A Retrospective Study Comparing Open And Closed Vaginal Vault Techniques After Elective Surgery For Gynaecologic Malignancies In A Regional Cancer Centre

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Abstract:

INTRODUCTION:

- Hysterectomy either alone or a part of removal of other structures (Ovaries / Pelvic nodes/ Omentum) is standard for the curative surgery performed for Gynaecologic malignancies.
- After hysterectomy, the vaginal vault can either be closed or left open.
- There are no standard recommendations or guidelines regarding the management of vaginal cuff, especially in gynaecologic malignancies and it is left to the operating surgeon's discretion.
- Till now, there are no studies demonstrating superiority of one technique over the other in the management of gynaecologic malignancies.
- Hence, we aimed to retrospectively analyse all the cases of gynaecologic malignancies, in which a minimum of at least simple hysterectomy was performed in our institution, and in which the decision either to close the vault or leave it open was left to the operating surgeon.

AIMS AND OBJECTIVES:

- To compare and analyze the following parameters between open and closed vaginal vault techniques following elective surgery for Gynaecologic malignancies in a single institution (GovtArignar Anna Memorial Cancer Hospital, Regional Cancer Centre, Kanchipuram);
- Operating time.
- Post operative Pain
- Post operative Vaginal Discharge
- Incidence of Post operative complications like Pelvic Haematoma/Pelvic Abscess, Wound Dehiscence, Vaginal Vault Dehiscence and Organ Prolapse, and Ascending infection
- To follow up both groups of patients and analyze whether vault recurrence is detected earlier in open vaginal vault method.

MATERIALS AND METHODS:

- All the patients undergoing elective surgery for gynaecologic malignancies in our institution over a period of 3 years (July 2020 July 2023) were included in our study after they have satisfied the inclusion and exclusion criteria devised.
- Patients who fit into our study were divided into two groups based on whether their vaginal vaults were closed or left open during the procedure.
- Patients were further stratified according to the nature of primary and other demographic and surgical details.
- The advantages and disadvantages of both techniques were analysed in respect to the parameters discussed above. Also, the patients were kept on routine follow up, to determine whether vault recurrences could be detected earlier in open vault method.

RESULTS:

The length of operating time was shorter in the open vault technique. But it was not statistically significant (p=0.08). Sutures were not routinely used in open vault technique.

DOI: 10.9790/0853-2212012433 www.iosrjournals.org 24 | Page

There is no significant difference between the rates of post operative complications, incidence of fever, and post operative pain perception between both groups.

The incidence of pelvic collections may be higher in closed group, but this does not translate into complications. Even though there is a theoretical advantage of earlier detection of vault recurrence of various malignancies, in our study we couldn't find any significant advantage in the time to detect vault recurrence in the open vault method group.

Key Word: vault closure, pelvic cancers, hysterectomy, open vaginal vault, gynaecologic malignancies, seroma, vaginal infection

Date of Submission: 24-11-2023 Date of Acceptance: 04-12-2023

I. Introduction

Hysterectomy is the most commonly performed Gynaecologic surgical procedure around the globe ¹. It is also recognized as one of the most frequently performed major surgical operations. Therefore, effective methods to improve the surgical technique of hysterectomy with the goal of optimizing health, reducing hospital costs and decreasing morbidity and mortality of every woman undergoing hysterectomy should be considered. Fibroid uterus is the most common indication for abdominal hysterectomy while other indications are Malignancy, Endometriosis, Abnormal uterine bleeding, Pelvic inflammatory disease, Hysterectomy as a part of benign ovarian cyst removal and Uterine Prolapse. ²

The surgical technique of hysterectomy may include either open or a closed vaginal cuff. It is the surgeon's preference whether open cuff or closed cuff method technique is used. At present, there are no standard recommendations or guidelines regarding management of vaginal cuff following hysterectomy.

Some Advantages and Disadvantages of Both Techniques:

The classical method of abdominal hysterectomy allows retroperitoneal drainage to occur through an open vaginal cuff method. Open vaginal cuff reduces the development of pelvic hematoma and decreases the risk of infection³. If the vaginal cuff is left open, the incidence of postoperative pelvic abscess is dramatically reduced⁴. But there is always a risk for organ prolapse through the vault¹⁴.

However, some surgeons prefer closed vaginal cuff technique. Proponents of this method consider that closed vault method eliminates peritoneal contamination by vaginal flora, thereby decreasing the incidence of vaginal vault infection and peritoneal or ascending infection and hence decreasing duration of hospital days³.

