IOSR Journal of Dental and Medical Sciences (IOSR-JDMS)
e-ISSN: 2279-0853, p-ISSN: 2279-0861.Volume 20, Issue 5 Ser.2 (May. 2021), PP 34-40
www.iosrjournals.org

An Observational Study Showing Vaginal Cleansing Before Cesarean Delivery Reduces Postoperative Morbidity and Mortality

Dr. Kajal Kumar Patra[1*], Dr Bibekananda Das[2*], Dr. Kaustav Halder[3]

1. *Professor, Dept of Obstetrics and Gynecology, Gouri Devi Institute of Medical Science, Durgapur, West Bengal*
2. *Associate Professor, Dept of Obstetrics and Gynecology, Burdwan Medical College and Hospital, Burdwan, West Bengal*
3. *PGT, Dept of Obstetrics and Gynecology, Burdwan Medical College and Hospital, Burdwan, West Bengal.*

** Corresponding Author: Dr Kajal Kumar Patra*
Professor, Dept of Obstetrics and Gynecology Gouri Devi Institute of Medical Science
GT Road, National Highway 2, Rajbandh, Durgapur, West Bengal 713212

Abstract
Introduction: *Cesarean delivery is one of the most common surgical procedures performed by obstetricians. Infectious morbidity after cesarean delivery can have a tremendous impact on the postpartum woman's return to normal function and her ability to care for her baby. Despite the widespread use of prophylactic antibiotics, postoperative infectious morbidity still complicates cesarean deliveries.* ***Objective:*** *The present study was conducted to observe whether cleansing the vagina with a povidone iodine solution before caesarean delivery decreases the risk of maternal infectious morbidities including endometritis and wound complications.* ***Methodology:*** *A interventional study was carried out among 100 women undergoing Cesarean section in the department of Obstetrics & Gynaecology, Burdwan Medical College & Hospital, Burwan during February 2019 to January 2020. Collected data was complied in pre-designed proforma and analysis was done using SPSS 20.0.* ***Result:*** *It was observed that mean age group of the patients was around 25 in both the groups. The mean gestational age of the fetus were 37.50 and 37.58 with a median value of 38 and 37 in the control and test group respectively. Mean surgical time were 45 minutes and 43.70 minutes with a median value of 45 and 40 in the control and test group respectively.* ***Conclusion:*** *The present study shows that pre operative vaginal scrubbing with povidone iodine before cesarean section reduces the post operative infective morbidities.*

Key words: *Observational Study, Vaginal Cleansing, Cesarean Delivery, Morbidity and Mortality*

Date of Submission: 29-04-2021 Date of Acceptance: 13-05-2021

I. Introduction:

Cesarean delivery is one of the most common surgical procedures performed by the obstetricians; Infectious morbidity is the most frequent complication of this operation and can have a tremendous impact on postpartum woman's health and her ability to care for her baby. During and after the procedure, the uterus is open to the vagina, specifically when the cervix is dilated. In many cases, the surgeon's hand, reaching below the infant's head or presenting part, is in direct contact with the vagina. Vaginal bacterial flora ascends directly to the uterus, abdominal cavity, and the abdominal incision. During cesarean section Cleansing of all body surfaces that could be in contact is the mainstay of asepsis. Although antiseptic dressing of the body surface does not always actually result in a sterile field, it may minimize the presence of bacterial organisms normally present on skin and mucous membrane, but ascending inoculation by vaginal bacterial flora are the causative organisms in most of the cases, also responsible for failure of antibiotic prophylaxis during cesarean deliveries, which may lead to development of resistant organisms following surgical prophylaxis. Post cesarean endometritis, up to ten times more frequent in cesarean deliveries, can cause serious complications such as bacteremia, peritonitis, intra abdominal abscess and sepsis. Caesarean deliveries are also associated with wound complications such as seroma, hematoma, infection and separation, leading to significant pain and discomfort, delay in a return to normal function, longer hospital stay, and possible readmission. Postpartum febrile morbidity is associated with PROM, prolonged labour, and multiple and frequent vaginal examinations.

