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Original Research Article

The efficacy & safety of paracervical block with conscious sedation in surgical evacuation of early pregnancy

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Abstract

Background: Regional anesthesia is an easy, safe and has much less complications than General anesthesia especially in minor surgical procedures. This study is done to assess the safety & feasibility of Paracervical Block with conscious sedation in surgical evacuation of early pregnancy.

Materials & methods: Our study was a prospective observational study carried out in a tertiary care teaching center in Pune. Total of 119 patients were included in the study who had undergone surgical evacuation of first trimester pregnancy between Aug 2014 to July 2016. Patients were given 10 ml of Lignocaine 2% in paracervical block & Inj Midazolam 0.04mg/Kg body wt. and Inj Fentanyl 0.002mg/Kg for conscious sedation. Primary outcome includes success of the procedure as assessed by the patients.

Results: The opinion of the patients immediately after and 24 hrs after the surgery has shown that 97.5% of our patients have accepted the technique. The vital parameters were quite stable in both intra operative and post operative period as compared to its pre operative values. Our technique in the study was well tolerated by most of the patients with only 5.8% patients had minor and non serious side effects. It is clearly evident by about 3 hours of procedure patients were back to normal pre operative state.

Conclusion: Paracervical block with conscious sedation is an effective and safe method for surgical evacuation of early pregnancy.

Keywords: Paracervical block, Conscious sedation, Early Pregnancy, Surgical evacuation, Efficacy.

1. Introduction

The bulk of gynecological workload of any busy operation theater includes relatively minor procedures like termination of first trimester pregnancy by suction evacuation (S & E), and other gynecological procedures like dilatation and curettage (D & C), cervical cauterization for the erosion and dilatation & evacuation for incomplete abortions [1]. The majority of such procedures are generally carried out under general anesthesia (GA) and it is associated with various complications which can be intra operative or post operative. Intra operative problems can be serious like laryngospasm, asphyxia. They may include fall in BP, arrhythmias, a systole; the respiratory problems like respiratory depression, hypercarbia, increased salivation, secretions and aspiration of gastric contents leading to acidic pneumonitis. Post op complications of GA include persistent sedation, impaired psychomotor dysfunction, emergence delirium, and cognitive defects. Prolonged excess cognitive defects are seen in some patients' especially elderly patient. Nausea, vomiting are very distressing side effects.

Regional anesthesia is definitively safer than GA and it is also very economical. Both these reasons are

responsible for the shift of using LA for most procedures. This can be achieved by infiltrating LA around paracervical region creating paracervical block thus facilitating excellent relaxation of cervical canal [2,3]. The patient is awake throughout the procedure, she can report change in condition to anesthesia provider. She recovers in 5 – 15 mins without nausea & headache which are side effects of GA. Conscious sedation is achieved by concomitant administration of tranquilizers & narcotics. It facilitates the performance in both therapeutic & diagnostic procedures. It is easy to administer and S&E due to conscious sedation are well tolerated by majority of patients [4]. Conscious sedation with paracervical block has shown to be safe and useful in pain control in minor gynecological procedures.

Adequate pain relief ensures that patient is not stressed & release of harmful stress related hormone is suppressed. This ensures early recovery. The maximum post op pain is in first 24 – 48 hrs and this is the forte of Regional Anesthesia. Cochrane review in 2013 concluded that the available evidence fails to show whether paracervical block is inferior, equivalent, or superior to alternative analgesic techniques in terms of efficacy and safety for women undergoing cervical dilatation and uterine interventions. Authors suggest that woman are likely to consider the rates and severity of pain during uterine interventions when performed awake to be unacceptable in the absence of neuraxial blockade, which are unaltered by paracervical block [5].

Surgical evacuation of early pregnancy (first trimester) is a common minor gynecological procedure in a busy hospital and RA has considerable advantages over GA. With these two facts in mind we attempted to study the effect & feasibility of paracervical block along with conscious sedation in these cases.

