**ORIGINAL ARTICLE** 





# Clinical Outcome in Patient Undergoing LSCS via ERAS Pathway versus Traditional Pathway: A Prospective Observational Study

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## Abstract

**Introduction** ERAS is an evidence-based management protocol for perioperative care, to accelerate patient recovery. The field of obstetrics has been a late adapter of ERAS pathway for CS, and the literature is limited from Indian population.

**Material and Methods** This prospective non-randomized comparative clinical study was conducted on 190 pregnant patients, out of which 95 were subjected to ERAS protocol (Group 1) and remaining 95 cases were enrolled in existing traditional protocol (Group 2). The primary objective was to compare quality of recovery based on obstetric-specific QoR 11 question-naire between patients undergoing ERAC and traditional protocol for elective LSCS. Secondary objective was to compare perioperative bleeding, breast feeding initiation and difficulties, first oral intake, ambulation attempts, decatheterization, surgical site infection and length of hospital stay.

**Results** At 24 h postoperatively, mean QoR score was significantly higher for patients in the ERAC group  $(85.5 \pm 7.46 \text{ vs} 57.1 \pm 11.33, p \text{ value} < 0.01)$ . In the ERAC group, 50.5% of the mothers started breastfeeding within first hour. The mean duration to start oral intake postoperatively was significantly lower in ERAC group. In the ERAC group, ambulation and decatheterization were attempted within 6 h postoperatively in 86.3%. The mean length of hospital stay was significantly lower for patients in the ERAC group ( $68.8 \pm 1.9 \text{ vs} 105.4 \pm 25.7 \text{ h}, p \text{ value} < 0.001$ ).

**Conclusion** The use of ERAC protocol at cesarean delivery significantly improves quality of recovery and length of hospital stay.

Keywords Cesarean section · ERAC · ERAS · Postoperative recovery

# Introduction

Enhanced recovery after surgery (ERAS) was first implemented in colorectal surgery in 1997 by a Dutch professor Henrik Kehlet [1]. ERAS is an evidence-based management protocol for perioperative care, to accelerate patient

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recovery. ERAS has been adopted by many surgical specialties including obstetrics. Enhanced recovery after cesarean (ERAC) aims at improving maternal outcomes, functional recovery, maternal-neonatal bonding and patient experience. ERAC involves the multidisciplinary team efforts of the anesthesiologist, obstetrician, neonatologist, lactation consultant, nursing staff, hospital and patient [2]. The basic principle of ERAC includes preoperative counseling, carbohydrate pre-loading to avoid prolonged perioperative fasting, fluid balance, regional anesthetic and non-opioid analgesic consideration, maintenance of normothermia, early ambulation, early initiation of breast feeding and appropriate thromboprophylaxis [3]. The field of obstetrics has been a late adapter of ERAS pathway for CS, and the literature is limited from Indian population. The aim of this study is to highlight evidence-based perioperative interventions which are considered as part of ERAS protocol for elective cesarean delivery and to compare the ERAC protocol with the traditional protocol in patients undergoing elective CS.

### **Material and Methods**

This prospective non-randomized comparative clinical study was conducted from Dec 2019 to Nov 2020 in the department of Obstetrics and Gynecology, at a tertiary care center in Southern Rajasthan, in line with the principles of declaration of Helsinki (GU/HREC/EC/2019/1744). All pregnant patients with gestational age > 37 weeks, ASA grade I-II, scheduled for elective cesarean section surgery who gave consent to participate were included in the study. The patients with pre-existing cardiac disease, preterm labor < 37 weeks, diabetes, autoimmune disorder, severe and uncontrolled hypertension, Rh negative, severe uncontrolled hypo/hyperthyroidism, abnormal placentation, i.e., abruptio placenta and placenta previa, severe renal or hepatic dysfunction, neurological/psychiatric illness, patient refusal, contraindication for spinal anesthesia like coagulopathy and known allergy to any of the study protocol drug were excluded from the study.

Using 95% confidence level with 9% absolute error, total sample size came out to be 170. Considering exclusions and 10% of dropouts, 20 more subjects were required; thus, the total of 190 participants were included in the study, out of which 95 were subjected to ERAS protocol (Group 1) and rest were enrolled in traditional protocol (Group 2). The members in each group were selected using non-random sampling technique.

Various guidelines proposed by American College of Obstetrics and Gynecology, ERAC society and Society of Obstetric Anesthesia and Perinatology were extensively discussed and a modified ERAC protocol was prepared following the core principle of improved patient outcome and in accordance with its feasibility. (Table 1).

#### **Outcome Variables**

#### Quality of Recovery (QoR-11)

Ciechanowicz et al. [4] developed the first obstetric-specific, 11-item QoR score questionnaire (Fig. 1),which was used to evaluate the quality of recovery by measuring several key elements, including physical comfort (nausea and vomiting, dizziness, shivering), pain relief, physical independence (mobilizing).

