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Original Research Article

To study the efficacy and safety between use of BICLAMP (bipolar coagulation forceps) in vaginal hysterectomy and conventional vaginal hysterectomy: A prospective study at tertiary care center, Maharashtra

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Abstract

Background: Bipolar vessel sealing systems (BVSS) are accepted to be safe and efficacious with possible advantages over conventional methods, namely fewer requirement of post-operative analgesics, less blood loss, shorter operative time and minimum hospital stay.
Objectives: To compare the efficacy and safety between use of BiClamp (Bipolar Coagulation Forceps) in Vaginal Hysterectomy and Conventional Vaginal Hysterectomy.
Materials and Methods: This prospective study was done among 80 cases indicating hysterectomy for benign diseases admitted in OBGY unit were selected randomly out of which 40 cases underwent Conventional Vaginal Hysterectomy and 40 cases underwent BiClamp Vaginal Hysterectomy at department of obstetrics & Gynecology in Government medical college and hospital, Latur during November 2012 to September 2014.
Results: Mean duration of hospital stay required for participants of cases and control group was 2.6 days and 4.2 days respectively ($p<0.05$). Mean duration of operation of cases and control group participants was 70.9 min and 75.5 min respectively ($p<0.05$). Mean blood loss during operation noted among the cases and control group participants was 90.1 ml and 115.9 ml respectively ($p<0.05$). During operation, three suture material required in in 0.0% participants of cases group and 82.5% of control group respectively ($p<0.05$). Post- op complications like fever, bladder injury, bowel injury & hemorrhage noted only in participants of control group.
Conclusion: BiClamp Vaginal Hysterectomy post-operative pain was less, intraoperative blood loss was less, operative time was significantly shorter, duration of hospital stay was less and BiClamp Vaginal Hysterectomy was more Cost effective than the Conventional Vaginal Hysterectomy.

Keywords: BiClamp Vaginal hysterectomy, complication, conventional vaginal, hysterectomy, hospital stay, operative time

Introduction

In the gynecology field, hysterectomy is globally the most common surgery performed [1]. The incidence of hysterectomy is about 4-6% of adult Indian women out of which 90% are carried out for benign indications in India [2]. Every year, in India around 2,310,263 women undergo hysterectomy and this women mostly come from rural area, engaged with the working class and are financially weaker class [3]. Keeping this socio-demographic characteristics of Indian community in mind, it is crucial that the procedure of hysterectomy for Indian population should be cost-effective and with minimum hospital stay [4].
Vaginal hysterectomy (VH) yields an early return to normal activity, less febrile incidence, minimum hospital stay, less operative duration and less blood loss [5, 6]. Due to the challenging surgical technique with limited access to deep vascular pedicles making haemostasis and suture ligation potentially problematic, still there is a hesitancy towards VH. Bipolar vessel sealing systems (BVSS) are accepted to be safe and efficacious with possible advantages over conventional methods, namely fewer requirement of post- operative analgesics, less blood loss, shorter operative time and minimum hospital stay [7-10].
The ERBE BiClamp® BVSS are insulated forceps with an automatic coagulation completion. The technique has related to anatomical principles to conventional methods, shortening the learning curve. It requires only two instruments; easing access and reducing trauma risk. Initial studies into VH using BiClamp® suggest that patients experience less postoperative pain and shorter operative duration6. So, the present study was conducted with the objectives to compare the efficacy and safety between use of BiClamp (Bipolar Coagulation Forceps) in Vaginal Hysterectomy and Conventional Vaginal Hysterectomy.

