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The efficacy of a single preoperative dose of sublingual misoprostol in reducing operative blood loss during abdominal hysterectomy done for symptomatic fibroid uterus

Suriya Desikan¹, Arumuga Lakshmi G², Aparna Govindavelu³, Esther Ruby⁴

1. Assistant Professor, Dept of Obstetrics & Gynaecology, Mahatma Gandhi Medical College and Research Institute, Sri Balaji Vidyapeeth, deemed to be University, Puducherry.

2. Professor of Obstetrics and Gynaecology, Rajiv Gandhi Government Women and Children Hospital, Puducherry.

3. Assistant professor, Dept of Obstetrics and Gynaecology, Mahatma Gandhi Medical College and Research Institute, Sri Balaji Vidyapeeth, deemed to be University, Puducherry.

4. Esther Ruby, Chief Medical Officer, Rajiv Gandhi Government Women and Children Hospital, Puducherry.

Corresponding Author details:

Email ID: aparbb@gmail.com

Aparna Govindavelu, Dept of Obstetrics and Gynaecology, Mahatma Gandhi Medical College and Research Institute, Sri Balaji Vidyapeeth, deemed to be University, Puducherry.

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Abstract:

Introduction

Hysterectomy done for fibroid uterus is a commonly performed gynaecological surgery and intraoperative hemorrhage is a critical complication encountered that necessitates blood transfusions. Various medications are being used intraoperatively to reduce blood loss. Misoprostol, a PG E1 analogue widely used uterotonic agent, has shown potential in minimising blood loss and is safer than presently used ones.

Aim:

The purpose of the study was to evaluate sublingual misoprostol's safety and effectiveness in lowering intraoperative blood loss

Material and Methods:

A randomized, double-blind controlled trial conducted at Rajiv Gandhi Government Women and Children Hospital, Puducherry, from January 2014 to August 2017. Seventy women with symptomatic fibroids undergoing total abdominal hysterectomy (TAH) were randomised into

two groups: the misoprostol group (n=35) received 400 mcg sublingually 30 minutes before surgery, while the placebo group (n=35) received a placebo. Intraoperative blood loss, hemoglobin (Hb) levels preoperatively and postoperatively, along with adverse effects, were documented.

Results:

The misoprostol group exhibited significantly lower mean intraoperative blood loss (270.09 ± 170.87 ml) compared to placebo group (455.49 ± 242.42 ml; $p=0.0001$). Although reduction in postoperative hemoglobin levels was not statistically significant ($p=0.32$), misoprostol effectively reduced the incidence of higher blood loss categories, with no cases of blood loss exceeding 750 ml

Conclusion:

Sublingual misoprostol significantly reduces intraoperative blood loss during abdominal hysterectomy without severe adverse effects. Also, its affordability makes it a valuable tool in resource-limited settings. Further studies are warranted to optimize its clinical application.

Keywords: Misoprostol, blood loss, abdominal hysterectomy, sublingual

Introduction

Abdominal hysterectomy is one of the most frequently carried out most important gynaecological surgeries worldwide. In patients with symptomatic fibroid uterus, this process offers definitive treatment but can be associated with significant intraoperative blood loss. Excessive bleeding during surgical procedure not only complicates the procedure but also increases the risk of postoperative complications and the need for blood transfusions.^{1,2}

Misoprostol, a synthetic prostaglandin E1 analogue, was extensively studied for its uterotonic properties in obstetrics.³ The sublingual administration offers rapid absorption and high bioavailability, making it an attractive option for preoperative use.⁴ Its ability to induce uterine contractions and reduce uterine blood flow has led researchers to explore its potential in gynaecological surgeries⁵. The sublingual route of administration offers rapid absorption and high bioavailability, making it an attractive option for preoperative use.⁴

Recent studies have shown promising results in utilising misoprostol to lessen blood loss during multiple gynaecological procedures, comprising cesarean sections and myomectomies.^{6,7} However, its efficiency in abdominal hysterectomy, particularly for symptomatic fibroid uterus, remains an active research area.^{8,9} This study aims to evaluate the efficacy of a single preoperative dose of sublingual misoprostol in reducing operative blood loss during an abdominal hysterectomy performed for symptomatic fibroid uterus. By potentially decreasing intraoperative bleeding, misoprostol could improve surgical outcomes, reduce the need for blood transfusions, and enhance patient recovery.^{4,5}

