VAGINAL HYSTERECTOMY USING VESSEL SEALING CLAMP VERSUS CONVENTIONAL SURGERY; A RANDOMISED TRIAL

Abstract

Objective: To compare the effects of electrical bipolar vessel sealing clamp and conventional suturing on postoperative pain, operative time, blood loss, and costs, in women undergoing vaginal hysterectomy.

Patients and Methods: 20 women scheduled to undergo vaginal hysterectomy for prolapsed and non prolapsed uterus with benign indication of hysterectomy. Women were randomized randomly into two groups; Conventional vaginal surgery Group and a Group using vessel sealing Erbe machine. Ten patient in each group. Operative time, intraoperative assessment of blood loss, postoperative pain, and estimated cost were evaluated and compared between both groups.

Results: Pain was evaluated few hours post-operative. Patients in the vessel-sealing clamp group showed statistically significant less pain (5.7 versus 4.5 on a scale of 0–10, P= 0.03), but this followed by comparable pain in both groups later. Operative time was shorter in vessel sealing clamp group (39 versus 61 minutes = P< 0.05). Amount of Blood lost was also less vessel sealing clamp group. However, regarding the estimated cost, no significant difference between both groups (2903 versus 3102, P=0.26).

Conclusion: Using electrical bipolar vessel sealing clamp during vaginal hysterectomy showed less pain on the first few hours after surgery but not in the following days, shorter operative time, less operative blood loss, with no statistically significant differences in cost were found between the two groups. (Pictures and videos available).

Introduction

Hysterectomy is the commonest gynecological operation done for many indications including benign conditions as abnormal uterine bleeding Flory et al., (2005) and Van den et al. (1998). Hysterectomy done to treat such conditions aims to improve patient’s life and of course, this involve avoidance of possible side effects of the operation. Vaginal hysterectomy is the preferred route with many advantages including fewer complications, shorter hospital stay and lower costs, Van den et al. (1998) and Johnson et al. (2006). Vaginal hysterectomy carries the difficulty of gaining access to the vascular pedicles, Hefni et al. (2015). To overcome such difficulty more traction on the pedicles is needed which may cause nerve injury, urinary bladder dysfunction and increase post-operative pain, Lakeman et al. (2010) and (2011). Electrosurgical bipolar vessel sealing clamp is used to obliterate tissue bundles and blood vessels up to 7mm in diameter. The clamp allow occluding blood vessels and cutting the tissues at the time which shorten the operative
time and may reduce the post-operative pain by applying less traction on the pedicles of the uterus. In addition, using electro-surgical bipolar vessel sealing clamp enable surgeons to cut tissues close to the uterus preserving the nerves extensively located in the supporting uterine ligaments. The advantages of vessel sealing clamps were evaluated by few randomized studies, which reported safety, efficacy, short operative time and less post-operative pain Hefini et al 2015, Elhao et al 2009 and Silva et al 2009. The effect on postoperative recovery and on the costs of the operation was not evaluated before. Although Vaginal Hysterectomy (VH) has many advantages, it represent a surgical challenge for surgeons where a narrow space to perform a major surgery and difficult hemostasis. This study is carried out compare electrical bipolar vessel sealing clamp and conventional suturing regarding pain after surgery, operative time, blood loss, and costs, in vaginal hysterectomy.

**Patients and Methods**

This randomized controlled trial was performed in a private hospital Alkhobar, Saudi Arabia to comparing electrical bipolar vessel clamp sealing with conventional suturing in vaginal hysterectomy. The study was preceded by a pilot study done upon 10 women at a private hospital in Mansoura, Egypt using the same inclusion criteria assessing the value of vessel sealing clamping in vaginal hysterectomy on postoperative pain, operative blood loss and duration of surgery. Cases diagnosed with benign lesions in the uterus and scheduled for hysterectomy vaginally were collected between April 2017 and March 2018. All cases were included after general, abdominal and local examination as well as pelvic ultrasound. The uterine size ranged from normal size to 10wks. Exclusion criteria were suspected adnexal pathology or pelvic adhesions. The study was approved by the medical ethical committee. After signing the informed consent, women were randomized to one of the treatment groups by computerized randomization. Conventional vaginal surgery Group and a Group using vessel sealing Erbe machine. Ten patient in each group.

The ERBE BiClamp BVSS are insulated forceps with an automatic coagulation completion. The technique has similar anatomical principles to conventional technique of vaginal hysterectomy. It uses only two instruments with easy access and lower risk of trauma. We investigated the use of ERBE BiClamp BVSS in VH with possible advantages over conventional suture ligation, namely less post-operative pain, reduced blood loss, shorter operative time and cost of surgery.

