A Comparative Study of Intra-Operative Complication of Bipolar Vessel Sealing System Versus Conventional Clamp Suture In Vaginal Hysterectomy

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Citation this Article: DR. B.S.Meena, Dr. Anant Chopra, Dr. Suniti verma, Dr. Neelam Bunkar, “A Comparative Study of Intra-Operative Complication of Bipolar Vessel Sealing System Versus Conventional Clamp Suture In Vaginal Hysterectomy ”, IJMSIR- March - 2020, Vol – 5, Issue -2, P. No. 66 – 69.

Type of Publication: Original Research Paper

Conflicts of Interest: Nil

Abstract

Background: This study was taken up to find out the easier alternatives in securing pedicles by using Electrosurgical Bipolar Vessel Sealer in Vaginal Hysterectomy.

Methods: A prospective observational study was conducted in the Department of Obstetrics and Gynaecology, SMS Medical College, Jaipur. A total of 60 patients posted for vaginal hysterectomy were enrolled after informed consent.

Results: Intra-operative haemorrhage was more in 4(13.33%) cases in conventional clamp group and in 1(3.33%) case in bipolar vessel sealer group.

Conclusions- We concluded that Bipolar Vessel Sealer surgery is suitable to be used for vaginal hysterectomy without serious complications.

Keywords: Blood loss, Conventional sutures, Electrosurgical bipolar vessel sealer, Vaginal hysterectomy

Introduction

EBVS devices allow for rapid sequential tissue and vessel sealing coagulation and transection of the pedicles in one handled tool.1 It is a combination of pressure and bipolar electric energy. It delivers controlled high power current with low voltage to melt collagen and elastin within the tissue to create a seal zone which appears as a distinctive translucent area and has plastic resistance to deformation. The vessel sealing mechanism produces significantly reduced thermal spread as energy is automatically switched off when tissue impedance reaches a critical level.2 The current delivered to achieve hemostasis is taken between 2 to 7 seconds hence, can be relatively faster compared with suture ligation. Bipolar diathermy overcomes some of the limitations of monopolar electrosurgery.3 Bipolar technology employs an active electrode and a return electrode into a single electrosurgical instrument with two small poles. Rather than passing through the patient to the grounding pad, the alternating current is distributed through the target tissue.4 Lower voltages
are needed to achieve the same tissue effect in bipolar electrosurgery as those achieved in monopolar because the poles are close to each other. Bipolar electrosurgery thus results less potential damage to surrounding tissues and less risk of capacitive coupling. The classic bipolar instrument is the Kleppinger bipolar forceps used most commonly for laparoscopic tubal sterilization and hemostasis of vascular pedicles. Bipolar forceps allow for firm grasping and reliable coagulation of vessels less than 3 mm in size. Newly developed vessel sealing devices build upon bipolar diathermy as well as ultrasonic technology to provide more consistent hemostasis with added functionality and increased efficiency.

Material & Methods

Place of Study: Study was conducted in department of obstetrics and Gynaecology, SMS Medical College & Attached Hospitals, Jaipur

Duration of Study: MAY 2018 to August 2019.

Study Type: Interventional (Randomised Comparative Study)

Study Design: Prospective Study

Sample size: Sample size was calculated at 80% study power and Error of 0.05 assuming SD Of 25 minute in operating time as founding in seed article. For minimum detectable mean difference of 20 minute in operating time , 25 cases in each group required sample size which was increased to 30 cases in each group expecting 20 % dropouts/attrition as final sample size.

Purpose of Study: To provide a safe technique for securing the pedicles in vaginal hysterectomy for reducing complications and hospital burden .

Selection Criteria

Inclusion Criteria

• Uterovaginal prolapse.

• Fibroid less than 14 weeks.

• Abnormal Uterine bleeding.

• Women giving consent.

Exclusion Criteria

• Women withdrawing consent.

• Women not co-operative and not able to understand.

• Known endometriosis, pelvic inflammatory disease.

• Uterine, cervical, ovarian malignancy.

Methodology

• Women undergoing vaginal hysterectomy on the basis of inclusion and exclusion criteria were selected.

• Informed consent of the women was taken prior to study.

• Institute review board and ethical committee approval was taken.

• Randomization was done to allocate women in each group using computer generated random numbers.

• Spinal anesthesia was given to all.