2. Materials & Methods

Our study was a Prospective Observational Study carried out in Tertiary Care teaching Center in Pune between Aug 2014 to July 2016. All the patients who were undergoing surgical evacuation for 1st Trimester Pregnancy during the study period were included. Written informed consent of the patients was taken. Patients not included in the study were (a) Lack of patients consent for the technique (b) Patients with the known history of allergy to the drugs used in the study (c) Patients with systemic illness like uncontrolled DM, HTN, cardiac disease, renal failure, immunocompromised condition (d) Infection at the site of block.

Night before Surgery patients were made familiar with the anesthesia procedure and all patients received Tab Lorez epam 1mg. Patients were kept nil orally after 0200 hrs and informed consent was taken from all the patients before shifting them to Operation Theater.

Conscious Sedation was given with Injection Midazolam (IV) in the dose of 0.04mg/Kg and Injection Fentanyl (IV) in the dose of 0.002mg/Kg; both the drugs were given slowly. The paracervical block was given bilaterally in lithotomy position and the injection of local anesthetic was given 1-2 cm from the epithelium in the lateral fornices of vagina after check aspiration to prevent accidental intravenous injection especially to cervical branch of uterine artery. We had infiltrated 10 ml of Inj. Lignocaine (2%) at 3 O'clock & 9 O, clock position on both side and interval of 5 min was observed between injection & surgery. Injection Ketamine (IV) (0.25mg/kg body wt.) was administered if patient complained of pain or surgeon finds difficulty in cervical dilatation.

Post operatively, primary outcome measure included success of procedure as assessed by the patients. Requirement of supplementary analgesia/ anesthesia intraoperatively was also assessed. Monitoring of vital parameters intra operatively, post operatively & comparing them with pre operative values to see for any obvious change. Secondary outcome measures were the incidence of complications, post operative activity and feasibility of the procedure to be done for Day Care. Patient satisfaction was also assessed on the following day.

Statistical analysis was carried out by using EPI 2007. For this study analysis of socio demographic factors, intra and postoperative vital parameters and side effects were done by calculating mean±SD, t value and p value. P values less than 0.05 was considered as statistically significant.

3. Results

There were 156 patients included in our study. Among them 20 patients refused to be part of the study. So from remaining 136 patients, 05 excluded due to uncontrolled HTN, 09 excluded due to uncontrolled DM & 01 patient has h/o of allergic reaction to the drug used in the study. So, 121 patients were given paracervical block with conscious sedation. However 02 patients were required to be given rescue anesthesia, so finally we had 119 patients in the study (Fig 1).

Demographic characteristics of the patients are in Table 1. 95% of the patients were below the age of 30 yrs and only 4.2% of the patients have BMI more than 30. Intra and postoperative monitoring vital parameters are shown in Table 2. The vital parameter that is pulse rate, systolic & diastolic blood pressure, respiratory rate and SpO_2 were quite stable in both intra operative and post operative period as compared to its pre operative values.

Side effects which the patients experience were shown in Table 3. Out of 119 patients who receive the paracervical block with conscious sedation only 02 patients experienced headache, 03 patients had vomiting and 02 patients had excessive bleeding per vaginum. Our technique in the study was well tolerated by most of the patients with only few patients with minor and non serious side effects. Post operative activity in the form of time to sit, time taken to start walking & time taken to void urine has been shown in Table 3. It is clearly evident by about 3 hours of procedure patients were back to normal pre operative state.

The opinion of the patients immediately after and 24 hrs after the surgery has shown most of our patient have accepted the technique as is evident in Table 4.