In gynaecological surgery, the outcomes of this study could possibly improve patient care and resource utilisation by facilitating the expansion of evidence-based protocols for perioperative management in abdominal hysterectomy. During abdominal hysterectomy for symptomatic myomas, the study intends to ascertain the secondary outcome of the postoperative decrease in haemoglobin and the requirement for blood transfusions by examining whether preoperative administration of sublingual misoprostol can minimise blood loss.⁸⁻¹⁰

Materials and Methods

Seventy women with symptomatic fibroids scheduled for total abdominal hysterectomy (TAH) with or without bilateral Salpingo-oophorectomy (BSO) participated in a randomized, double-blind controlled trial. From January 2014 to August 2015, the study was conducted at the Rajiv

Gandhi Government Women and Children Hospital (RGGWCH), in Puducherry. The institute's Scientific and Ethics Committee granted approval for the study.

The study was an interventional nature and was interpreted as a randomized effectiveness study with double blindness to ensure that participants, supervisors, investigators, and the starters of the group were not aware of group assignment. The main purpose of the study was to evaluate the effectiveness of treatment in reducing surgical blood loss. The attempt was carried out in the Department of Obstetrics and Gynecology at RGGWCH, which includes over a year in two phases: January to April 2014 and January - August 2015

The study recruited women undergoing TAH with or without BSO for symptomatic fibroids. A total of 70 participants were included, with 35 randomized to the placebo group (Group A) and 35 to the intervention group (Group B). Randomization was performed utilizing a computer-generated random number. The sample size was calculated using OpenEpi version 3.0, based on a prevalence rate of 31% among the exposed population, with an odds ratio of 8.5 and a risk/prevalence difference of 26%.

Inclusion criteria required participants to be between 36 and 55 years old, have a uterine size of 8 to 24 weeks, and have a preoperative hemoglobin level of 10 to 13 g%. Exclusion criteria included contraindications to misoprostol, such as glaucoma, asthma, liver disease, severe hypertension, mitral stenosis, hematologic disorders, or known allergy to prostaglandins. Participants with a history of pelvic or ovarian endometriosis, previous myomectomy, or previous treatment with GnRH analogues or mifepristone were also excluded. Eligible participants who were hospitalized were counseled about the study and informed consent was obtained. Participants were randomly assigned to either the placebo group or the intervention group. The placebo group received two tablets of vitamin C, while the intervention group received 400 mcg of misoprostol. To maintain blinding, sealed opaque packets were prepared by the hospital pharmacy and administered sublingually by surgical staff 30 minutes before surgery. All surgeries were performed under regional anesthesia by one of eight experienced gynecologists, each with more than five years of surgical experience. This approach minimized bias related to variations in surgical skill. Blood loss during surgery was assessed using three methods: the volume of blood in the suction container, the weight difference between soaked and dry surgical pads, and the weight of any blood clots. The total blood loss was calculated by summing these measurements, using the conversion of 1.06 g = 1 mL of blood. Pads used for skin and subcutaneous layers were excluded from the analysis.

The secondary results included the hemoglobin levels measured 24 hours after the operation, the need for blood transfusions during or after the operation as well as side effects of misoprostol such as fever, diarrhea, chills, nausea or vomiting. The data collected was entered in Microsoft Excel and analyzed with SPSS version 19.0. Descriptive statistics, including frequencies and shares, were used for categorical variables, while mean values and standard deviations (or median) were applied to continuous variables. Chi square tests and independent T-tests were used to evaluate differences in the proportions or mean values.

RESULTS

Preoperative haemoglobin levels, menstrual complaints, age distribution, parity, BMI, and a number of pads used do not differ significantly ($p > 0.05$) in Table 1. Menorrhagia and dysmenorrhea were the most prevalent menstrual complaints, and the majority of participants had an abdominal circumference of 25 (obese) BMI. Misoprostol did, however, considerably lessen blood loss. Compared to the placebo group (175 mL), the misoprostol group had a lower median volume of suctioned blood (100 mL). A statistically significant difference ($p = 0.009$) was also observed in the mean weight of soaked pads, which was significantly lower in the misoprostol group (162 g) than in the placebo group (236.37 g).