Materials and Methods

This prospective study was done among 80 cases indicating hysterectomy for benign diseases admitted in OBGY unit were selected randomly out of which 40 cases underwent Conventional Vaginal Hysterectomy and 40 cases underwent BiClamp Vaginal Hysterectomy at department of obstetrics & Gynecology in Government medical college and hospital, Latur, Maharashtra during November 2012 to September 2014. Data collection was done after ethical permission from institutional ethical committee and informed consent of clients. Inclusion Criteria was patients who had given written informed valid consent for Vaginal Hysterectomy, non-descent uterine prolapse, 2nd degree uterine prolapse, 3rd degree uterine prolapse, benign uterine diseases (Adenomyosis, fibroid uterus, dysfunctional uterine bleeding, Cervicitis) and uterine size less than 12 weeks. Exclusion Criteria was 1st degree uterine prolapse, procidentia, suspected malignancy, uterus size more than 12 weeks and any pelvic pathology & surgeries for the same.
A detailed menstrual and obstetric history of the case was noted in a separate questionnaire sheet by interviewing. Detailed clinical obstetric examination was done and history of the signs and symptoms were noted. The cases were studied with respect to Operative time, Estimated blood loss, Post-Operative Analgesia and Postoperative pain relief, Hospital stay, Hospital cost and Cost effectiveness, and Complication rates. General examination and systemic examination was done as per the protocol. The data were recorded in an Excel sheet and descriptive analysis was performed, of which data are presented in the tables. To know the association between dependent and independent variables chi-square was applied accordingly. P value less than 0.05 was considered as statistically significant.

Results

Table 1: Clinico-social factors of study participants [N=80]

Variable	Group (%)		p value
	Case (n=40)	Control (n=40)	
Age [in year]			
24-34	4 (10)	2 (5)	0.29
35-44	1 (2.5)	3 (7.5)	
45-54	8 (20)	12 (30)	
55-64	12 (30)	15 (37.5)	
≥65	15 (37.5)	8 (20)	
Mean age ± SD	49.5 ± 14.4	55.1 ± 11.7	0.23
Parity			
1	8 (20)	4 (10)	0.27
2	11 (27.5)	7 (17.5)	
3	6 (15)	10 (25)	
>3	15 (37.5)	19 (47.5)	
Type of anesthesia used			
Spinal	38 (95)	36 (90)	0.39
Epidural	2 (5)	4 (10)	

Table 1 shows that 10%, 2.5%, 20% 30% & 37.5% participants of case group and 5%, 7.5%, 30%, 37.5% & 20% of control group were belonged to age group 24-34, 35-44, 45- 54, 55-64 & ≥65 years respectively (p>0.05). Mean age participants of cases and control group was 49.5 years with 14.4 SD and 55.1 years with 11.7 SD respectively (p>0.05). Around 20%, 27.5%, 15% & 37.5% participants of case group and 10%, 17.5%, 25%, & 47.5% of control group had parity 1, 2, 3 & >3 respectively (p>0.05). Around 95% & 90% Participants of case and control group had induced with spinal anesthesia respectively (p>0.05).

Table 2: Post-operative events among study groups [N=80]

Post-operative events	Group		p value
	Case (n=40)	Control (n=40)	
Hospital Stay [in day]			
Mean ± SD	2.6 ± 0.49	4.2 ± 1.09	0.001
Operative Time [in minutes]			
Mean ± SD	70.9 ± 11.7	75.5 ± 16.5	0.001
Blood Loss (in ml)			
Mean ± SD	90.1 ± 50.4	115.9 ± 61.0	0.02
Suture Material needed			
1	29 (72.5)	0 (0.0)	0.01
2	11 (27.5)	7 (17.5)	
3	0 (0.0)	33 (82.5)	
Post-op complication			
Fever	0 (0.0)	2 (5)	0.03
Bladder Injury	0 (0.0)	2 (5)	0.01
Bowel Injury	0 (0.0)	1 (2.5)	0.04
Post-op Hemorrhage	0 (0.0)	1 (2.5)	0.02
Post-operative analgesics doses required			
1	0 (0.0)	0 (0.0)	0.001
2	33 (82.5)	4 (10)	
3	6 (15)	6 (15)	
4	1 (2.5)	30 (75)	

Table 2 shows that mean duration of hospital stay required for participants of cases and control group was 2.6 days with 0.49 SD and 4.2 days with 1.09 SD respectively (p<0.05). Mean duration of operation of cases and control group participants was 70.9 min with 11.7 SD and 75.5 min with 16.5 SD respectively (p<0.05). Mean blood loss during operation noted among the cases and control group participants was 90.1 ml with 50.4 SD and 115.9 ml with 61 SD respectively (p<0.05). During operation, suture material required in number of 1,2,3 noted in 72.5%, 27.5% & 0.0% participants of cases group and 0.0%, 17.5% & 82.5% of control group respectively (p<0.05). Post-op complications like fever, bladder injury, bowel injury & hemorrhage noted only in 5% (p<0.05), 5% (p<0.05), 2.5% (p<0.05) & 2.5% (p<0.05) participants of control group. Post-operative analgesic dose 1,2,3,4 required in 0.0%, 82.5%, 15% & 2.5% participants of case group and 0.0%, 10%, 15% & 75% of control group respectively (p<0.05).