Figure 1: Flow Chart

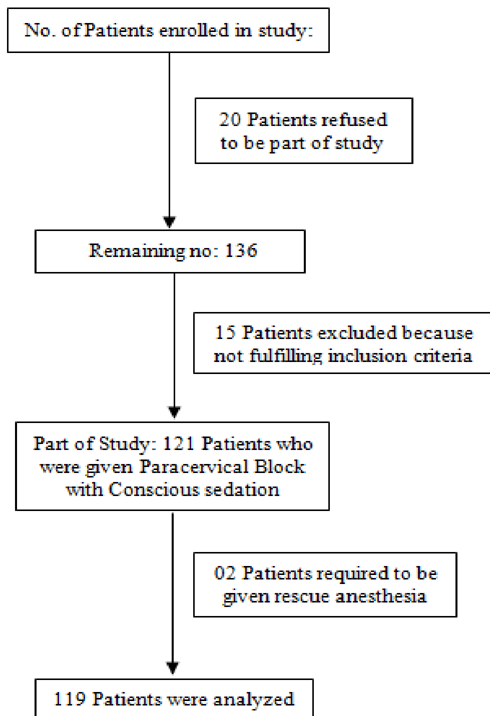

Table 1: Demographic Data of the Participants

Characteristics :	Numbers (%)
1. Age :	
≤ 20 years	12 (10.08)
21 – 25 years	57 (47.89)
26 – 30 years	41 (34.45)
≥ 30 years	9 (07.56)
2. BMI :	
18 – 24.9	49 (41.17)
25 – 29.9	65 (54.62)
≥ 30	4.20
3. Parity :	
0	11 (09.24)
1 – 2	86 (72.22)
≥ 3	22 (18.48)
4. Previous births	
Vaginal	89 (74.78)
01 LSCS	12 (10.08)
≥ 02 LSCS	18 (15.12)
5. Comorbidities	
Nil	108 (90.72)
HTN	03 (02.52)
Hypothyroidism	04 (03.36)
DM	04 (03.36)

Table 2: Intra and post operative monitoring

Parameters	Mean ± SD	t – Value	P Value
1. Pulse Rate(min)			
a) Pre Op	78.93 ± 6.36	-	-
b) Intra Op			
i) 5 mins	79.44 6. ± 19	-1.82	>0.05
ii) 15 mins	78.88 ± 5.35	- 0.06	>0.05
c) Post Op			
i) 6 hrs	79.79 ± 4.77	-1.17	>0.05
ii) 12 hrs	79.95 ± 4.97	-1.38	>0.05
2. Systolic BP (mm Hg)			
a) Pre Op	116.80 ± 11.71	-	-
b) Intra Op			
iii) 5 mins	114.21 ± 10.33	1.71	>0.05
iv) 15 mins	114.38 ± 8.75	1.80	>0.05
c) Post Op			
iii) 6 hrs	118.49 ± 6.08	-1.38	>0.05
iv) 12 hrs	118.93 ± 3.48	-1.38	>0.05
3. Diastolic BP (mm Hg)			
a) Pre Op	69.40 ± 7.40	-	-
b) Intra Op			
i) 5 mins	71.3 ± 7.79	-1.95	>0.05
ii) 15 mins	70.04 ± 3.27	-0.79	>0.05
c) Post Op			
iii) 6 hrs	70.96 ± 3.36	-1.96	>0.05
iv) 12 hrs	70.86 ± 3.18	-1.87	>0.05
4. Respiratory Rate			
a) Pre Op	17.95 ± 2.82	-	-
b) Intra Op			
i) 5 mins	17.63 ± 2.77	0.40	>0.05
ii) 15 mins	17.29 ± 1.65	1.87	>0.05
c) Post Op			
iii) 6 hrs	18.39 ± 1.72	-1.39	>0.05
iv) 12 hrs	17.67 ± 1.61	-0.88	>0.05
5. SpO_2			
a) Pre Op	97.86 ± 0.92	-	-
b) Intra Op			
i) 5 mins	97.82 ± 0.92	0.31	>0.05
ii) 15 mins	98.07 ± 0.74	-1.66	>0.05
c) Post Op			
iii) 6 hrs	97.57 ± 1.05	1.89	>0.05
iv) 12 hrs	97.99 ± 1.07	-0.88	>0.05

Table 3: Side effects & post operative activity:

S No	Side effects	No. of cases
1.	Headache	02
2.	Vomiting	03
3.	Excessive bleeding p/v	02
Post operative activity		**Time(min) Mean ± SD**
1.	Sit	131.3 ± 24.47
2.	Walk	181.75 ± 28.41
3.	Void urine	126.45 ± 14.34

Table 4: Opinion of patient regarding the procedure

S No.	Opinion of Patients	At end of surgery	24 hrs after surgery
1.	Comforable	26	29
2.	Acceptable	70	63
3.	Tolerable	20	22
4.	Unacceptable	03	05