**Surgical procedure:**

Vaginal hysterectomy was done following steps of the standardized technique. Vaginal wall was incised circumferentially anteriorly below the bladder base. The Douglas pouch was incised posteriorly and a retractor was used to retract vaginal wall. The urinary bladder was then dissected from the vagina wall. The uterosacral ligaments were clamped, cut and ligated by Vicryl No. 1 sutures that kept long to be fixed to the vault later. In cases of conventional surgery, the rest of pedicles were clamped, cut and ligated by Vicryl No. 1 sutures. In cases of the vessels sealing clamp group the pedicles were clamped, transected and sealed using the Erby bipolar vessel-sealing device. Vault closure was done in the same manner in both groups by Vicryl No. 1 sutures.

The amount of lost blood was calculated by the amount collected by a suction machine during the surgery and the total number of gauzes used during the procedure. This amount was estimated by the operation assistant and nurse.

**Pain management:**

Analgesics included morphine and nonsteroidal anti-inflammatory drugs as indicated combined with paracetamol for 3 days postoperatively were given according to a standard protocol.

**Outcome measurements:**

We used the visual analogue scale (VAS) to measure postoperative pain as a primary outcome during the first week after surgery. Operative time, amount of blood loss and estimated total cost were the secondary outcomes.
**Results.**

**TABLE 1:** Baseline Characteristics Of Women According To Surgical Approach.

<table>
<thead>
<tr>
<th>PARAMETER</th>
<th>CONVENTIONAL SURGERY GROUP</th>
<th>VESSEL SEALING GROUP</th>
</tr>
</thead>
<tbody>
<tr>
<td>NUMBER OF WOMEN</td>
<td>10</td>
<td>10</td>
</tr>
<tr>
<td>AGE</td>
<td>49.1</td>
<td>50.0</td>
</tr>
<tr>
<td>PARITY (MEDIAN, RANGE)</td>
<td>2.0(1-5)</td>
<td>2.0(0-6)</td>
</tr>
<tr>
<td>BODY MASS INDEX KG/M2</td>
<td>27.6</td>
<td>26.9</td>
</tr>
<tr>
<td>PREVIOUS ABDOMINAL SURGERY INCLUDING CS</td>
<td>3</td>
<td>2</td>
</tr>
<tr>
<td>MEDICAL DISORDERS</td>
<td></td>
<td></td>
</tr>
<tr>
<td>DIABETES</td>
<td>3</td>
<td>1</td>
</tr>
<tr>
<td>HYPERTENSION</td>
<td>4</td>
<td>2</td>
</tr>
</tbody>
</table>

**MAIN INDICATION FOR VH**

| ABNORMAL UTERINE BLEEDING               | 2                          | 2                    |
| POSTMENOPAUSAL BLEEDING                 | 1                          | 2                    |
| PELVIC PAIN                             | 3                          | 1                    |
| UTERINEPROLAPSE                         | 4                          | 5                    |
| THYROID DISORDERS                       | 1                          | 2                    |

**TABLE 2:** Duration And Average Intraoperative Blood Loss:

<table>
<thead>
<tr>
<th>OUTCOMES</th>
<th>CONVENTIONAL SURGERY GROUP</th>
<th>VESSEL SEALING GROUP</th>
<th>P VALUE</th>
</tr>
</thead>
<tbody>
<tr>
<td>DURATION OF SURGERY/ MINUTRS</td>
<td>61.3</td>
<td>39.6</td>
<td>&lt; 0.05 S.SIG.</td>
</tr>
<tr>
<td>BLOOD LOSS/ML</td>
<td>427.7</td>
<td>231.0</td>
<td>&lt; 0.05 S.SIG.</td>
</tr>
</tbody>
</table>

Operative duration was shorter for vessel sealing group (39.6 versus 61.3 = \(P < 0.05\)) statistically significant. Blood loss was less in vessel sealing group (231.0 versus 427.7 = \(p < 0.05\)) statistically significant.

Women in the vessel-sealing group showed significantly less pain few hours after surgery (5.7 versus 4.5 on a scale of 0–10, \(P = 0.03\)) which was significant, but after that pain scores were similar in both groups.