In the present study, QoR11 was assessed at 24 and 48 h.

### **Statistical Analysis**

Data were recorded on a structured proforma and transferred to a Microsoft Excel database. SPSS version 22 was used to perform statistical analysis. Mean  $\pm$  SD was used to represent the quantitative data, while frequency and percent were used to demonstrate qualitative data. Independent t test, Chi-square test and student t test were used to compare data between the two groups. p value of < 0.05 was considered statistically significant (Table 2).

#### Results

In this study, 190 patients were included, 95 in each group. Mean age of the patients in the ERAC group and traditional group was similar (28.88 ± 4.4 vs 28.7 ± 4.46 years, p value = 0.85). Mean BMI of patients in the ERAC group was 26.3 ± 5.1 and of patients in the traditional group (26.6 ± 5.2 kg/m2) (p value = 0.66). The incidence of HDCP in ERAC and traditional group was 8.4% and 17.9%, respectively (p value = 0.53). The mean duration of preoperative fasting was 3 ± 1.37 h for patients in the ERAC group and 11.82 ± 0.96 h in the traditional group (p value < 0.01). The incidence of postpartum hemorrhage was 10.5% in the traditional group (p value = 0.29).

In the ERAC group, 50.5% of the mothers started breastfeeding within first hour, and 34.7% started feeding 2 to 4 h postoperatively. There were 14 mothers who started breastfeeding after 6 h as the neonates were shifted to NICU. In the traditional group, none of the mothers started breastfeeding within the first hour, 32.6% started 2 to 4 h later, 41.1% after 5 to 6 h and 26.3% after 6 h. The difference was statistically significant (*p* value < 0.001). (Table 3).

The incidence of feeding difficulty was 16.8% in the ERAC group and 18.9% in the traditional group (p value = 0.71).

The mean duration to start oral intake postoperatively was significantly lower in ERAC group. (Table 4).

In the ERAC group, ambulation was attempted within 6 h postoperatively in 86.3% and in 6 to 12 h postoperatively in rest of the patients. In the traditional group, ambulation was attempted after 24 h in all patients. The difference was statistically significant (p value < 0.001). (Table 5).

In the ERAC group, catheter was removed within 6 h postoperatively in 86.3% and catheter was removed in the rest of the patients in 6 to 12 h postoperatively. In the traditional group, catheter was removed after 24 h in all patients. The difference was statistically significant (p value < 0.001). (Table 6).

80% of ERAC patients required oral analgesic only till second day and 20% required oral analgesic on third day postoperative. On the other hand, 100% of the patients in the traditional group required oral analgesic till day 3.

At 24 h postoperatively, mean QoR score was significantly higher for patients in the ERAC group as compared to those in the traditional group  $(85.5 \pm 7.46 \text{ vs } 57.1 \pm 11.33, p)$ 

	ERAC protocol	Traditional protocol	Both
Preoperative day before surgery	Counseling for enhanced protocol included details of ERAC program; its goals and benefits, spinal anesthesia, early skin to skin contact and breast feeding. Evening head to toe bath with Chlorhexidine scrub Glucose drink (100 gm in 800 ml of water) at 10 pm	No additional educational material was provided	VAS score was explained to all the patients in both the protocol for postoperative pain assessment
On the day of surgery	Fasting for solid 6 h prior to surgery and clear liquid was allowed till 2 h before surgery. 50 g of glucose dissolved in 200 ml of water 2 h before surgery	Nothing by mouth after 10 pm IV Ringer lactate at a rate 20 ml/kg/h started at 7:00 am in the morning	Anti-hypertensive agent morning dose with sips of water (if on medication) Thyroxin morning dose with sips of water (if on medication)
Immediate pre-operative preparation	External genital parts preparation, preoperative chlorhexidine scrub	Surgical site preparation and normal preoperative bath	18 gauge intravenous cannula was inserted in non- dominant upper limb
1 h before surgery:	Inj. Pantoprazole 40 mg slow IV, Inj. Metoclopra- mide 25 mg slow IV, Inj. Ceftriaxone 1 gm slow IV; AST		
	Inj. Pantoprazole 40 mg slow IV, Inj. Ondanse- tron 4 mg slowIV, Inj. Ceftriaxone 1 gm slow IV; AST		
Intraoperative	PCM/ diclofenac rectal suppository was inserted. Inj Ondansetron 4 mg i.v. stat and Inj Dexametha- sone 8 mg i.v. stat. Painting with chlorhexidine Delayed cord clamping(after1 min) Immediately baby was put on mothers abdomen before handing over to neonatologist( early skin to skin contact)	Inj ondansetron 4 mg i.v. stat Painting with betadine cord clamping within 1 min	Standard ASA monitoring (Pulse oximetry, NIBP, ECG) Foley's no 16 urinary catheter inserted under aseptic conditions. Misgav-ladach technique of cesarean section was followed. Any difficulty in micturition or retention thereafter was to be noted
Postoperative Analgesia	Inj PCM 0.45 gm 6 hourly was resumed at 6:00 h after spinal anesthesia) Inj. Diclofenac Sodium 75 mg 8 hourly Inj. Tramadol 100 mg iv SOS was given as rescue analgesia if the VAS score $\geq$ 3 along with Inj. Ondansetron4mg iv. Total dose of Tramadol and time to request for first and subsequent rescue doses were noted	Inj. Diclofenac sodium 75 mg IV slowly in 100 ml dilution; and Inj PCM 0.45 g IV slow in running drip; 8 hourly was resumed after 6 h of spinal anesthesia. (Given till 24 h) Tablet Ace- clofenac (100 mg)+Paracetamol (325 mg) P/o every 8th hourly was started 24 h after surgery	
Resumption of oral intake	Chewing gum/Lozenges and sips of water at 2 h, Clear fluid/juices at 6 h, Semisolid at 8 h after surgery	Clear fluids after 24 h and semisolid On third day after surgery	
Decatheterization	Early decatheterization within 6 h of surgery was done in ERAC protocol	Patients were de-catheterized on third day or more after surgery depending upon ease of ambulation	