Table 1: Demographic and baseline details of the study participants

| Parameter | Placebo (N = 35) | Misoprostol (400 mcg) (N = 35) | Total (N = 70) | Chi-square, df, p-value |
|---------------------------------|---------------------------|--------------------------------|-------------------|-------------------------|
| Age Distribution (Years) | | | | |
| <40 | 10 (58.8%) | 7 (41.2%) | 17 (100.0%) | 1.68, 3, > 0.05 |
| 40-45 | 15 (53.6%) | 13 (46.4%) | 28 (100.0%) | |
| 46-49 | 8 (42.1%) | 11 (57.9%) | 19 (100.0%) | |
| ≥50 | 2 (66.7%) | 1 (33.3%) | 3 (100.0%) | |
| Parity | | | | |
| P1L1 | 2 (50.0%) | 2 (50.0%) | 4 (100.0%) | 7, 7, > 0.05 |
| P2L1 | 0 (0.0%) | 1 (100.0%) | 1 (100.0%) | |
| P2L2 | 21 (58.3%) | 15 (41.7%) | 36 (100.0%) | |
| P3L2 | 1 (25.0%) | 3 (75.0%) | 4 (100.0%) | |
| P3L3 | 9 (52.9%) | 8 (47.1%) | 17 (100.0%) | |
| P4L3 | 0 (0.0%) | 2 (100.0%) | 2 (100.0%) | |
| P4L4 | 2 (50.0%) | 2 (50.0%) | 4 (100.0%) | 1.3, 5, 0.9 |
| P5L5 | 0 (0.0%) | 1 (100.0%) | 1 (100.0%) | |
| Menstrual Complaints | | | | |
| Continuous Bleeding | 4 (57.1%) | 3 (42.9%) | 7 (100.0%) | 2.2, 2, > 0.05 |
| Dysmenorrhagia | 7 (46.7%) | 8 (53.3%) | 15 (100.0%) | |
| Menometrorrhagia | 1 (50.0%) | 1 (50.0%) | 2 (100.0%) | |
| Menorrhagia | 17 (51.5%) | 16 (48.5%) | 33 (100.0%) | |
| Metrorrhagia | 1 (25.0%) | 3 (75.0%) | 4 (100.0%) | |
| Polymenorrhagia | 5 (55.6%) | 4 (44.4%) | 9 (100.0%) | |
| BMI Groups | | | | |
| >25 (Obese) | 12 (40.0%) | 18 (60.0%) | 30 (100.0%) | 1.9, 3, > 0.05 |
| 18.5 to 22.9 (Normal) | 12 (54.5%) | 10 (45.5%) | 22 (100.0%) | |
| 23 to 24.9 (Overweight) | 11 (61.1%) | 7 (38.9%) | 18 (100.0%) | |
| Preoperative Hb% | | | | |
| <11 | 15 (60.0%) | 10 (40.0%) | 25 (100.0%) | 7, 7, > 0.05 |
| 11 to 11.9 | 2 (33.3%) | 4 (66.7%) | 6 (100.0%) | |
| 12 to 12.9 | 8 (48.0%) | 6 (52.0%) | 14 (100.0%) | |
| >13 | 6 (42.9%) | 8 (57.1%) | 14 (100.0%) | |
| Number of Pads | | | | |
| 2 | 4 (50.0%) | 4 (50.0%) | 8 (100.0%) | t = 2.681, p = 0.009 |
| 3 | 7 (41.2%) | 10 (58.8%) | 17 (100.0%) | |
| 4 | 8 (44.4%) | 10 (55.6%) | 18 (100.0%) | |
| 5 | 3 (33.3%) | 6 (66.7%) | 9 (100.0%) | |
| 6 | 4 (57.1%) | 3 (42.9%) | 7 (100.0%) | |
| 7 | 4 (80.0%) | 1 (20.0%) | 5 (100.0%) | |
| 8 | 3 (100.0%) | 0 (0.0%) | 3 (100.0%) | |
| 9 | 2 (66.7%) | 1 (33.3%) | 3 (100.0%) | |
| Volume of Suctioned Blood (mL) | Median: 175 | Median: 100 | | |
| Weight of Pads (g) | Mean: 236.37 (SD: 124.18) | Mean: 162.00 (SD: 107.27) | Difference: 74.37 | |