**TABLE 3:** Estimated Cost Of Surgery (SR) *:

<table>
<thead>
<tr>
<th>COST PARAMETER</th>
<th>CONVENTIONAL SURGERY GROUP MEAN COST</th>
<th>VESSEL SEALING GROUP MEAN COST</th>
<th>P VALUE</th>
</tr>
</thead>
<tbody>
<tr>
<td>INPATIENT HOSPITAL CARE</td>
<td>2903(2651-3225)</td>
<td>3102(2958-3250)</td>
<td>0.26 NS</td>
</tr>
<tr>
<td>OUTPATIENT HOSPITAL CARE</td>
<td>57(37-79)</td>
<td>115(71-167)</td>
<td>0.037</td>
</tr>
<tr>
<td>TOTAL</td>
<td>2943(2692-3264)</td>
<td>3188(3040-3341)</td>
<td>0.18 NS</td>
</tr>
</tbody>
</table>

*SR: SAUDI RIYALS*
Outpatient hospital costs (i.e. care by medical staff the GP, physiotherapist and company physician) of the vessel-sealing group were significantly higher compared with conventional surgery. Fourcase-neededmultiple outpatient clinic visits because of different complaints: constipation, pain and urinary tract infection. All of them were in the vessel-sealing group, which increased the cost. However, the total cost was similar in both groups.

Discussion

This randomized controlled trial evaluated the effects of using electrical bipolar vessel sealing on postoperative pain, operative time, blood loss, and cost. Vessel sealing machine group showed less Postoperative pain few hours after surgery, but pain was similar in both groups after that. Operative time and blood loss was lower in electrical bipolar vessel sealing group. Total costs were similar in both groups with no statistically significant differences.

Both cases as well as the medical staff following them after surgeries remained blinded to the used technique. As a result, bias in the counseling on experienced pain, based on the cases’ or the nurses’ preferences was avoided. A validated questionnaire was used before and after surgery to evaluate pain and analgesia effects.

One of the most important outcomes was the postoperative pain. In accordance with previous clinical trials showing that pain was less few hours after vaginal hysterectomy when using vessel-sealing clamp CRONJE ET AL (2005) AND SILVA ET AL (2009). The current study found the decreased postoperative pain few hours after operation in the vessel-sealing group, which became similar in both groups after the first day of surgery. The overall low pain scores found in both studied groups after the first postoperative day probably explain this.

Comparing the results of the our study with previous studies included women scheduled for abdominal hysterectomy LAKEMAN ET AL (2008), the overall pain scores were significantly high following abdominal hysterectomy owing to pain of the abdominal incision JONSON ET AL (2006).

The mean hospital stay was slightly long in this study in contrast to previous studies CRONJE ET AL (2005), SILVA ET AL (2009) AND DING ET AL (2005). However, when compared with hospital stay in other studies for cases of vaginal hysterectomy, it was within average range JONSON ET AL (2006). The large difference in hospital stay duration could be explained by local cultural factors, and by surgeon, as well as participant expectations matched with a meta-analysis done by KROFT ET AL (2011). Hospital stay in our study was shorter, but not statistically significant among women in the vessel-sealing group.

Our study results regarding the operative time were similar to previous studies comparing vessel sealing with conventional method. All reported reduced operation time HETFNI ET AL (2015), ELHAW ET AL (2009), LEVY ET AL (2003), SILVA ET AL (2009) AND DING ET AL (2005). This could be explained by the ability of the vessel-sealing clamp to rapidly seal, coagulate and cut the pedicles in one hand-held tool LAMBERTON ET AL (2008).

Reduction of the operative time is a matter of discussion. Although the reduction was as high as 40%, it does not mean a quicker recovery or shorter hospital stay. However, reduction in the operative time reduced the cost of the operation.

Decrease in blood loss using vessel sealing was found by many studies LEVY ET AL (2003), SILVA ET AL (2009) AND DING ET AL (2005). Results of the current study are in agreement with these studies. However, studies on larger scale did not find significant difference in estimated blood loss ELHAW ET AL (2009).

Vessel-sealing technique cost was expected to be higher than the conventional method owing to the cost of the device. The cost was slightly higher in the vessel-sealing cases (2903 versus 3102 SR P=0.26), which is explained by the added cost of the ERBE BICLAMP device. However, this is compensated by shorter operative time (conventional surgery 688 SR versus vessel sealing 616 SR), and shorter hospital stay after vessel sealing (conventional surgery 1852 SR versus vessel sealing 1713 SR).

Conclusion

It seems that ERBE BiClampBVSS is a safe, effective technique for vaginal hysterectomy compared to conventional method. The technique resulted
in less pain, shorter operative times, less blood loss, shorter hospital stay and lower total cost. The reduced post-operative pain observed allowed rapid mobilization and recovery.

**Recommendations**

Further studies with more number of patients is recommend, as well as studies concerning the effects of the two different methods for vaginal hysterectomy on the urinary bladder function and pelvic floor function.

**References**


