Original Article

Deep Sedation or Paracervical Block for Daycare Gynecological Procedures: A Prospective, Comparative Study

Nishant Sahay[1,*], Mukta Agarwal[2], Mamta Bara[1], Nutan Raj[2], Divendu Bhushan[3]

Departments of [1]Anesthesiology, [2]Obstetrics and Gynecology and [3]General Medicine, AIIMS, Patna, Bihar, India

Abstract

Context: Many minor gynecological procedures are done for diagnostic and therapeutic reasons. A balance has to be struck between ability to discharge a patient at the earliest with minimum procedure-related discomfort to ensure patient safety as well as satisfaction.

Aim: This prospective randomized study was designed to compare deep sedation versus paracervical block for minor gynecological surgeries comparing the time to discharge readiness, pain after the procedure, and overall patient satisfaction.

Setting and Design: This prospective randomized comparative study was conducted at a tertiary level hospital after institutional ethics committee approval and registry of trial at CTRI (India).

Methods: Seventy young women underwent minor gynecological procedures under these two modes of anesthesia. Time to discharge readiness from hospital to home was assessed using modified postanesthesia discharge score system (PADSS). Pain after procedure as well as patient satisfaction was evaluated. Patients were also asked whether they would recommend the same anesthetic technique for the procedure in the future. Answers were noted on a Likert scale.

Results: Patients were ready to be discharged faster in deep sedation group compared to paracervical block group based upon modified PADSS score (1 h 9.6 min vs. 1 h 18 min) ($P = 0.005$). Pain in the perioperative period was analyzed using repeated-measures ANOVA and found to be significantly lesser in deep sedation group when considered till 80 min after surgery. The mean satisfaction score in patients who underwent deep sedation was 91.24 (standard deviation [SD] 2.8) compared to patients given paracervical block which was low at 64.67 (SD 15.8). All patients given deep sedation were ready to recommend the anesthesia technique as compared to only 53.3% of patients who were given paracervical block.

Conclusions: Deep sedation may be preferred over paracervical block for daycare minor gynecological procedures.

Keywords: Deep sedation, discharge, paracervical block, patient satisfaction

Introduction

Advances in technology have enabled minor gynecological procedures to provide a clinician with either a definitive diagnosis or a therapeutic trial. Practitioners prefer local or regional anesthesia in the form of paracervical block in many such patients so that discharge from hospital on the same day may be ensured. Patient discomfort and pain are oftentimes explained to be a price patients need to pay for early discharge and safety.

Evidence has not been conclusive with regard to utility of paracervical blocks for minor gynecological procedures. There is controversy in literature regarding effectiveness of paracervical block in the management of procedural pain.[1-3] Renner *et al*., however, have shown that paracervical block, often used for daycare procedures, reduces pain of minor gynecological surgeries, including dilation pains.[4]

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Address for correspondence: Dr. Nishant Sahay, House No. 112, Type 4 Block 1, AIIMS Residential Complex, Khagaul, Patna, Bihar, India.
E-mail: nishantsahay@gmail.com

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Even for daycare procedures, there is no uniform operational definition of readiness for hospital discharge, which exists in the literature.[5] For assessment of discharge readiness, modified postanesthesia discharge score system (PADSS) score has been proposed. In a study which used this score, >80% of patients were ready to be discharged as early as 30 min after gastrointestinal endoscopy.[6] Patient satisfaction is an aspect of care which is oftentimes neglected. Time to discharge readiness and effect of choice of anesthesia on patient satisfaction after paracervical block versus deep sedation for such minor gynecological procedures have not been described in literature. We thus compared these parameters as well as the pain scores during and after the procedure in this study.