 Table 1
 Comparison between components of ERAS and traditional protocol

Both

mobilizing the patient from bed to chair first

followed by walking with support)

followed by walking with support (10–12 h) according to patient's comfort level and pain

status)

Within 6–8 h (mobilize from bed to chair in 6–8 h Mobilization started after 12–24 h (start with

**Fraditional** protocol

ERAC protocol

value < 0.01). Similarly, we observed that mean QoR score atr 48 h postoperatively was significantly higher for patients in the ERAC group as compared to those in the traditional group ( $90.1 \pm 7.87$  vs  $68.5 \pm 7.97$ , *p* value < 0.01).

It was seen that 42.1% of the mothers in the ERAC group had adverse effects, while 40% of mothers in the traditional group had adverse effects. The difference was not statistically significant. In the ERAC group, shivering (13.7%) and itching (11.6%) were the most common adverse outcomes. In the traditional group, fever (12.6%), breast engorgement (8.4%) and headache (8.4%) were the commonly observed adverse effects.

The incidence of SSI was 3.2% in the ERAC group and 6.3% in the traditional group (*p* value = 0.49). The mean length of hospital stay was significantly lower for patients in the ERAC group as compared to those in the traditional group ( $68.8 \pm 1.9$  vs  $105.4 \pm 25.7$  h, *p* value < 0.001).

## Discussion

Cesarean delivery is the commonest surgery which is being performed in obstetrics with the rate of approximately 17.2% of total live birth according to NFHS-4 in India [5]. The growing cesarean delivery rate is causing a financial burden over hospital infrastructure as well as patient. Majority of patients are young and healthy with a potential for faster recovery and motivation to return to normal state of function to care for baby. Various guidelines have been introduced to improve maternal and neonatal outcome through better intraoperative and postoperative care. ERAC aims at optimizing the standard of care in these patients. In 2018, ERAS society has released guidelines for cesarean delivery [6]. Although ERAS protocols have been successfully infiltrated in various specialties so far, but data are limited in obstetrics [7].

This study aimed primarily at comparing Quality of recovery based on obstetric-specific QoR 11 questionnaire between patients undergoing ERAC and Traditional protocol for Elective LSCS. Secondary focus was to compare perioperative bleeding, breast feeding initiation and difficulties, first oral intake, ambulation attempts, decatheterization, SSI, and length of hospital stay.

There was no statistical difference in demographic features of patients in both ERAC and Traditional group. Obesity has been shown to be associated with longer periods of hospitalization and greater hospital costs. However, no prior studies have examined the correlation between BMI and the ERAC protocol in patients undergoing cesarean section. In a recent study, Shin et al. [8] reported that higher BMI patients were benefited with ERAS protocol in the form of speedy recovery and decreased length of hospital stay. Future studies are required to assess the same in patients undergoing cesarean section. There was no statistical difference of

 Table 1
 (continued)