The results in Table 2 demonstrate a statistically significant reduction in intraoperative blood loss in the misoprostol group compared to the placebo group ($p = 0.02$). Specifically, 80% of participants in the misoprostol group experienced blood loss <150 mL, while the placebo group had higher blood loss in categories >450 mL, indicating the efficacy of misoprostol. Postoperative haemoglobin levels were comparable between the groups ($p > 0.05$), though more participants in the placebo group had Hb <10 g/dL, suggesting better blood conservation in the misoprostol group. There was no significant difference in the need for blood transfusions ($p > 0.05$), although all participants requiring two units were in the placebo group. Adverse reactions were more common in the placebo group (68.4% vs. 31.6%), with vomiting, nausea, and mild fever being predominant. At the same time, diarrhoea and tachycardia occurred only in the misoprostol group, though these differences were not statistically significant ($p > 0.05$). Key parameters further highlight the benefits of misoprostol, with significantly lower total blood loss (270.09 ± 170.87 mL vs. 455.49 ± 242.42 mL, $p < 0.001$), suctioned blood (120.77 ± 83.29 mL vs. 232.43 ± 166.23 mL, $p = 0.001$), and weight of surgical pads (162.00 ± 107.27 g vs. 236.37 ± 124.18 g, $p = 0.009$). Overall, misoprostol effectively reduced intraoperative blood loss while maintaining comparable safety and tolerability.

Table 2: Comparative Analysis of Misoprostol (400 mcg) vs. Placebo on Blood Loss, Hemoglobin Levels, Blood Transfusion, and Adverse Reactions

| Parameter | Placebo (N = 35) | Misoprostol (400 mcg) (N = 35) | Total (N = 70) | Chi-square, df, p-value |
|----------------------------------|------------------|--------------------------------|----------------|-------------------------|
| Blood Loss Volume (mL) | | | | |
| <150 | 3 (20.0%) | 12 (80.0%) | 15 (100.0%) | 13.2, 5, p = 0.02 (S) |
| 150 to 300 | 9 (47.4%) | 10 (52.6%) | 19 (100.0%) | |
| 300 to 450 | 7 (50.0%) | 7 (50.0%) | 14 (100.0%) | |
| 450 to 600 | 4 (55.6%) | 2 (44.4%) | 6 (100.0%) | |
| 600 to 750 | 2 (33.3%) | 4 (66.7%) | 6 (100.0%) | |
| Total | 35 (50.0%) | 35 (50.0%) | 70 (100.0%) | |
| Postoperative Hb% | | | | |
| <10 | 6 (75.0%) | 2 (25.0%) | 8 (100.0%) | 7.7, 4, > 0.05 (NS) |
| 10 to 10.9 | 13 (43.3%) | 17 (56.7%) | 30 (100.0%) | |
| 11 to 11.9 | 12 (63.2%) | 7 (36.8%) | 19 (100.0%) | |
| 12 to 12.9 | 2 (66.7%) | 1 (33.3%) | 3 (100.0%) | |
| 13 to 13.9 | 2 (100.0%) | 0 (0.0%) | 2 (100.0%) | |
| Blood Transfusion (Units) | | | | |
| 1 Unit | 15 (60.0%) | 10 (40.0%) | 25 (100.0%) | 0.69, 1, > 0.05 (NS) |
| 2 Units | 0 (0.0%) | 14 (100.0%) | 14 (100.0%) | |
| Total | 15 (41.7%) | 24 (58.3%) | 39 (100.0%) | |
| Adverse Reactions | | | | |
| Vomiting | 6 (60.0%) | 4 (40.0%) | 10 (100.0%) | 7.8, 6, > 0.05 (NS) |
| Nausea | 5 (100.0%) | 0 (0.0%) | 5 (100.0%) | |
| Mild Fever | 2 (100.0%) | 0 (0.0%) | 2 (100.0%) | |
| Bradycardia | 1 (100.0%) | 0 (0.0%) | 1 (100.0%) | |
| Diarrhea | 0 (0.0%) | 4 (100.0%) | 4 (100.0%) | |
| Tachycardia | 0 (0.0%) | 3 (100.0%) | 3 (100.0%) | |
| Gaseous Distension | 0 (0.0%) | 2 (100.0%) | 2 (100.0%) | |

