performed a manual search on the sites of the following agencies: Blue Cross / Blue Shield TEC (US), AHRQ (US), NICE (England and Wales), CADTH (Canada - formerly CCOHTA), ASERNIP and MSAC (Australia), DIMDI (Germany) and HAS (France). We also searched the InaHTA database hosted by the Centre for Reviews and Dissemination at University of York (UK). Only reports published after 2000 were retained in this review.

Appendectomy, Cholecystectomy and Hysterectomy

There have been very few HTA assessments for these three procedures. The search from major agencies websites did not yield any assessment for Lap Cholecystectomy. However, from the CRD website, we found two reports from Argentina (IECS-2005) and Malaysia (2003). The Malaysian report was on several Minimally Invasive Procedures and yielded a favorable recommendation for lap chole: "The evidence shows significant advantages of laparoscopic
surgery over open cholecystectomy, like shorter hospital stay, earlier return to work, and less post operative pain. However, the duration of laparoscopic surgery is longer. Ductal stones are now safely and effectively approached by a single stage laparoscopic technique." The IECS analysis from Argentina was namely a systematic review of the literature on the laparoscopy usefulness in the management of biliary tract stones: "ERCP and LECBD are alternative therapeutic methods for the treatment of common bile duct stones, bearing in mind that the surgeon’s capacity is a limiting variable for LECBD. Both techniques are equally effective and relatively safe. For both methods the effectiveness reported is near 90%, with approximately 1% mortality. There are many potential advantages of LECBD as regards short and long term complications, as well as a shorter hospital stay, but there is no certain information in the literature to support this fact. It is worth pointing out that the literature about LECBD comes from highly specialized centers in the field."

Only one HTA report out of Germany has been found for Lap Appendectomy (Dimdi, 2006). The report’s conclusion is neutral, acknowledging overall similar clinical outcomes and costs: "the decision between the two alternatives should be met by the physicians individually." The report from Malaysia leads to a similar conclusion: “Laparoscopic appendicectomy was shown to be a safe and effective alternative to open appendicectomy. However, it involves higher cost.” The report from Malaysia did not specify the perspective chosen for the cost analysis whereas the German analysis was based on a societal perspective.

For Lap Hysterectomy, NICE (England and Wales) issued in November 2007 a favorable Interventional Procedure guidance: “current evidence on the safety and efficacy of laparoscopic techniques for hysterectomy […] appears adequate to support their use, provided the normal arrangements are in place for consent, audit and clinical governance.” It should be noted that, IP guidance does not cover any sort of cost effectiveness assessment. The report from Malaysia covered this aspect and did not conclude favorably for the laparoscopic technique: “As for laparoscopic-assisted vaginal hysterectomy(LAVH), evidence shows that it is safe and cost effective when vaginal hysterectomy is not suitable, with minimal complications when performed by an experienced
laparoscopist, although the operating time is longer. However vaginal hysterectomy is the best procedure and more cost effective than laparoscopic-assisted vaginal hysterectomy." NICE (England and Wales) also published a clinical guideline on management of heavy menstrual bleeding (NICE, 2007) in which a comparison between laparoscopic and open hysterectomy was provided. Their conclusions are similar to the ones from Malaysia and position the laparoscopic route as an alternative when the open approach is not recommended: "under circumstances such as morbid obesity or the need for cophorectomy during vaginal hysterectomy, the laparoscopic approach should be considered, and appropriate expertise sought."

Colorectal Cancer

When assessing both the literature and HTA reports on laparoscopic treatment of colorectal cancer, it is critical to distinguish the literature published before and after the publication of the landmark COST trial the New England Journal of Medicine (2004). The COST trial and, a year later, the COLOR 1 trial along with the CLASICC trial put to rest any doubts the scientific and HTA communities might have had regarding oncological safety of laparoscopic surgery for colorectal cancer. Therefore in this review, we retained only the HTA reports that were posterior to these key publications. Three HTA reports were retrieved (2 from the searched HTA agencies and one from the CRD database).

In France, the HAS published its report on laparoscopic surgery for colorectal cancer in 2005. The assessment was based on a review of the clinical evidence only while cost effectiveness was not addressed. The main focus was to assess the long term effectiveness of the laparoscopic approach. The recommendation from HAS was favorable to the laparoscopic route: “In colon cancer, 4-year survival and recurrence rates were similar after laparoscopic and open surgery. In colorectal cancer, quality of resection (resection margins and lymph node clearance) and risk of wound recurrence were also similar for both techniques. In colorectal cancer, pain, ileus, reduced postoperative respiratory function and blood loss were lower after laparoscopy than after open surgery although the clinical relevance of these observations is debatable. The technique used had
little effect on changes in immune response. Hospital stay was shorter after laparoscopy.” HAS also mentioned the lack of data for rectal cancer.