• A circumferential vaginal incision was made around the anterior portion of the cervix between the transverse cervical ligaments and extended postero-medially in a V-shaped manner. The bladder was then dissected off the vagina anteriorly and the pouch of Douglas was opened posteriorly. After this step, either the bipolar vessel sealing system or conventional ‘clamp, cut and suture’ technique was used for securing the hysterectomy pedicles. The bipolar device consists of a bipolar radio-frequency generator, the generator delivers a low voltage high power current.
• When the suturing technique was used, the pedicles were clamped, cut, transfixed and doubly ligated using Vicryl No.1 sutures.
• The vault was closed similarly in both groups by continuous interlocking suture.
• Intraoperative parameters and postoperative condition of women till follow up period of 45 days was assessed and recorded as per Performa.
• To control inter-observer variability same surgeon, same anesthetist and same drugs during and after surgery were prescribed.

**Intra Operative Parameters**

• Time from circumferential incision (on anterior portion of cervix) to vault closure by continuous interlocking sutures
• Blood loss was assessed by weighing the dry and soaked mops preoperatively and postoperatively respectively and adding the blood in suction jar
• Preoperative and postoperative (after 24 hours) haemoglobin was done of all women and difference in haemoglobin was noted.
• Any complication during surgery was noted.

**Statistical Analysis**

Linear variables were described as mean and SD and were compared by using unpaired ‘t’ test.

Catagorical variables were described as percentages and was compared by using X2 test/fisher exact test. P-value <0.05 will be taken as significant.

**Results**

Table 1: Duration of surgery (minutes)

<table>
<thead>
<tr>
<th></th>
<th>Conventional Clamp Group</th>
<th>Bipolar Vessel Sealer Group</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean</td>
<td>55.60</td>
<td>48.07</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>SD</td>
<td>5.21</td>
<td>5.08</td>
<td></td>
</tr>
<tr>
<td>Operative time</td>
<td>49-70 min</td>
<td>35-58 min</td>
<td></td>
</tr>
</tbody>
</table>

The operative time was significantly higher in conventional clamp group (55.60±5.21 mint.) as compared to bipolar vessel sealer group (48.07±5.08 mint.).

Table 2: Blood Loss (ml)

<table>
<thead>
<tr>
<th></th>
<th>Conventional Clamp Group</th>
<th>Bipolar Vessel Sealer Group</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean</td>
<td>92.90</td>
<td>81.77</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>SD</td>
<td>10.09</td>
<td>8.61</td>
<td></td>
</tr>
<tr>
<td>Range</td>
<td>80-118 ml</td>
<td>60-105 ml</td>
<td></td>
</tr>
</tbody>
</table>

The blood loss was significantly higher in conventional clamp group (92.90±10.09 ml) as compared to bipolar vessel sealer group (81.77±8.61 ml).

Table 3: Intra Op. Complications

<table>
<thead>
<tr>
<th></th>
<th>Conventional Clamp Group</th>
<th>Bipolar Vessel Sealer Group</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of cases</td>
<td>30</td>
<td>30</td>
</tr>
<tr>
<td>%</td>
<td>100.00</td>
<td>100.00</td>
</tr>
</tbody>
</table>

Haemorrhage was seen in 4(13.33%) cases in conventional clamp group and in 1(3.33%) case in bipolar vessel sealer group. (p-value 0.350)

**Discussion**

The operative time was significantly higher in conventional clamp group (55.60±5.21 min.) as compared to bipolar vessel sealer group (48.07±5.08 min.) in our study. In concordance with our findings, previous studies comparing vessel sealing with conventional clamping, all reported reduced operation time. The most plausible explanation for this finding is that energy-based vessel-sealing devices allow for
rapid vessel sealing, coagulation and transection of the pedicle in one handheld tool.\textsuperscript{6,7} The clinical relevance of 7.52-minute difference in operating time is a point of discussion, especially as this 15\% shortening of operation duration did not seem to induce a quicker recovery or shorter hospital admission. However every minute shorter the operation lasts, does reduce the costs of the procedure.

In conclusion, Bipolar Vessel Sealer surgery is an expensive but convenient surgical procedure. With more experiences, Bipolar Vessel Sealer surgery demonstrates more benefits than conventional clamping methods in many ways for abdominal hysterectomy. The method provides a convenient procedure for vessels sealing resulting in less operative time, less blood loss and less postoperative pain. Furthermore this procedure needs less suture materials that can overcome an expensive cost if used in hospitals with high volume of patients. Even expensive, but its convenience and other direct and indirect benefits can overcome its disadvantage on high price. Therefore Bipolar Vessel Sealer surgery is suitable to be used for abdominal hysterectomy without serious complications.

Conclusion

In conclusion, Bipolar Vessel Sealer surgery is an expensive but convenient surgical procedure. With more experiences, Bipolar Vessel Sealer surgery demonstrates more benefits than conventional clamping methods in many ways for vaginal hysterectomy.

References