There are two pathways for these infections, one being the polymicroorganisms of cervix and vagina ascending into the uterus and another with haematogenous spread through exposed edges of incised

myometrium .There is evidence in the literature to support the use of preoperative vaginal scrub with povidone-iodine before hysterectomy to decrease the incidence of postoperative infectious morbidity.[1] Vaginal scrub with povidone iodine may decrease the quantitative load as well as removal of vaginal microorganisms, may be considered as a prophylactic measure to reduce post caesarean infectious morbidity but there is limited information in the literature regarding this issue.[2]

Despite the widespread use of prophylactic antibiotics, postoperative infectious morbidity still complicates cesarean deliveries. Endometritis, an infection of the uterus in the postpartum period, can complicate the postoperative course of a cesarean delivery 6% to 27% of the time.[3,4]

Haas DM et al suggested a rate of wound infection of 97 per 1000 and 68 per 1000 for emergency and elective caesarean section, respectively; for endometritis the rates were 184 per 1000 versus 39 per 1000.[5]

Surgical site infections are infections of the incision, organ or space after a procedure and are responsible for infections in patients undergoing surgery. This complication is about 10 times more common when compared with vaginal delivery and can lead to sepsis.[6,7]

In this observational control study, we observed that vaginal preparation with povidone iodine scrub before a cesarean delivery will decrease the incidence of postoperative endometritis, wound infection, and overall postoperative febrile morbidity. Our objective is to observe whether vaginal preparation with 5 % povidone iodine before caesarean section would reduce the rates of fever or other postoperative infective symptoms. The primary outcome will be a composite of postoperative fever, sepsis, endometritis readmission, wound infection, separation .In addition, data will also be collected (where available) on adverse events of treatment, the number of postoperative days with fever and other complications, need for additional antibiotic administration, length of stay and any adverse infant outcomes.

II. Methodology:

Study Area *:* Department of Obstetrics & Gynaecology of Burdwan Medical College & Hospital, a tertiary teaching institute after approval of the study by the ethical committee.

Study Population : 100 women undergoing Cesarean section in the department of Obstetrics & Gynaecology

Sample Size : Sample size estimation was done based on a 10% absolute difference in fever rate between the two study groups, assuming 15% fever incidence in control group and 5% in povidone iodine group. It was estimated that 45 subjects would be required per group in order to detect such a difference with 80% power and 5% probability of type I error. Assuming a 15% non-evaluable record rate, the recruitment target is being kept at 50 subjects per group.

Inclusion criteria: The study will be open to all pregnant women who will undergo caserean section and must have these following criteria:

a. mother's age must be above 18 years

b. can give valid informed consent.

Exclusion criteria: Exclusion from enrollment for the study was related solely to

1. medical contraindications to the vaginal preparation required for the trial
2. highly emergent caesarean section like active eclampsia, coed prolapse etc
3. planned cesarean hysterectomy
4. allergy to povidone iodine, iodine, or shellfish
5. bleeding placenta previa
6. active genital herpes.

Counseling and consent forms will be available in both Bengali ,Hindi and English.

Study Period : February 2019 to January 2020, a period of 12 months.

Study Type*:* interventional, i.e in this study the participants received a kind of intervention, povidone iodine for protection against post operative complications

Study Design: Prospective observational controlled study, i.e it is a longitudinal cohort study follows over a period of time and involves a group of patients differ with repect to certain factors under study and in this study the patients are observed for the outcomes to be measured.

Once informed consent is obtained from the patients, subjects will be randomly assigned to any one of the 2 groups.

Intervention group: The vaginal scrub will consist of 3 sponge sticks soaked in 5% povidone iodine. The vaginal scrub would encompass the vaginal apex to the introitus with attention to the anterior, posterior, and lateral walls including all fornices.

Control group: The control group will receive the standard abdominal scrub, only, without the vaginal preparation with povidone iodine.

Ethical Considerations: The study was conducted only after obtaining due ethical clearance from the Institutional Ethical Committee of BMCH. Informed and written consent was taken from all participants before enrolment in the study.

The statistical software SPSS version 20 has been used for the analysis. An alpha level of 5% has been taken, i.e. if any p value is less than 0.05 it has been considered as significant.

III. Results:

It has been seen that mean age group of the patients recruited for the study was around 25 in both the groups with median of 24 and 25 in the control and test group respectively showing no statistical significance. P value 0.328. It was further subdivided into three groups, i.e. from 18-20, from 21-30 and from 31-40 years of age. Most of the patients lied in the age group of 21-30 years of age.