Methods

This was a prospective randomized trial conducted after obtaining the AIIMS Patna Institutional Ethics Committee clearance, and the institutional review board project No. 66 was obtained on 14th July in 2016. This research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors. Patients with American Society of Anesthesiology Grade I or II status between 15 and 50 years of age with a body mass index of <30 kg/m^2 posted for minor gynecological surgeries such as endometrial biopsy, medical termination of pregnancy, hysteroscopy-guided procedures with scope size of 4.0 mm were included. Informed written consent was obtained from all patients, and then, they were randomized as per computer-generated sequence into two groups; Group GA: Deep sedation and Group PC: Paracervical of 35 patients each.

Any patient with known coagulopathies, allergies to local anesthetic agents, psychiatric illnesses, or cardiac pathology was excluded from this study. In the operating room, after connecting routine preinduction monitors, all baseline parameters were noted. Based on the group allocated, patients were either given deep sedation or regional anesthesia.

For patients belonging to Group GA (deep sedation), anesthesia was provided using injection fentanyl 1.5 mcg/kg and injection propofol titrated to loss of verbal response. Further top-ups of propofol at 200 μg/kg were given every 2–3 min. Additional top-ups of propofol at 200 μg/kg were also given if the heart rate and/or blood pressure increased by 10% of baseline values or if there was patient movement.

For patients belonging to group PC, taking all aseptic precautions, paracervical block was given in lithotomy position by an experienced gynecologist with >5 years' experience as a consultant in the presence of a trained anesthesiologist.

Procedure

For a paracervical block, a 3- or 4-inch 21-gauge needle was used and 5 ml xylocaine 1% without adrenaline was infiltrated at the 4 o'clock position and 8 o'clock position in each lateral fornix. 5 ml was then infiltrated into each uterosacral ligament. A total maximum dose of 5 mg/kg of lignocaine was used.

In case of inadequate block effect intraoperatively supplementation by intravenous fentanyl at 1 mcg/kg was given and repeated at 5 min' interval, when the patient complained of pain >3/10 on the numeric pain rating scale.

All patients were shifted to recovery after adequate response to verbal commands was ensured. They were assessed for pain using the numeric rating scale (NRS) on a scale of 0–10 once they were shifted into the recovery room and 10 and 30 min thereafter. The pain NRS was described to the patient as a score of 0, which meant no pain and score of 10, which indicated maximum and unbearable pain.

After 1 h, investigators noted down the modified PADSS score. This score takes into account the hemodynamic stability, activity levels, nausea or vomiting, pain, and surgical bleeding after a procedure. Various scores have been given based upon the parameters described in Table 1. Modified PADSS score was noted every 10 min after the 1st h till PADSS score >9 was attained. Patients were discharged ready only if PADSS score >9/10 was achieved and pain score was <2/10. Minimum time to attaining a score of >9 on PADSS scale with pain score <2/10 was noted for every patient in both groups. Activity level was assessed only once PADSS score of 8 was achieved using other parameters.

In all patients, investigators also took down the overall satisfaction score on a scale of 1–100 (1 being the worst possible experience and 100 being the best possible). We also noted whether they would recommend similar anesthesia to their family for the same procedure on a Likert scale. The scale included "yes strongly recommend, yes recommend, maybe recommend, may not recommend, not recommend, strongly discourage."

The sample size for the study was estimated based on a pilot study conducted in 20 patients. The mean time to achieve PADSS score of 10 was 80.5110 min with a combined standard deviation (SD) of 16.130. At 5% level of significance and 80% power to detect a 10% change in this time to achieve a PADSS score of 10, the sample size estimated was 60 subjects. Considering 10% of dropouts leading to exclusion from the process, we included 35 subjects in each group.

Data were analyzed using SPSS (Windows ver. 16.0, SPSS Inc., Chicago, IL, USA) and the results were presented as mean ± SD. Statistical analysis was performed using *t*-test and Chi-square tests to evaluate statistical significance between two groups for the demographic profile. *T*-test was used to compare variables when compared within the group and

between the groups. For assessment of postoperative pain progression among the groups, repeated-measures ANOVA test was used with group-by-time interaction using the Bonferroni correction. Statistical significance was defined as a $P < 0.05$.