II. TECHNIQUE OF VAULT CLOSURE IN CLOSED METHOD⁵:

- Before transection of the vagina, the inferior most level of the cervix is palpated and a curved artery forceps / Heaney clamp is applied across the vagina from both sides. The vaginal tissue above the level of these clamps is transected and specimen is removed.
- Transfixing sutures are placed below the clamps and then the clamps are removed.
- Upward and lateral traction of these sutures by leaving a long end, helps to elevate the vaginal cuff.
- The full thickness of the anterior and posterior incised vaginal walls are then reapproximated with a running suture line using a delayed absorbable 0 gauge suture or using 'Figure of 8' sutures.
- The peritoneum overlying the posterior vaginal margin is included in this closure to reduce the risk of postoperative oozing. Anteriorly, the bladder should be kept clear of the suture line.

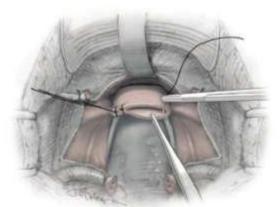


Fig 1 – Technique of Vault Closure

III. OPEN VAGINAL VAULT METHOD⁶:

In the classical technique, Straight Ochsner clamps / Curved artery forceps are applied to the anterior vaginal mucosa, the lateral angles of the vagina, and the uterosacral ligaments. One lateral corner of the vaginal dome is closed with a Vicryl 1-0 suture with the stitch passing from front to back through the anterior vaginal mucosa, back out through the lateral aspect of the mucosa, transfixing the stump of the cardinal ligament, brought again through the lateral aspect of the mucosa and back out posteriorly. The suture is then tied. The opposite lateral corner of the vaginal dome is closed in a similar manner. Both corners are then tagged to ensure hemostasis and held in traction. The remainder of the vaginal dome is allowed to remain open. Some surgeons prefer not to suture the corners also and leave the entire vagina open.

In our technique, bilateral Round ligaments, Anterior and Posterior leaves of Broad Ligaments, Infundibulo-Pelvic ligaments, Uterine artery Pedicle and Cardinal Ligaments and UV fold of peritoneum are all taken down by energy source and vault is opened and Hysterectomy is completed with Ligasure energy source.

IV. REVIEW OF LITERATURE:

Many methods to close the vault have been described in surgical textbooks. Till now there is no consensus whether to leave the vault open or to suture close it or to suture the vaginal angles alone, especially in hysterectomies performed for gynaecologic malignancies. Some studies were performed to compare the open and closed vault techniques in respect to post operative complications and length of hospital stay and operating time.

- Aharoni et al⁷ studied 100 patients who underwent simple hysterectomy for benign causes, with 50 patients undergoing the procedure with open technique and 50 patients with closed technique. The authors demonstrated that, the Open vaginal cuff method had a significantly longer operative time than the closed method, due to the need to achieve accurate hemostasis. In this study, the visceral peritoneum was also closed. The closed method was associated with an increased incidence and size of pelvic fluid collections than the open method. However the length of hospital stay and incidence of complications were similar in both arms.
- M Neuman et al⁸ evaluated the effect of open vaginal vault in reducing postoperative febrile morbidity after hysterectomy. No significant differences were observed between the open and closed vaginal cuff methods.
- M Moustafa et al⁹, randomised 53 women undergoing vaginal hysterectomy into two groups, with one group undergoing closed technique after hysterectomy and another group undergoing open method. There were no statistically significant differences observed in the incidence of vault haematoma, fever, haemorrhage and urinary tract infections. Prolapse of fallopian tube was noted in one patient in open method.
- Jimmy A Billod et al¹⁰ randomized 88 women undergoing hysterectomy to either open or closed method. There were no significant differences in terms of Hospital stay, Length of operating time and incidence of postoperative complications.
- A german study, by Nagele et al¹¹, compared the postoperative course in 127 patients undergoing abdominal hysterectomy who were randomly assigned to either staple closure of the vaginal cuff or open method. 2 patients in the open method had to undergo later laparotomies due to adhesions between the bowel and vault mucosa.
- JK Lodhi et al¹² in Pakistan, randomized 100 people undergoing laparoscopic hysterectomy to either closure of vault with Intracorporeal 1 Vicryl sutures or leaving vault open. The authors concluded that there is no significant differences in both groups with regards to Vaginal dehiscence and other postoperative complications like bleeding, pelvic haematoma, UTI, port site infections etc. No difference was also found in the incidence and degree of postoperative pain in both groups.
- Colombo et al¹³, randomized 273 patients undergoing elective abdominal hysterectomy for benign lesions into two groups one with a closed vaginal vault with two layers of continuous 3-0 polyglactin suture versus open vaginal vault. No statistically significant differences were observed between both methods in terms of operating time and hospital stay and postoperative complications. The authors concluded that a careful and meticulous surgical technique and antibiotic prophylaxis remain the most important factors in preventing postoperative morbidity.
- Another Asian study by A P Malla et al¹⁴ in Nepal, also demonstrated that there was no significant differences between both the techniques and hence couldn't recommend a definitive technique based on statistical superiority.
- In a randomized study by Tsafrir et al¹⁵ in 2017, the outcomes of different vaginal closure techniques in robotic assisted hysterectomies was compared and no significant differences were observed.
- All the currently available literature compared the two techniques for hysterectomies performed for benign lesions only. None of the studies reported the histopathological analysis of their hysterectomy specimens