The mean gestational age of the fetus were 37.50 and 37.58 with a median value of 38 and 37 in the control and test group respectively. It has been seen that most of the patients were in the group p1+0, 53%, probably due to abundant numbers of post cesarean pregnancy.

Mean pre cesarean haemoglobin of the subjects were 10.37 and 10.31 with a median value of 10.20 and 10.15 in the control and test group respectively showing no statistical significance. P value 0.534. Mean body mass index of the patients were 21.91 and 22.09 with a median value of 21.75 and 22 in the control and test group respectively showing no statistical significance. P value 0.650. Patient's blood glucose level was also a matter of interest in our study. It has been seen that only 6 % patients having biochemically proven diabetes mellitus or impaired glucose tolerance during the time of delivery. **(Table-1)**

Table 2 shows that in parameters like Age, AGA, Parity, IND and Labour difference between control and test group are not statistically significant. All patients under this study received prophylactic injectable antibiotic (inj ceftriaxone 1gm iv) hence there is no difference between two groups. In blood loss and post partam tubal ligation difference between control and test group are also not statistically significant.

Patients developed post operative fever (more than 100.4 deg F, for more than 24 hrs) in both test and control group. It has been seen that the occurrence of post operative fever is as much higher in the control group that it is statistically significant. Various wound infections like seroma ,haematoma, discharge in both groups It has been seen that the occurrence of post operative wound infections are as much higher in the control group that it is statistically significant. Incidence of wound separation in both groups It has been seen that the occurrence of post operative wound separation is as much higher in the control group that it is statistically significant.

Table 3 demonstrates a figure of composite co morbidities including all the post operative infective complications classified under these two groups. All the post operative infective parameters occurs more in the control group and of them occurrence of fever, wound infection and separation are statistically significantly lower in the test group.

IV. Discussion:

In this study we recorded all the patient parameters, including all the demographical and labour events of the patient. Demographical parameters include: age, gestational age, parity, status of pre and post-operative anaemia, obesity and labour events include dilatation of cervix and time since rupture of membranes and P/V examinations. Surgical time, amount of blood loss, status of PPL and post-operative hemoglobin are also recorded in the study. Different post-operative infective parameters including fever, endometritis, wound separation, wound infection, need for additional antibiotic, need for readmission, total number of days staying at hospital were thoroughly recorded.

Intra Partam Parameters

It has been seen that only 15% patients were in the phase of active labour during the time of cesarean section, of them 8 patients were allocated in the test group not having any statistical significance. (p value: 0.401). this may be due to more cases of post cesarean section pregnancies.

Mean dilatation of cervix at the time of delivery were 3.24 and 3.2, wherever applicable, with a median value of 2.00 in the control and test group respectively showing no statistical significance. (p value: 0.687)

Mean time since rupture of membranes expressed in hours wherever applicable were 6.20 and 5.92 with median value of 6.00 (both) in the control and test group respectively showing no statistical significance. (p value:0.669)

Mean number of per vaginal examinations were 1.56 and 1.40 with a median value of 1.00(both) in the control and test group respectively showing no statistical significance. (p value: 0.454)

Surgical Parameters

In this study all the indications for cesarean delivery were recorded and classified into both test and control groups. It has been seen that most cases were due to post cesarean section pregnancies, a value of 32%, and next due to non progress of labour.

All patients received prophylactic injectable antibiotic (inj ceftriaxone 1gm) following the clamping of the cord).

Mean surgical time were 45 minutes and 43.70 minutes with a median value of 45 and 40 in the control and test group respectively showing no statistical significance. (p value:0.187).

We also kept record for any improvisations done during delivery of the fetal presenting part. It was seen that in 90% cases no such method was applied. In 7 % cases (4 in control and 3 in test group) application of vaginal hand thereby pushing the fetal head upwards, was incorporated whether in 3 % cases (1 in control and 2 in test group) forceps were applied. The value shows no statistical significance between test and control group (p value: 0.788)

Total approximate blood loss of the patient was recorded. In our study 96% patient's blood loss was within 500 ml only 4% patient's blood loss was more than 500 ml but within 1000 ml. The value shows no statistical significance between test and control group (p value:1.000)

Mean post cesarean haemoglobin of the subjects were 10.01 and 9.91 with a median value of 10.00 and 9.95 in the control and test group respectively showing no statistical significance. P value: 0.475.