Results

A total of 59 patients were analyzed after accounting for the dropouts. Both groups were comparable with respect to age, weight, height, and body mass index, as depicted in Table 2. Patients who received paracervical block alone had significant procedural discomfort with mean pain score of 5.4. None of these patients were pain-free. Three patients were managed without fentanyl boluses. Another three required a single 1 mcg/kg bolus, but all the rest required 2 µg/kg fentanyl supplementation. Pain score during procedure ranged from 2 to a maximum of 8 out of 10. In contrast, none of the patients in deep sedation group complained about intra procedural discomfort or pain, awareness, or recall. Trend of pain may be seen in Figure 1. A one-way repeated-measures anova was conducted to compare pain measured at different time points after surgery. Two such analyses were done for time periods up to 80 min postsurgery and up to 130 min postsurgery. There was a significant effect of intervention on pain scores up to 80 min after surgery. Wilks' Lambda = 0.287, F (4,55) = 34.215, P = 0.000; however, when comparing pain scores till 120 min after surgery, this relation was lost (Wilks' Lambda = 0.05, F[4,1] = 4.41, P = 0.34). Trend of pain may be seen in Figure 1. Pain and discomfort were significantly higher in paracervical group. The patients in deep sedation group were ready to be discharged earlier as compared to paracervical block. (1 h 9.6 min vs. 1 h 18 min) (P - 0.005) [Table 3]. The satisfaction levels were also very high in patients given deep sedation. The mean satisfaction score in these patients was 91.24 (SD 2.8). In contrast, patients given paracervical block had mean satisfaction score of 64.67 (SD 15.8) which was statistically and clinically significantly lower [Table 4]. All of the patients in deep sedation group were ready to recommend the technique to their relatives as may be seen in Table 5.

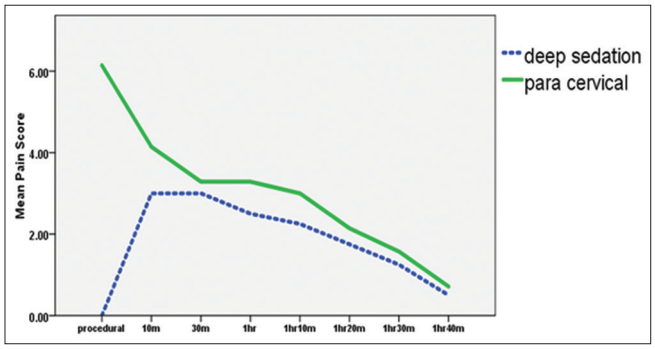

Figure 1: Pain score trend in the two groups. No patient who was given deep sedation complained of pain during procedure. Pain was higher in the paracervical group till 1 h 20 min after procedure but thereafter, pain in both groups was similar and mild

Discussion

Most minor gynecological procedures are undertaken these days on a daycare basis. Pain relief, time to discharge, and

Table 1: Details of postanesthesia discharge scoring system score

PADSS	Score
Vital signs: Must be stable and consistent with age and preoperative baseline BP and PR within 20% preoperative baseline	2
BP and PR within 20%-40% preoperative baseline	1
BP and PR >40% preoperative baseline	0
Activity level: Must be able to ambulate at preoperative level	
Steady gait, no dizziness, or meets preoperative level	2
Requires assistance	1
Unable to ambulate	0
Nausea and vomiting: Should have minimal nausea and vomiting	
Minimal: Successfully treated without medication	2
Moderate: Successfully treated with IV/IM injection	1
Severe: Continues after repeated treatment	0
Pain: Must have minimal or no pain before discharge, controlled by oral analgesia, location, type and intensity of pain consistent with anticipated postoperative discomfort	
Pain acceptable	2
Pain not acceptable (<2/10 NRS)	1
Surgical bleeding: Postoperative bleeding should be consistent with expected blood loss for the procedure	
Minimal: Does not require dressing change	2
Moderate: Up to two dressing changes required	1
Severe: More than three dressing changes required	0