Figure 1 shows that indication for hysterectomy like non-descent vaginal hysterectomy, 2nd degree uterine prolapse, 3rd degree uterine prolapse, dysfunctional uterine bleeding, adenomyosis, fibroid uterus & cervicitis noted in 37.5%, 25%, 25%, 2.5%, 2.5%, 5%, & 2.5% participants of case group and 10%, 37.5%, 40%, 2.5%, 5%, 5% & 0% of control group respectively (p<0.05).

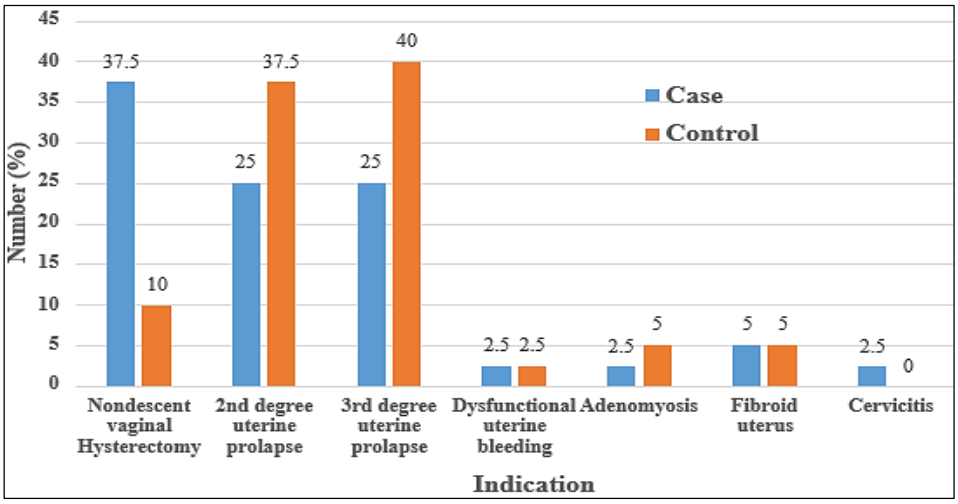

Fig 1: Indication for hysterectomy among study groups [N=80]

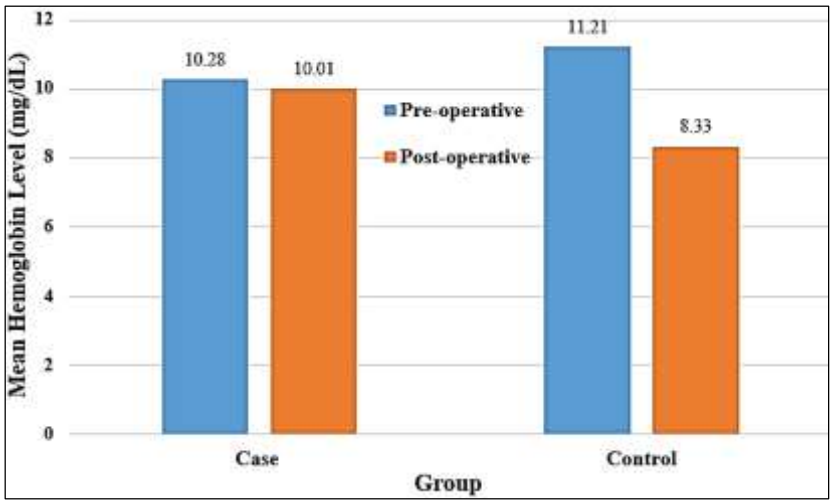

Fig 2: Comparison of 'mean hemoglobin level' among study groups [N=80]

10.28 mg/dL and 11.21 mg/dL respectively and mean post-operative Hb of participants of case & control group was 10.01 mg/dL and 8.33 mg/dL respectively (p<0.05).