In total 32% cases post partam tubal ligation was done, 18 cases were in the control and 14 cases were in the test group. The value shows no statistical significance between test and control group (p value: 0.391)

Post Operative Parameters

In our study all patients received standard post operative antibiotic prophylaxis. But among them 11% patients needed additional antibiotic therapy due to their infective post operative period. Of them 7 patients were in the control and 4 patients were in the test group. The value shows no statistical significance between test and control group (p value: 0.338)

This study shows that total 13% patients developed post operative fever, of them only 2 patients were in the test group and the rests were in the control group. ***The value shows statistical significance between test and control group (p value: 0.007).***

This study demonstrates only 3% patients developed post operative endometritis, i.e, uterine tenderness, foul smelling lochia, fever, all lying into the control group. No patient in the test group developed such symptom. The value shows no statistical significance between test and control group (p value: 0.242)

We have seen that total 14% patients developed post operative wound infection in the form of seroma, hematoma, discharge(most common), of them12 patients were in the control group and only 2 patients were in the test group. ***The value shows statistical significance between test and control group (p value: 0.004)***

This study shows that total 19% patient developed post operative wound separation. Of them only 4 patients were in the test group and rest 15 were in the control group. ***The value shows no statistical significance between test and control group (p value: 0.005)***

The mean number of days staying in hospital was 6.68 and 6.44 with a median value of 6.00 (both) in the control and test group respectively showing no statistical significance. p value: 0.287

Among all the patients 4% patients needed readmission, and of them 3 were in the control and 1 was in the test group. The value shows no statistical significance between test and control group (p value: 0.617)

Comparison of this study with other studies

study name	endometritis		Fever		Wound infection		Sample size	Test cohort
	T	C	T	C	T	C		
Present	0	3	2	11	2	12	100	50
Charoenviboonphan, 2011[8]	0	8	34	93	1	4	599	299
Mohamed, 2015[9]	6	16	10	23	5	9	200	100
Haas, 2010[5]	0	4	2	7	7	10	300	155
Barat, 2016[10]	11	15	10	14	12	13	400	200
Pitt, 2001[11]	8	19	15	21	5	3	224	112

This study shows that post operative complications are much reduced after application of povidone iodine vaginal scrub. Some of the parameters also showed statistically significant values although there are chances of bias in the result due to some simultaneously operating co factors, hence some of the values might be over diagnosed or under diagnosed. Adequately powered and well equipped study is required to eliminate all these co factors to remove the biased data.

Limitations of the study

The main advantage of the study was that there was no drop out. There were some limitations of this study.

- More than half of the subjects were not in labour at the time of the caesarean section, many of the caserean section was due to post CS pregnancy. So relation of labour events with post operative infections were not properly justified.
- In our setup post operative patients did not maintain a good hygienic environment to herself and her baby, contributing more chances of wound infection despite receiving adequate post operative antibiotic prophylaxis, may be a probable cause of more cases of wound separation and wound infection than the other studies.
- There are many other reasons for post cesarean fever, such as breast engorgement or breast abscess, or any other systemic infections which are non uterine in origin, causing bias in the results, thereby creating more cases of post operative fever comparing to other studies.
- many cases of endometritis does not present with the classical triad of foul smelling lochia, fundal tenderness or fever from the first post operative day. So chances of missed cases of endometritis may be there. Many post op cases of endometritis may be lost due do development of symptoms after being discharged.
- Women needed re admission for post operative cases may not present to the same facility although being thoroughly counseled, so many cases with having need for re admission may be lost and under diagnosed.

V. Conclusion& Recommendations:

In this observational study we conclude that pre operative vaginal scrubbing with povidone iodine before cesarean section reduces the post operative infective morbidities. Some of the values were statistically significant, some were not. There might be chances of bias due do simultaneously acting co factors during data collection, for which the study procedure hampers a bit. Adequately powered and well equipped studies may reduce these factors resulting more appropriate results.

Acknowledgements

Authors would like to acknowledge all the patients who participated in this research study.

Funding: No funding sources
Conflict of interest: None declared
Ethical approval: The study was approved by the institutional ethics committee

Table: 1 : Demonstrates all the patient parameters, including all the demographical and labour events of the patient.