At the same period, in Spain, UETS performed a similar literature review including economic outcomes. Based on this review, UETS concludes that the laparoscopic approach is as effective as the open one but more costly and therefore does not recommend minimally invasive surgery: ”Laparoscopic surgery has the same long term efficacy than open surgery but it is more expensive, so it would be considered to use open surgery in the treatment of colorectal cancer.” However, in this conclusion, UETS did not take into consideration two key factors: the impact of the short term benefits of laparoscopic surgery on the overall cost effectiveness ratio and the impact of the learning curve on the overall outcomes.

NICE (England and Wales) realized the most recent HTA assessment of laparoscopic surgery for colorectal cancer in 2006. This assessment was an update of a previous negative assessment conducted in 2003 (hence before the findings of the COST, CLASICC and COLOR trials were known). For this technology guidance, NICE commissioned a literature review (clinical and economic outcomes) and an economic model in order to assess the cost effectiveness of laparoscopic surgery. NICE reversed their 2003 guidance and concluded that: ”Laparoscopic resection is recommended as an alternative to open resection for individuals with colorectal cancer in whom both laparoscopic and open surgery are considered suitable.” Contrary to UETS, NICE took into consideration the significant impact of experience and learning curve (see box 4 in this value dossier) : ”Laparoscopic colorectal surgery should be performed only by surgeons who have completed appropriate training in the technique and who perform this procedure often enough to maintain competence.”

**Conclusion**

Overall, minimally invasive procedures have not often been a high priority for HTA agencies. In this review, we retrieved 8 HTA reports whereas in the same period there were around 20 reports for bariatric surgery. When HTA agencies focus only on clinical outcomes, the recommendations are always favorable to
laparoscopic surgery and can be summarized with a similar efficacy and better short term outcomes. However, when cost considerations come into the scope of the assessment, conclusions are more heterogeneous, depending on the economic metrics considered. All HTA reports reviewed here conclude that laparoscopic leads to higher costs and depending on the procedure and countries willingness to pay, laparoscopic surgery is either deemed cost effective or not. It should be noted than in none of these HTA reports was a societal perspective adopted; hence the savings generated by shorter time to return to normal activity were not considered.

References for box 1


APPENDIX A, Bibliography

5. Uterine Leiomyomas From: http://www.mayoclinic.com/health/uterine-fibroids/DS00078; Stenchever: Comprehensive Gynecology, 4th ed; Current Diagnosis & Treatment Obstetrics & Gynecology - 10th Ed. (2007); Best Practice & Research Clinical Obst and Gyn V20,6,p841-879, 2006; MD Consult, Menstruation patient education information


Vaginal hysterectomy

Laparoscopic supracervical hysterectomy (LSH) Source:


APPENDIX B, Figures sources

Fig. 1: Source: U.S. Uro-Gynecological Surgical Devices Markets, Frost & Sullivan, 2005

Fig. 2: Source: Medical Illustration © 1999 – 2007 Nucleus Medical Art, Inc., www.nucleusinc.com

Fig. 3: Source: Medical Illustration © 1999 – 2007 Nucleus Medical Art, Inc., www.nucleusinc.com

Fig. 4: Source: Medical Illustration © 1999 – 2007 Nucleus Medical Art, Inc., www.nucleusinc.com
APPENDIX C, Tables

Table 1: Source: Millennium Research Group, U.S. Markets for Gynecological Devices, 2007

Table 2: Source: Medtech Insight, U.S. Surgical Procedure Volumes, February 2007

Table 3: Source: Medtech Insight, European Surgical Procedure Volumes, July 2006

Table 4: Source: OBGyn.net
http://www.obgyn.net/women/women.asp?page=/ah/articles/specialtwo 6-99,


Table 7: Sources:


This document may include demonstration of the use of surgical devices; it is not intended to be used as a surgical training guide. Other surgeons may employ different techniques. Individual surgeon preference and experience, as well as patient needs, should always dictate variation in procedure steps.

Before using any medical device, including those demonstrated or referenced in this document, review all relevant package inserts, with particular attention to the indications, contraindications, warnings and precautions, and steps for use of the device.

©2012 Ethicon Endo-Surgery, Inc. All Rights Reserved. DSL#12-0010.LAVH
Optional 5mm

Port placement in umbilicus unless uterus is large.

5 or 11mm

Port placement may be moved up for a larger uterus.

5 or 11mm

Use port if vertical midline incision is present from prior surgery. Then use LUQ approach to start.

Camera

GYN Procedure
Port Placement

Total Laparoscopic Hysterectomy (TLH)

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GYN Procedure
Port Placement

Laparoscopic Supracervical Hysterectomy (LSH)

Port placement in umbilicus unless uterus is large.

Camera

5 or 11mm

Port placement may be moved up for a larger uterus.