IV/IM: Intravenous/intramuscular, NRS: Numeric rating scale, BP: Blood pressure

Table 2: Patient characteristics in both groups

	Patient characteristics				*P*
Group	***n***	**Mean**	**SD**	**SEM**	
Age (years)					
GA	29	39.3448	11.43077	2.12264	0.117
PC	30	35.3333	7.62181	1.39155	
Height (cm)					
GA	29	153.5345	3.64724	0.67727	0.250
PC	30	152.4333	3.62637	0.66208	
BMI (kg/m^2)					
GA	29	22.8831	4.26595	0.79217	0.173
PC	30	24.4024	4.19310	0.76555	
Weight (kg)					
GA	29	53.6897	8.53189	1.58433	0.215
PC	30	56.5667	9.15266	1.67104	

Demographically both groups were similar with regards to sex, age, height, weight, and BMI. BMI: Body mass index, GA: Deep sedation, PC: Paracervical, SD: Standard deviation, SEM: Standard error of the mean

Table 3: Comparison of the satisfaction scores and (postanesthesia discharge scoring system score)

	Satisfaction	Time taken to reach PADSS 10
Mann-Whitney U	1.000	255.500
Wilcoxon W	466.000	690.500
Z	−6.718	−2.852
Asymp. Sig. (two-tailed)	0.001	0.004

P < 0.05 significant. Patient satisfaction as well as time taken to achieve a PADSS score of 10 was significantly faster in GA group. PADSS: Postanesthesia discharge scoring system, GA: Deep sedation

Table 4: Detail of satisfaction scores in the two groups

Satisfaction	*n*	Minimum (%)	Maximum (%)	Mean score (%)	SD
GA	29	85	98	91.24	2.824
PC block	30	30	85	64.67	15.862

SD: Standard deviation, GA: Deep sedation, PC: Paracervical

Table 5: Patient recommendations regarding choice of same anesthesia for a future procedure

	Group	
	GA (*n*)	PC (*n*)
Strongly recommend	11	0
Recommend	13	11
Maybe recommend	5	5
Maybe not recommend	0	10
Will not recommend	0	3
Strongly discourage	0	1
Total	29	30

All patients given GA recommend the anesthesia out of which >33% patients strongly recommended the anesthesia given. Conversely almost half of patients given PC block did not recommend the anesthesia technique. None of these patients strongly recommended paracervical block. GA: Deep sedation, PC: Paracervical

overall anesthetic satisfaction are important considerations when a daycare procedure is planned. General anesthesia (deep sedation) has the advantage of reliable amnesia and analgesia. Patient satisfaction is higher with general anesthesia; however, it has its own perils even in young patients. Regional anesthesia especially the paracervical block for minor gynecological is widely used; however, controversy exists regarding effectiveness of paracervical blocks. Vercellini *et al*. reported that paracervical anesthesia was ineffective in reducing pain and discomfort during outpatient hysteroscopy.[7] In another study, even when paracervical block was given, patients found pain of injection for the block to be as unpleasant as a hysteroscope insertion.[7] In 2012, however, authors reported definite advantage of paracervical block, especially in control of dilation pains compared to placebo.[4] In our study, all patients who were given paracervical block had some discomfort or pain during procedure. Mean pain during procedure in the paracervical group was 5.14 on NRS. Maximum pain was experienced during dilation by hysteroscope in our trial. This is consistent with certain other studies which have reported severe pain as high as 7–9 out of 10 on NRS, during procedure under paracervical block.[8] In our cases, pain scores remained higher in the paracervical group till 1 h 20 min after the procedure [Table 3]. Thereafter, pain was similar in both groups and mild in nature. Deep sedation was a significantly better option with regards to procedural and post-procedural discomfort and pain. Pain is also an important aspect during assessment of discharge readiness. All patients had to have pain scores of 2 or less on the NRS to be considered discharge ready in our study.