Demographical parameters include: age, gestational age, status of pre and post operative anaemia, obesity and labour events include dilatation of cervix and time since rupture of membranes and P/V examinations. Surgical time and number of days staying in hospital are also depicted in this table

	Povidone Iodine Vaginal Scrubbing							
	No			Yes				
	Mean	Median	Std. Deviation	Mean	Median	Std. Deviation	p Value	Significance
AGE	24.26	24.00	2.73	25.28	25.00	3.87	0.328	Not Significant
AGA	37.50	38.00	1.62	37.58	37.00	1.51	0.924	Not Significant
Pre Caesarean Haemoglobin	10.37	10.20	0.77	10.31	10.15	0.78	0.534	Not Significant
BMI	21.91	21.75	1.80	22.09	22.00	2.00	0.650	Not Significant
Dilatation of The Cervix Expressed In Cm	3.24	2.00	2.00	3.21	2.00	1.94	0.687	Not Significant
Time since the rupture of membrane expressed in hours	6.20	6.00	2.29	5.92	6.00	2.47	0.669	Not Significant
Number of per vaginal digital examination	1.56	1.00	1.05	1.40	1.00	0.93	0.454	Not Significant
SUR.TIM	45.00	45.00	6.55	43.70	40.00	6.04	0.187	Not Significant
Post HB	10.01	10.00	0.67	9.91	9.95	0.76	0.475	Not Significant
Days	6.68	6.00	1.28	6.44	6.00	1.26	0.287	Not Significant

Table 2 : Distribution of patients according to Povidone Iodine Vaginal Scrubbing

		Povidone Iodine Vaginal Scrubbing		Total		
		No (%)	Yes (%)		p Value	Significance
Age	18-20	7(14)	5(10)	12(12)	0.134	Not Significant
	21-30	43(86)	41(82)	84(84)		
	31-40	0(0)	4(8)	4(4)		
AGA	34-37	24(48)	29(58)	53(53)	0.316	Not Significant
	38-41	26(52)	21(42)	47(47)		
Parity	P0+0	18(36)	20(40)	38(38)	0.133	Not Significant
	P1+0	28(56)	25(50)	53(53)		
	P2+0	4(8)	1(2)	5(5)		
	P3+0	0(0)	4(8)	4(4)		
Diabetes	NO	47(94)	47(94)	94(94)	1.000	Not Significant
	YES	3(6)	3(6)	6(6)		
IND	BOH	0(0)	1(2)	1(1)	0.263	Not Significant
	BREECH	4(8)	2(4)	6(6)		
	CPD	3(6)	3(6)	6(6)		
	ELD CPD	0(0)	1(2)	1(1)		
	HDP	0(0)	1(2)	1(1)		
	HDP IF	3(6)	3(6)	6(6)		
	IF	1(2)	3(6)	4(4)		
	IUGR	1(2)	6(12)	7(7)		
	MSL	4(8)	3(6)	7(7)		
	NPL	6(12)	4(8)	10(10)		
	OLIGO	1(2)	1(2)	2(2)		
	POST CS	21(42)	11(22)	32(32)		
	PROM	2(4)	1(2)	3(3)		
	REPT CS	3(6)	3(6)	6(6)		
	TRANSE	0(0)	4(8)	4(4)		
	TWIN BR	1(2)	3(6)	4(4)		
Labour	NO	41(82)	44(88)	85(85)	0.401	Not Significant
	YES	9(18)	6(12)	15(15)		
Pre-ANT	YES	50(100)	50(100)	100(100)	NA	NA
Method	FORCEPS	1(2)	2(4)	3(3)	0.788	Not Significant
	VAGINAL	4(8)	3(6)	7(7)		
	NONE	45(90)	45(90)	90(90)		
Bl. Loss	Below 500 ml	48(96)	48(96)	96(96)	1.000	Not Significant
	Between 500 to 1000 ml	2(4)	2(4)	4(4)		
Post Partam Tubal Ligation	NO	32(64)	36(72)	68(68)	0.391	Not Significant
	YES	18(36)	14(28)	32(32)		
POS ANB	YES	43(86)	46(92)	89(89)	0.338	Not Significant
	ADDITION	7(14)	4(8)	11(11)		
Fever	NO	39(78)	48(96)	87(87)	0.007	**Significant**
	YES	11(22)	2(4)	13(13)		
Endometritis	NO	47(94)	50(100)	97(97)	0.242	Not Significant
	YES	3(6)	0(0)	3(3)		