The results in Table 3 reveal significant differences in blood loss parameters between the placebo and misoprostol groups. The total blood loss volume was significantly lower in the misoprostol group (270.09 ± 170.87 mL) compared to the placebo group (455.49 ± 242.42 mL, $p < 0.001$), with a mean difference of 85.3–285.4 mL. Similarly, suctioned blood volume was markedly reduced in the misoprostol group (120.77 ± 83.29 mL vs. 232.43 ± 166.23 mL, $p = 0.001$), demonstrating the efficacy of misoprostol in minimising intraoperative bleeding. Although postoperative haemoglobin levels were slightly higher in the misoprostol group (11.03 ± 0.99 g/dL) compared to the placebo group (10.76 ± 1.22 g/dL), the difference was not statistically significant ($p = 0.310$). The weight of soaked pads was significantly lower in the misoprostol group (162.00 ± 107.27 g) compared to the placebo group (236.37 ± 124.18 g, $p = 0.009$), further supporting the reduced blood loss with misoprostol. Overall, these findings confirm the effectiveness of misoprostol in reducing blood loss during surgery, while other parameters, such as postoperative haemoglobin, remained comparable between groups.

| Group Statistics | Drug Used | N | Mean | SD | t | Sig. | 95% CI of Difference |
|----------------------|-----------------------|----|--------|---------|-------|--------|----------------------|
| Total Vol Blood (mL) | Placebo | 35 | 455.49 | 242.421 | 3.698 | <0.001 | 85.3-285.4 |
| | Misoprostol (400 mcg) | 35 | 270.09 | 170.870 | | | |
| Suctioned Blood (mL) | Placebo | 35 | 232.43 | 166.229 | 3.52 | 0.001 | 47.9-173.3 |
| | Misoprostol (400 mcg) | 35 | 120.77 | 83.292 | | | |
| Post-Op Hb | Placebo | 35 | 10.757 | 1.2181 | 1.023 | 0.310 | -0.8011 to 2.5822 |
| | Misoprostol (400 mcg) | 35 | 11.029 | 0.9910 | | | |
| Weight of Pads (g) | Placebo | 35 | 236.37 | 124.178 | 2.681 | 0.009 | 19.0 to 129.7 |
| | Misoprostol (400 mcg) | 35 | 162.00 | 107.267 | | | |

Discussion

In the present study, the age group of patients between 36 and 55 years with an average age of 43 years in the placebo group and 44 years in the Misoprostol group, with a standard deviation of 5 years (43 ± 5 and 44 ± 5). The comparison with previous studies showed similar results. Celik et al. reported an average age of 32.7 ± 4.4 years in the Misoprostol group and 32.2 ± 2.9 years in the placebo group, while Chang et al. observed 45.9 ± 3.6 years in the Misoprostol group and 46.1 ± 4.8 years in the placebo group.^{11,12} Other studies, including Biswas et al., Tabatabai et al., and Panichpongpan et al., presented comparable results, with no significant differences between the groups statistically as p-values > 0.05 .^{4,13,14}

With an average uterus size of 14.34 ± 3.68 weeks in the placebo group and 14.29 ± 4.18 weeks in the Misoprostol group, the study included patients with uterus sizes ranging from 8 to 24 weeks. There was no discernible difference between the groups according to a T-test ($P > 0.05$). Similar findings were reported by Celik et al. Biswas and associates. Furthermore, Panichpongpan et al. found no discernible difference in uterine size between studies.^{11,14,15}

Blood loss during surgery was assessed using soaked pads, pad weight, and suctioned blood volume. The misoprostol group showed a significant reduction in intraoperative blood loss compared to the placebo group. Patients were categorised into six groups based on blood loss, with a higher proportion of misoprostol patients experiencing lower blood loss. In contrast, greater blood loss was more prevalent in the placebo group. Notably, in the 750–900 ml range, all patients (100%) were in the placebo group, while none were in the misoprostol group.

Statistical analysis confirmed a significant difference in blood loss between groups, with mean blood loss of 455.49 ± 242.42 ml in the placebo group and 270.09 ± 170.87 ml in the misoprostol group ($p = 0.0001$). Similar trends were observed in studies by Tabatabai et al., Chang et al., Biswas et al., and Celik et al., reinforcing misoprostol's efficacy in reducing blood loss.^{11–13,15} However, Panichpongpan et al. and Chai J et al. did not find a significant reduction, indicating possible variations in study conditions.^{14,16}

Additionally, pre-operative and post-operative hemoglobin (Hb) levels were analyzed, showing no significant differences between groups. The mean Hb reduction in the placebo group was 0.48 ± 1.33 g/dL, while in the misoprostol group, it was 0.54 ± 1.08 g/dL ($p = 0.32$). This suggests that while misoprostol significantly reduces blood loss, it does not significantly impact post-operative hemoglobin levels.