DOI: 10.9790/0853-2212012433 www.iosrjournals.org 26 | Page

and hence we could not analyse whether their studies included invasive/ in situ malignancies. Also we could note that in some of the studies, Diagnosis of a malignancy was an exclusion criteria.

- Also, the two techniques and their effect on post operative complications were compared for minimally invasive procedures like Laparoscopic Hysterectomy and even between Laparoscopic and Robotic Hysterectomy. But none of the studies evaluated the same for Gynaecologic malignancies.
- There are even studies comparing different suture materials for vaginal cuff closure and different surgical techniques for the same.
- Hence we decided to proceed with this study of ours in which both techniques would be compared and analysed following surgery for Gynaecologic malignancies.

V. Material And Methods

Study Centre: Govt. Arignar Anna Memorial Cancer Hospital, Karapettai, Kanchipuram.

Period of the study: July 2020 to July 2023

Study design: Retrospective study

Sample size: All the patients who underwent elective surgery for gynaecologic malignancies, satisfying our devised Inclusion Criteria. All the patients were registered in our institutional Multidisciplinary Tumor Board and treatment was initiated according to Institutional guidelines.

INCLUSION CRITERIA:

- Patients of age >18 years and undergoing elective surgery (in which Hysterectomy is a part) for Gynaecologic malignancies (Carcinoma Ovary/Endometrium/Cervix Uteri)
- Patients who have already received Radiotherapy/ Chemotherapy prior to the procedure.

EXCLUSION CRITERIA:

- Patients undergoing surgeries for recurrent malignancies (Pelvic Exenteration)
- Patients in whom the uterus had already been removed earlier for some other disease process.
- Patient undergoing fertility sparing procedures in whom the uterus was not removed.
- Patients who fit into our study were divided into two groups based on whether their vaginal vaults were closed or left open during the procedure. Since this is a retrospective study, there was no randomization followed to divide the patients into above two groups. At the time of surgery, it was the operating surgeon's discretion to follow either of the techniques. The choice of suture material was also at the operating surgeon's technique, but most commonly 1-Vicryl was used.
- All patients received prophylactic IV antibiotics 3rd generation Cephalosporins.
- All patients received prophylactic unfractionated Heparin 5000U s.c BD for three days after surgery and they were mobilized on the evening of surgery.
- For all uncomplicated cases, clear liquids were started on the evening of the day of surgery and diet was gradually increased based on the patient's progression.
- For all uncomplicated cases, Foley's catheter was removed on POD-1.
- All patient's vital signs including temperature were monitored hourly and any rise in temperature was documented.
- The patients were further sub- classified according to the site of the primary tumor namely Endometrium/Ovary/Cervix.
- Patients were also stratified according to age, grade of tumor and whether they had undergone upfront surgery or surgery after prior Radiotherapy/ Chemotherapy.
- The advantages and disadvantages of both techniques were analyzed in terms of;
- Operating time
- Post operative Pain
- Post operative Vaginal Discharge

Incidence of Post Operative complications:

- -Pelvic Haematoma
- -Pelvic Abscess
- -Wound Dehiscence
- -Vaginal Vault Dehiscence
- -Ascending Infection etc
- Post operative pain was analyzed using the Visual Analog Scale.
- Pelvic Haematoma was routinely screened for on POD 3, using transvaginal sonography technique and if present, its volume was calculated. All the imaging were done by a single radiologist to maintain validity.