4. Discussion

Many surgical procedures for minor gynecological diseases can be done in the ambulatory or outpatient basis. Potential advantage of outpatient surgery includes more rapid return to the comfort of home environment, diminished chances for nosocomial infections, and increased available beds for more complex surgeries. Moreover the cost of outpatient surgery is much less than the inpatient surgery. A large variety of minor gynecological procedures like first trimester abortions, suction & curettage and various miscellaneous conditions have been shown to be amenable to surgery on a day – case regimen [6]. Ambulatory surgery is facilitated by local anesthetic technique, which also provides post operative pain relief for several hours. While such techniques are established in several fields of ambulatory surgery, the techniques are not yet standardized for minor gynecological procedures and more often local anesthetic has been used complimentary to the GA to provide post op pain relief.

Most commonly the first trimester abortions are in younger age& number of complications is also more in this age group. In our study, 91% of the patients are < 30 yrs of age and out of that 69% are <25 yrs of age. In Meenambiga *et al* [1], the age group of patients is 43 ± 5 yrs but in our study age group of majority of patients is below 30 yrs as we are mainly dealing with Obstetric cases of early pregnancy not the gynecological cases. Most of the patients that is 96% had BMI < 30 Kg/m^2. Our study included both primipara and multipara patients with 18% of the patients have more than 3 children. Post LSCS patients were also included in the study and 15% of them have 2 or more previous LSCS. Though most of the patients were ASA grade 1(89%) as the patients in our study were young, in about 9% of patients we found co morbidities that is approx 3% having HTN, 3% having DM & 3% having hypothyroidism.

Vital parameter monitoring during and after the surgery/procedure has shown minimum change in the parameters of Systolic BP, Diastolic BP, Pulse Rate, Spo2 and Respiratory rate. Patients were relatively stable both in intra-operative and post-operative period and there was minimum variation of these parameters as compared to their pre-operative values shows that patients had adequate analgesia during the procedure. The vitals during the intra op period of 05 min and 15 min as shown in table 2 were not significantly different from pre op period emphasizing the adequacy of the technique used during the study. Maximum dose recommendations concerning local anesthetics should ideally, as stressed by Scott, take into consideration factors such as varying absorption at different injection sites (such as the parametrium) as well as patient characteristics (e.g. age). However, no such ideal recommendations exist [7]. We have used 10 ml of 2% of Lignocaine in the paracervical block.

While paracervical block is a relatively low-risk option, there is an approximately 10% incidence of vasovagal reaction with cervical injections [8] as well as a small risk of accidental vascular administration of an anesthetic that can cause systemic toxicity. The unclear efficacy of paracervical block should be considered with each patient when the relative risks and benefits are considered. While conscious sedation has not consistently shown to improve pain control, studies indicate patient satisfaction is improved and distress is decreased in those patients who receive conscious sedation. This information is important to take into consideration in counseling patients regarding expectations with the use of conscious sedation [9]. The technique in our study was well tolerated by the patients which is evident by the few cases of side effects. There were 02 cases of headache, 03 cases of vomiting and 02 cases of excessive bleeding. In the post-operative period patients were able to void urine in about 2 hrs, sit in about 2 hrs and walk in about 3 hrs. These patients are back to routine activity in approx 6 hrs. In our study we found patients have a very high level of satisfaction with the anesthesia administered to them. Most of them were ambulatory by evening of the surgery without experiencing any significant side effects.

The opinion of the patient's taken immediately after and 24 hrs after the surgery has shown most of our patient have accepted the technique. Approx 25% patients were comfortable, for 65% patients the technique was acceptable, for about 18% of patients technique was tolerable and about 2.5% of patients was unacceptable. However, after 24 hrs after the procedure 4.2% of patients told that the technique was unacceptable though there percentage is quite less.

5. Conclusion

Paracervical block with conscious sedation is an effective and safe method for surgical evacuation of early pregnancy. It has multiple benefits which includes rapid return to the home environment, diminished nosocomial infections, increased availability of OT for more complex surgeries & low cost.

Conflict of interest

None identified

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