Wound Infection	NO	38(76)	48(96)	86(86)	0.004	**Significant**
	YES	12(24)	2(4)	14(14)		
Wound Separation	NO	35(70)	46(92)	81(81)	0.005	**Significant**
	YES	15(30)	4(8)	19(19)		
Re-Admission	NO	47(94)	49(98)	96(96)	0.617	Not Significant
	YES	3(6)	1(2)	4(4)		

Table 3 : *Composite co morbidities including all the post operative infective complications classified under two groups.*

	Povidone Iodine Vaginal Scrubbing			
Comorbidities	**No (%)**	**Yes (%)**	**p Value**	**Significance**
Fever	11(22)	2(4)	0.007	Significant
Endometritis	3(6)	0(0)	0.242	Not Significant
Wound Infection	12(24)	2(4)	0.004	Significant
Wound Separation	15(30)	4(8)	0.005	Significant
Re-Admission	3(6)	1(2)	0.617	Not Significant

References

[1]. Haeri AD, Kloppers LL, Forder AA, Baillie P. Effect of different pre-operative vaginal preparations on morbidity of patients undergoing abdominal hysterectomy. S Afr Med J 1976;50:1984 –6.

[2]. Reid VC, Hartmann KE, McMahon M, Fry EP. Vaginal preparation with povidone iodine and postcesarean infectious morbidity: a randomized controlled trial. Obstet Gynecol 2001;97:147–52.

[3]. Guzman MA, Prien SD, Blann DW. Post-cesarean related infection and vaginal preparation with povidone-iodine revisited. Primary Care Update for OB/GYNS 2002;9(6):206–9.

[4]. Smaill FM, Grivell RM. Antibiotic prophylaxis versus no prophylaxis for preventing infection after cesarean section.Cochrane Database of Systematic Reviews 2014, Issue 10. DOI: 10.1002/14651858.CD007482.pub3

[5]. Haas DM, Pazouki F, Smith RR, et al. Vaginal cleansing before caesarean delivery to reduce postoperative infectious morbidity: a randomized, controlled trial. Am J Obstet Gynecol. 2010; 202: 310.e1-6.PMid:20207251. https://doi.org/10.1016/j.ajog.2010. 01.005]

[6]. Shahneela Memon, Roshan Ara Qazi, Seema Bibi, Naheed Parveen,Effect of preoperative vaginal cleansing with an antiseptic solution to reduce post caesarean infectious morbidity,J Pak Med Assoc,Vol. 61, No. 12, December 2011 1,1179-1183

[7]. French LM, Smaill FM. Antibiotic regimens for endometritis after delivery. Cochrane Database Syst Rev. 2004; 2: CD001067.https://doi. org/10.1002/ 14651858. CD001067.pub2.

[8]. Charoenviboonphan P. Preoperative vaginal painting with 1% povidone-iodine before cesarean delivery to reduce postoperative febrile morbidity: a randomized control trial. Region 4-5 Medical Journal 2011; 30:117-214.

[9]. Mohammed HE, Hassan SI, Hemida R. Vaginal preparation with antiseptic solution before cesarean section for reducing post partum morbidity. *Journal of Nursing and Health Science.* 2015: 75-80.

[10]. https://pdfs.semanticscholar.org/e36c/d8a7b688d9ef87946b73a3be99060468bf34.pdf. Accessed 2021 April, 26.

[11]. Barat S, Bouzari Z, Ghanbarpour A, Zabihi Z. Impact of preoperative vaginal preparation with povidone iodine on post cesarean infection. Caspian J Reprod Med 2016;2:2–8.

[12]. Pitt C, Sanchez-Ramos L, Kaunitz AM. Adjunctive intravaginal metronidazole for the prevention of postcesarean endometritis: a randomized controlled trial. Obstet Gynecol 2001;98:745-50

Dr. Kajal Kumar Patra, et. al. "An Observational Study Showing Vaginal Cleansing Before Cesarean Delivery Reduces Postoperative Morbidity and Mortality."*IOSR Journal of Dental and Medical Sciences (IOSR-JDMS)*, 20(05), 2021, pp. 34-40.