- The occurrence of Ascending Infections, Febrile complications and Pelvic Abscess were strictly screened for using Total Leucocyte count and Differential Count measurements on POD 1, POD 4 and comparison with preoperative values. Vaginal swabs and blood cultures were taken when necessary. All investigations were done in our Institutional laboratory with qualified personnel.
- Also, both groups of patients were followed up as per institutional protocols to detect recurrences.
- First 6 months Monthly; then 3 monthly for 2 years; followed by 6 monthly. Follow up was continued even if the patient developed recurrence and was given other treatments (Chemo/Radiotherapy).
- If they do developed recurrence, it was also assessed whether the recurrence was detected earlier and easier with clinical examination in Open vault method.

Statistical analysis:

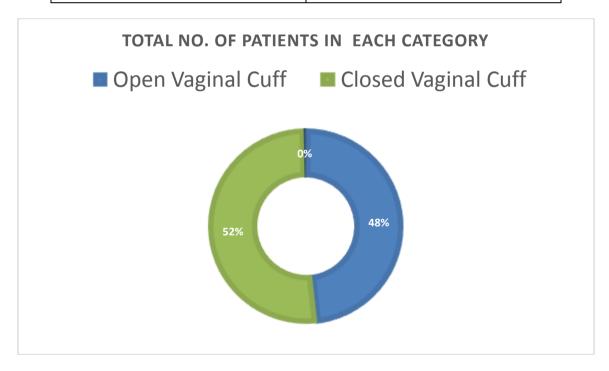
The independents sample t test was used to compare differences between continuous variables namely age, operating time and length of hospital stay. Statistical tool used to compare pelvic hematoma and other complications was the Chi-square test on two proportions. A p value of <0.05 was considered significant.

VI. Result

• Between July 2020 and July 2023, a total of 457 patients were included in our study after applying the devised inclusion and exlusion criteria. Out of which, open vaginal cuff technique was performed in 221 patients and closed cuff method in 236 patients.

Table 1 – Total no. of patients in each category

TECHNIQUE	NUMBER OF PATIENTS
Open vaginal cuff	221
Closed vaginal cuff	236
Total	457



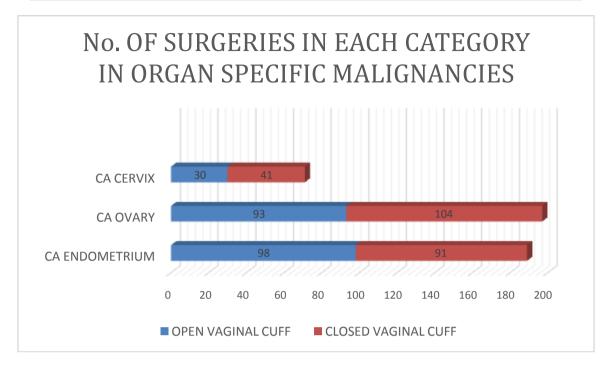
• Of the 457 surgeries, 189 procedures were performed for Carcinoma Endometrium, while 197 procedures were performed for Carcinoma Ovary and 71 procedures were performed for Carcinoma Cervix. Number of surgeries in each category followed in each organ specific malignancies are given below.

Table 2 – No. of surgeries in each category in organ specific malignancies

SNO	ORGAN OF PRIMARY MALIGNANCY	TOTAL	OPEN VAGINAL CUFF	CLOSED VAGINAL CUFF
1	Endometrium	189	98	91
2	Ovary	197	93	104

DOI: 10.9790/0853-2212012433 www.iosrjournals.org 28 |

3	Uterine Cervix	71	30	41
	Total	457	221	236



Mean age of the patients in Open vaginal cuff method was 51 years and in Closed vaginal cuff method was
 51.3 years. (No statistical difference)

Table 3 – Mean age in both categories

SNO	CATEGORY	MEAN AGE (In years)
1	Open vaginal cuff	51
2	Closed vaginal cuff	51.3

The following tables presents the number of cases with comorbidities in each categories in individual malignancies.