Optional 5mm

11 or 12mm

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GYN Procedure
Steps to the Procedure

Laparoscopically Assisted Vaginal Hysterectomy (LAVH)

1. Place in dorsal lithotomy position.
2. Obtain pneumoperitoneum. Place ports.
3. Explore abdomen.
4. Ligate and divide round ligament, fallopian tube and ovarian ligament just lateral to uterine wall.
5. Divide broad ligament down to vesicouterine fold.
6. Repeat steps 4 and 5 on opposite side.
7. Incise peritoneum anterior to cervicouterine junction and dissect bladder away from anterior uterus.
8. Incise peritoneum posterior to uterus.
10. Ligate and divide uterosacral ligaments.
11. Ligate and divide cardinal ligaments.
12. Ligate and divide uterine arteries.
13. Remove uterus through vagina.
15. Close vaginal cuff.
16. Inspect pelvis and abdomen.
17. Remove trocars and close incisions.

Products Used
In The Procedure

- **ENSEAL® TRIO** Tissue Sealing Device
- **HARMONIC ACE®** Curved Shears
- **ECHELON FLEX™** ENDOPATH® Stapler
- **ENDOPATH® XCEL™** Bladeless Trocar
- **Optional 5mm Camera**

Port Placement

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GYN Procedure
Steps to the Procedure

Total Laparoscopic Hysterectomy (TLH)

1. Place in dorsal lithotomy position.
2. Obtain pneumoperitoneum. Place ports.
3. Explore abdomen.
4. Ligate and divide round ligaments, fallopian tube and ovarian ligament.
5. Repeat step 4 on opposite side.
6. Incise anterior peritoneum in vesicouterine space and dissect bladder off of anterior cervix.
7. Skeletonize uterine artery then ligate and divide.
8. Divide cardinal and uterosacral ligaments.
9. Incise vagina circumferentially.
10. Remove uterus.
11. Close vaginal cuff.
12. Inspect abdomen and irrigate.
13. Remove trocars and close incisions.

Products Used
In The Procedure

- HARMONIC ACE® Curved Shears
- ENSEAL® Round Tip Tissue Sealing Device
- ECHELON FLEX™ ENDOPATH® Stapler
- GYNECARE MORCELLEX™ Tissue Morcellator
- LAPRA-TY™ Suture Clip Applier
- ENDOPATH® XCEL™ Bladeless Trocar

Port Placement

Optional 5mm

5 or 11mm

Port placement may be moved up for larger uterus. Port placement in umbilicus unless uterus is large. Use port if vertical midline incision is present from prior surgery. Then use LUQ approach to start.

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GYN Procedure
Steps to the Procedure

1. Place in dorsal lithotomy position.

2. Obtain pneumoperitoneum. Place ports.

3. Explore abdomen.

4. Ligate and divide round ligament, fallopian tube and ovarian ligament close to uterine wall.

5. Repeat step 4 on opposite side.

6. Incise peritoneum anterior and posterior to cervicouterine junction.

7. Ligate and divide ascending branch of uterine arteries.

8. Transect uterus at cervicouterine junction.

9. Remove uterus.

10. Ablate endocervical epithelium.

11. Close peritoneum over cervical stump.

12. Remove trocars and close incisions.

Products Used
In The Procedure

HARMONIC ACE® Curved Shears
ENSEAL® TRIO Tissue Sealing Device
ECHELON FLEX™ ENDOPATH® Stapler
GYNECARE MORCELLEX™ Tissue Morcellator
ENDOPATH® XCEL™ Bladeless Trocar

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1. Place in dorsal lithotomy position.

2. Incise vaginal mucosa anteriorly. Develop plane between cervix and bladder.

3. Incise anterior peritoneum.

4. Incise vaginal mucosa posteriorly at junction with cervix. Enter posterior peritoneum.

5. Ligate and divide uterosacral ligaments.

6. Ligate and divide cardinal ligaments.

7. Ligate and divide uterine arteries.

8. Retrovert uterine fundus.

9. Ligate and divide round ligament, fallopian tube and ovarian ligament.


11. Close vaginal cuff.

Choosing the Route of Hysterectomy
It is the position of the AAGL that most hysterectomies for benign disease should be performed either vaginally or laparoscopically and that continued efforts should be taken to facilitate these approaches. Surgeons without the requisite training and skills required for the safe performance of VH or LH should enlist the aid of colleagues who do or should refer patients requiring hysterectomy to such individuals for their surgical care.

AAGL Position Statement

Products Used
In The Procedure

- ECHELON FLEX™
- ENDOPTH® Stapler
- ENSEAL® Super Jaw Tissue Sealing Device
- HARMONIC FOCUS®
- Long Curved Shears

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1. Place in supine position.
2. Make abdominal incision.
3. Explore abdomen.
4. Ligate and divide round ligament midway between uterus and pelvis.
5. Ligate and divide fallopian tube and ovarian ligament.
6. Repeat steps 4 and 5 on opposite side.
7. Incise peritoneum in vesicouterine space and dissect bladder from anterior cervix.
8. Skeletonize uterine artery and vein. Ligate and divide.
9. Incise posterior peritoneum.
10. Divide cardinal ligaments and uterosacral ligaments.
11. Incise vagina circumferentially.
12. Remove uterus.
13. Close vaginal cuff.
15. Close incision.

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Thank you.