Discussion

Present study statistically not significantly found that Maximum patients in this study in both Control and Study group were between 55 to 64 years of age. According to the study of Chandana C *et al.* (2014) [11] majorities of patients were in the age group of 41-45 years and 40-49 years according to Bharatnur S *et al.* (2010) [12]. Present study statistically not significantly noted that highest number participants of both the groups had parity >3. According to Chandana C *et al.* (2014) [11] majority of patients are Para 2 and above. According to Bharatnur S *et al.* (2010)12 who conducted comparative study between abdominal hysterectomy and vaginal hysterectomy mean parity was 3.8 for vaginal hysterectomy.

Present study observed that Non descent vaginal Hysterectomy, 2nd degree uterine prolapse & 3rd degree uterine prolapse were the most common indication for hysterectomy in both the groups ($p<0.05$). Ghirardini G and *et al.* (2013) [13] found that the main indication for VH was uterine prolapse in 52.0% (n = 260) of cases; uterine fibroids in 37.4% (n = 187). Patel R *et al.* (2014) [14] found that the indications for Vaginal hysterectomy were uterine Leiomyoma in 539 patients (33.1%), Adenomyosis in 341 cases (20.94%).

Present study found that participants of case group had required statistically significantly less time (2.4 days vs. 4.2 days) to post-operative stay in hospital compared to control group ($p<0.05$). This findings are correlate with the study done by Levy B *et al.* [15], Malinowski A *et al.* [16], Zubke W *et al.* [17], Kroft J *et al.* [18] and Ghirardini G *et al.* [13].

Present study found that participants of case group had required statistically significantly less operative time (70.9 min vs. 75.5 min) compared to control group ($p<0.05$). This Findings are correlate with the study done by Li L *et al.* [19], Macario A *et al.* [20] and Silva-Filho AL *et al.* [21].

Present study found that blood loss during operation had statistically significantly had noted less (90.1 ml vs. 115.9 ml) in case group compared to control group ($p<0.05$). This findings are correlate with the study done by Ding Z *et al.* 22 and Levy B *et al.* [15]. Present study noted that suture material required statistically significantly in less number during operation in case group compared to control group ($p<0.05$). This findings are comparable with the study done by Silva-Filho AL *et al.* [21] and Cronje HS *et al.* [23]. Present study observed not a single incidence of post-operative complication among the participants of case group. Present study noted that post-operative analgesic required statistically significantly in less number after operation in case group compared to control group ($p<0.05$). This findings are correlate with the study done by Ding Z *et al.* 22 and Levy B *et al.* [15].

Present study observed that in the case group mean preoperative haemoglobin of 10.28 ± 0.28 gm/dl and mean postoperative haemoglobin 10.01 ± 0.26 gm/dl. Comparison between the two groups revealed no significant fall in haemoglobin ($p>0.05$). This also shows that intraoperative blood loss in BiClamp vaginal hysterectomy is not significant.

Conclusion

BiClamp Vaginal Hysterectomy post-operative pain was less, Intraoperative blood loss was less, Operative time was significantly shorter, duration of hospital stay was less and BiClamp Vaginal Hysterectomy was more Cost effective than the Conventional Vaginal Hysterectomy. Ease of use ratings and overall assessment of haemostatic method showed significant advantages of the BiClamp when used by experienced surgeons over Conventional Vaginal Hysterectomy. The use of BiClamp forceps in Vaginal Hysterectomy is effective, safe and does not increase the number of complications, provided that special precautions are taken with respect to the thermal effects. At the same time the use of BiClamp forceps allows for quick and smooth implementation of the procedure. The patient who underwent hysterectomy with the BiClamp return to full health more quickly as compared to the Conventional Vaginal Hysterectomy. Because of all above reasons BiClamp Vaginal Hysterectomy is good

alternative to the traditional method of vaginal hysterectomy in recent years.

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Ethical approval: The study was approved by the Institutional Ethics Committee.

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