Tables 4 & 5 – Incidence of Co-Morbidities

OPEN VAGINAL CUFF METHOD:

SNO	ORGAN OF PRIMARY MALIGNANCY	TOTAL NUMBER OF PATIENTS	DIABETES MELLITUS	HYPERTENSION	HEART DISEASE	OTHERS(ASTHMA, KIDNEY DISEASE, SEIZURES etc.)
1	Endometrium	98	32(32.65%)	34(34.69%)	5	9
2	Ovary	93	24(25.8%)	27(29%)	4	7
3	Uterine Cervix	30	8(26.66%)	4(13.33%)	2	4
	Total	221	65(29.4%)	65(29.4%)	11(4.97%)	20(9.04%)

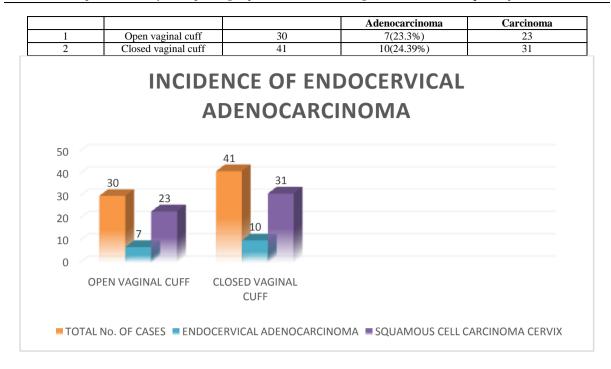
CLOSED VAGINAL CUFF METHOD:

	SNO	ORGAN OF PRIMARY MALIGNANCY	TOTAL NUMBER OF PATIENTS	DIABETES MELLITUS	HYPERTENSION	HEART DISEASE	OTHERS(ASTHMA, KIDNEY DISEASE, SEIZURES etc.)
ſ	1	Endometrium	91	37(40.65%)	39(42.85%)	7	11
ſ	2	Ovary	104	21(20.19%)	28(26.9%)	11	16
	3	Uterine Cervix	41	9(21.95%)	4(9.75%)	3	2
ſ		Total	236	67(28.3%)	71(30.08%)	21(8.89%)	29((12,2%)

• Of the cases performed for carcinoma cervix, In open Vaginal Cuff method, 7 cases were Endocervical Adenocarcinoma and in Closed method, 10 cases were Endocervical Adenocarcinoma.

Table 6 – Incidence of Endocervical Adenocarcinomas.

SNO Category	Total no. of cases	Endocervical	Squamous Cell
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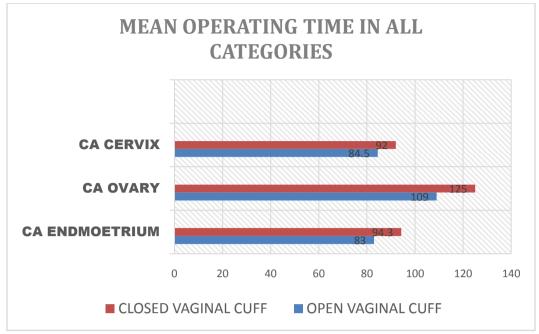


- Of all the Carcinoma Endometrium cases 11 cases (11.22%) in the Open method were Poorly differentiated endometroid carcinomas and 5 cases (5.10%) were Uterine Sarcomas and 15 cases(16.4%) in the Closed method were Poorly differentiated endometroid carcinomas and 4 cases(4.39%) were Uterine Sarcomas.
- Of all the cases of Carcinoma ovary, only 4 cases (4.3%) in the Open method group and 3 cases (2.88%) in the Closed method were upfront candidates for surgery. Rest all cases were taken up after Chemotherapy (Interval Cytoreduction). All the cases were serous papillary tumors.

The following table shows the mean operating time in all categories:

Table 7 – Mean operating time in all categories

SNO	Category		Operating time	Category		Operating time
1	OPEN VAGINAL CUFF	Endometrium	83 mins	CLOSED VAGINAL CUFF	Endometrium	94.3 mins
2		Ovary	109 mins		Ovary	2 hours and 5 mins
3		Uterine Cervix	84.5 mins		Uterine Cervix	92 mins

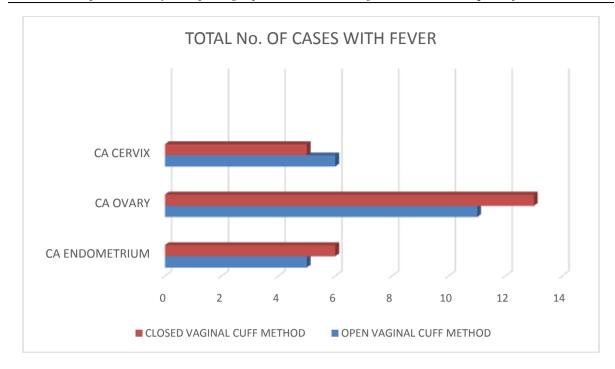


- The slightly higher operating time in Closed vaginal cuff method was not statistically significant.
- There was no significant differences observed in the perception of post operative pain in both categories.
- All patients reported a serosanguinous to serous vaginal discharge for a few days following open vaginal vault method.
- There was not a single case with organ prolapse through vault in either groups.