We have used PADSS score to assess discharge readiness to home in our patients.[9] The internal consistency reliability of PADSS (alpha = 0.65) was found to be superior to other criteria for assessment of discharge readiness.[10] PADSS score includes hemodynamic stability, activity, nausea vomiting, pain, and surgical bleeding as parameters to come at a score to define discharge to home readiness[10] [Table 1]. We noted that patients in deep sedation group could be discharged faster at a mean time of 1 h 9.6 min versus 1 h 18 min ($P = 0.005$) in patients who received paracervical block. While assessing the PADSS score, mobility of patient is also considered. We noted that patients in the paracervical group experienced more difficulty during assessment of mobility than patients who received systemic analgesics in deep sedation group. Although this difference may not be reflected in our results, it could be a consideration in certain gynecological patients who may demand normal gait after a daycare procedure. We feel deep sedation may be a better option compared to paracervical block when this aspect is considered.

Patients were asked about their satisfaction levels on a scale of 1–100, 1 being least satisfied and 100 being most satisfied. The satisfaction levels were high in patients given deep sedation. The mean satisfaction score in these patients was 91.24 (SD 2.8). In contrast, patients given paracervical block had mean satisfaction score of only 64.67 (SD 15.8) which was statistically and clinically significant. The discomfort during procedure in the paracervical group was the main reason for their dissatisfaction. Some patients had given good satisfaction scores despite having moderate pain (>3/10) during or after the procedure. In these ladies, we believe, the fear of general anesthesia and relief that their procedure was over, may have played a significant part. Dissatisfaction in the deep sedation group was significantly less. Main causes of dissatisfaction among patients in deep sedation group were due to pain and discomfort after the procedure. Nausea and vomiting was noted in two patients.

By means of a Likert scale-based questionnaire, we assessed that if patients would recommend the anesthesia, they

received for their procedure. All patients in the deep sedation group recommended the same anesthesia for the next time, but only 53.4% of patients in paracervical group advocated their mode of anesthesia. Of the patients who were given deep sedation, 37.9% patients strongly recommended it and in contrast none of the patients who received paracervical block would strongly recommend it. 3.3% of these patients, on the contrary, strongly discouraged paracervical block.

Complications

We noted certain side effects during the study. In patients who received deep sedation, there was apnea, requiring airway clearing maneuvers with jaw thrust and chin lift with manual mechanical ventilation in one patient. This patient was a hypothyroid patient and had a body mass index of 30 kg/m^2. In three other patients, there was airway obstruction which was cleared with head extension and chin lift. One patient moaned during the procedure; however, on being questioned later, she had no recall of any event during the procedure and had a high satisfaction score. There was shivering in one patient which was managed by giving tramadol and this patient was excluded from the study. No patient complained of awareness or recall to any intraoperative event during the study in deep sedation group.

A clinical practice advisory reviewed the incidence of adverse effects of propofol during deep sedation. It mentions respiratory depression or apnea, leading to assisted ventilation may be seen in 0%–3.9% of patients given deep sedation. Other adverse effects such as transient hypotension may be seen in 2.2%–6.5% patients, nausea or emesis in 0%–0.5% of patients, and pain with injection in 2%–20% of patients.[11]

The main adverse effect which we noted in the paracervical group was apprehension and intraoperative discomfort during the procedure. Authors have reported adverse effects such as hypotension and vasovagal episodes.[12] One study also reported symptoms of lignocaine toxicity after paracervical block in 3/27 of their study population.[13]

Propofol sedation has been attempted successfully by practicing gastroenterologists. They concluded that with close graphic assessment of respiratory activity, propofol infusion may be a safe option even at the hands of a second qualified gastroenterologist for prolonged upper endoscopic procedures. Propofol sedation resulted in high levels of patient satisfaction and rapid recovery times in their study of 10 patients.[14]

Conclusions

Patients undergoing minor gynecological procedures under deep sedation suffer lesser pain and may be discharged earlier compared to those given paracervical block. Patient satisfaction scores are significantly better with deep sedation, and they are ready to recommend deep sedation much more frequently than paracervical block alone.

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Conflicts of interest

There are no conflicts of interest.

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