These findings align with those of Tabatabai et al., who also observed no statistically significant change in hemoglobin levels between the placebo and misoprostol groups.¹³ However, studies by Chang et al., Biswas et al., and Celik et al. reported a greater drop in post-operative hemoglobin levels in the placebo group, indicating higher blood loss.^{11,12,15} These contrasting results suggest that while misoprostol effectively reduces blood loss, its impact on hemoglobin levels varies across studies.

The present study confirms that misoprostol significantly reduces intraoperative blood loss compared to the placebo group, with a mean blood loss difference of 185.4 ml and a highly significant p-value of 0.0001. However, no statistically significant changes in hemoglobin levels were observed between the two groups. These results support previous studies demonstrating misoprostol's efficacy in reducing blood loss, particularly in resource-limited settings where blood transfusions may not be readily available.

A 400 mcg dose of misoprostol was administered sublingually 30 minutes before surgery, a route known for its rapid onset, maximum plasma concentration, and high bioavailability. This ensures quick absorption and an immediate pharmacological effect, which may contribute to its role in reducing blood loss. Other studies have evaluated different dosages and administration routes, with Tabatabai et al. using rectal administration, Chang et al. combining rectal misoprostol with IV oxytocin, and Celik et al. opting for vaginal administration.^{12,13} Several studies, including those by Biswas et al., Panichpongpan et al., and Chai J et al.,

followed the sublingual route with varying administration times (30–60 minutes preoperatively). The present study adopted sublingual administration 30 minutes before surgery, consistent with many of these trials.^{14,16}

Regarding adverse effects, no significant differences were noted between the misoprostol and placebo groups. Among 35 women in the misoprostol group, 4 patients (11.43%) experienced mild and self-limiting diarrhea, and 3 patients (8.57%) developed mild fever. In the placebo group, 2 patients (5.71%) had mild fever, but importantly, no febrile morbidity ($T > 38^{\circ}\text{C}$) was observed in either group. Nausea and vomiting were infrequent, and no severe adverse effects were reported. These findings are consistent with other studies, which also found no major adverse effects or morbidity in either group.

Multiple studies have assessed misoprostol's effectiveness in reducing intraoperative blood loss. Tabatabai et al. administered misoprostol rectally, Celik et al. used the vaginal route, and Chang et al. combined rectal administration with an IV oxytocin drip, all of which demonstrated effective blood loss reduction.^{11–13} However, Panichpongpan et al. and Chai J et al. found no significant reduction in blood loss, despite using the same dose and route as the present study.^{14,16} This suggests that misoprostol's effectiveness may depend on patient characteristics, surgical conditions, or additional interventions.

Overall, the findings reinforce misoprostol's efficacy and safety as a preoperative intervention to reduce blood loss. While some inconsistencies exist in the literature, the current study supports the use of sublingual misoprostol for its rapid absorption, high bioavailability, and potential to minimize surgical blood loss effectively.

Conclusion

This study shows that Misoprostol (400 mcg), administered sublingually 30 minutes before the operation, is an effective and safe intervention to reduce intraoperative blood loss. The significant reduction in blood loss ($p = 0.0001$) underlines the potential to minimise surgical risks, especially in resource-limited settings where blood transfusions may not be readily available. Although no significant difference has been observed in postoperative haemoglobin mirrors, the overall reduction of blood loss indicates clinically significant benefits. Misoprostol was well tolerated, with only light and self-limiting side effects such as diarrhoea and fever, and no serious complications were reported. Due to its simple administration, quick absorption, and cost efficiency, sublingual Misoprostol offers a valuable option for improving surgical results. Further examinations should examine patient-specific factors, optimal dosage strategies and combination therapies to maximise the clinical advantages.

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Ethical committee approval:

Approved by General Hospital Institute Ethics Committee, IGGGH & PGI, Puducherry,

The data is with the first author and produced only on absolute need

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