The following table represents the incidence of fever in both groups (>38.4 degrees);

Table 8 – Incidence of fever in both groups

SNO	Category		Total no of cases with fever	Category		Total no of cases with fever
1	OPEN VAGINAL CUFF	Endometrium (98)	5 (5.10%)	CLOSED VAGINAL CUFF	Endometrium(91)	6 (6.5%)
2		Ovary (93)	11 (11.8%)		Ovary(104)	13 (12.5%)
3		Uterine Cervix (30)	6 (20%)		Uterine Cervix(41)	5 (12.19%)



- All were monitored with Total Count, in case of raising trends, Blood cultures and swab were done. All cases settled with conservative management.
- On Ultrasonography, sonoluscency due to the presence of fluid in the vicinity of the vault was observed in 47 patients(21.26%) in the Open method and 31 patients(13.31%) in the closed method. But none of the patients experienced any complication/symptoms due to fluid collection.
- There was no other significant differences in the incidence of any other post operative complications like Vault Dehiscence, Organ Prolapse, Ascending Infection etc. This was similar irrespective of the grade of the primary malignancy, histology and whether surgery was performed Upfront or after Chemo/Radiotherapy.
- On regular follow up, none of the cases of Carcinoma Endometrium developed recurrence. 21 cases of carcinoma ovary in the Open vaginal vault method and 18 cases in the Closed method developed vault recurrence. 1 case of carcinoma cervix developed recurrence in both open and closed methods.

Table 9 – Incidence of Recurrence

SNO	MALIGNANCY	NO OF PATIENTS DEVELOPING RECURRENCE		
		OPEN METHOD	CLOSED METHOD	
1	ENDOMETRIUM	NIL	NIL	
2	OVARY	21(22.5%)	18(17.3%)	
3	CERVIX	1(3.33%)	1(2.43%)	
	TOTAL	22(9,95%)	19(8.40%)	

Average time interval to develop recurrence was similar in both groups.

Open Method - 243 days Closed Method- 239 days

Thus Most of the cases of recurrence in carcinoma ovary was classified as Platinum sensitive recurrence only.

VII. Discussion

- Carcinoma cervix was the malignancy for which the least number of hysterectomies were performed, reflecting the difficulties in detecting the disease in its earlier stages for which upfront surgery (Wertheim's Hysterectomy) can be performed.
- Carcinoma endometrium has the highest number of patients with co-morbidities, which is confirmatory of the strong association between endometrial cancer and metabolic diseases.
- The low number of ovarian malignancies taken up for upfront surgery, is due to the fact the most common stage of presentation of ovarian carcinoma is FIGO Stage IIIC, for which upfront surgery is not indicated, rather Neoadjuvant Platinum based chemotherapy is given, following which response of the disease is assessed and only then cytoreduction is done.

- There was no significant difference in any post-operative complications in both methods, implying that it is meticulous surgical technique, proper case selection, accurate hemostasis, vigilant post-operative care and preoperative optimization of the patients are the major determinants of incidence of post operative complications in gynaecologic malignancies.
- These observations reflect the results of most of the other studies done in hysterectomies performed for benign reasons.
- In the closed vault technique, recurrences occurring at the vault may get buried inside the two layers of the vault mucosa and hence are detected later. But in our study, in both groups, recurrences were detected at similar intervals, probably due to the fact that all patients were followed up by qualified oncologists with accurate clinical examination.

VIII. Conclusion

There is non-significant difference in Operating time between the two methods, with a shorter operating time in Open method. Pain Perception and incidence of Post operative fever and other complications were similar in both groups. Though the incidence of serous/serosanguinous vaginal discharge may be higher in Open vaginal cuff method, it is not particularly distressing to the patient, especially if counselled by the operating surgeon. The incidence of Vault Collections is higher in closed vaginal cuff group, but this does not seem to translate into increased risk of pelvic infections/sepsis.

Though there is a theoretical advantage of earlier detection of vault recurrences in the Open vaginal cuff method, in our study we couldn't find any significant difference in the time to detect recurrence in both groups.

IX. LIMITATIONS AND RECOMMENDATIONS:

This is a single centre, retrospective study. To validate the outcome of the study, multicentre prospective studies with increased sample size and analysis with surgeons performing different techniques is needed.

Conflict of Interest:

The authors declare that there is no conflict of interest with any party related/unrelated with this study/ general patient care.

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