Ambulation

	SQOR-11 Questionnaire							Stu	dy II	D:		
24	Hour Questionnaire		Date: Tir				îme:					
How have you been feeling in the last 24 hours? (0 to 10, where: 0 = very poor and 10 = excellent)												
							•					<u>.</u>
		Stron	gly agr	66 →	→	<b>→</b>	· →	<b>→</b>	<b>→</b>	Stron	ıgly dis	agree
		0	1	2	3	4	5	6	7	8	9	10
1	I have had moderate pain	0	0	0	0	0	0	0	0	0	0	0
2	I have had severe pain	0	0	0	0	0	0	0	0	0	0	0
3	I have had nausea or vomiting	0	0	0	0	0	0	0	0	0	0	0
4	I have been feeling dizzy	0	0	0	0	0	0	0	0	0	0	0
5	I have had shivering	0	0	0	0	0	0	0	0	0	0	0
							•					<u>.</u>
		Stron	gly dis	agree	->	->		→	<b>→</b>	→St	rongly	Agree
		0	1	2	3	4	5	6	7	8	9	10
6	I have been comfortable	0	0	0	0	0	0	0	0	0	0	0
7	I am able to mobilise independently	0	0	0	0	0	0	0	0	0	0	0
8	I can hold baby without assistance	0	0	0	0	0	0	0	0	0	0	0
9	I can feed/nurse my baby without assistance	0	0	0	0	0	0	0	0	0	0	0
10	l can look after my personal hygiene/toilet	0	0	0	0	0	0	0	0	0	0	0
11	I feel in control	0	0	0	0	0	0	0	0	0	0	0
ma th s	aginable 😥 💷 💷			1		1				<b>:</b>	Be	est in heal

Fig. 1 Quality of recovery -11 questionnaire

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<b>Table 2</b> Comparison ofparameters between ERAC and	Parameter	Traditional	ERAC	p value
traditional group	Mean age (years)	$28.7 \pm 4.46$	$28.88 \pm 4.4$	0.85
	Mean BMI	$26.6 \pm 5.2$	$26.3 \pm 5.1$	0.66
	Incidence of HDCP in present pregnancy	17.9%	8.40%	0.53
	Mean duration of fasting (h)	$11.82 \pm 0.96$	$3 \pm 1.37$	< 0.01
	Incidence of PPH (%)	6.3%	10.5%	0.29
	Mean duration of initiation of breastfeeding within 1 h	0	50.5%	0.001
	Incidence of breast feeding difficulties	18.90%	16.80%	0.71
	Ambulation within 6 h of surgery	0	86.3%	< 0.001
	Decatheterization within 6 h of surgery	0	86.3%	< 0.001
	Need of oral analgesic on day 3	100%	20%	< 0.01
	Mean 24 h QoR score	$57.1 \pm 11.33$	$85.59 \pm 7.46$	< 0.01
	Mean 48 h QoR score	$68.53 \pm 7.97$	$90.12 \pm 7.87$	< 0.01
	Incidence of adverse events	40%	42.1%	0.76
	Incidence of surgical site infection	6.3%	3.2%	0.49
	Mean duration of LOSH (h)	$105.4 \pm 25.72$	$68.82 \pm 19.97$	< 0.001

Table 3 Comparison of mean duration of initiation of breastfeeding

Breastfeeding	GROUP	Total	
	ERAC Traditional		
Within 1 h			
Ν	48	0	48
%	50.50%	0.00%	25.30%
2–4 h			
Ν	33	31	64
%	34.70%	32.60%	33.70%
5–6 h			
Ν	1	39	40
%	1.10%	41.10%	21.10%
More than 6 h			
Ν	13	25	38
%	13.70%	26.30%	20.00%
Total			
Ν	95	95	190
%	100.00%	100.00%	100.00%
	<i>p</i> value < 0.001		

incidence of Hypertensive disease complicating pregnancy (HDCP) and postpartum hemorrhage (PPH) in patients of both ERAS and Traditional group. This is similar to previous study done by Cojocaru et al. [9] where no difference was found in the incidence of PPH post ERAC implementation. It is a known fact that early initiation of breast feeding within one hour of life provides protection against neonatal infection and has been shown to prevent neonatal death due to sepsis, pneumonia, diarrhea and hypothermia [10-12]. Also, it creates an emotional bonding between mother and child by promoting skin to skin contact, more holding and stroking [13]. As ERAC promotes early initiation of breast feeding, so in this study, 50.5% mothers started breast feeding within first hour and in rest delayed initiation of breast feeding was due to shifting of their babies to NICU. In Traditional group, none of the mother could start breast feeding within first hour mainly due to pain and various other social and cultural factors. Although at our setup we promote universal initiation of breast feeding within first hour. The difference was statistically significant (p value < 0.001). In addition, the incidence of feeding difficulty was 16.8% in the ERAC group and 18.9% in the traditional group. The difference was not statistically significant (p value = 0.71).

Table 4 Comparison of mean duration of time of oral intake

	ERAC		Traditional	p value*	
	Mean	SD	Mean	SD	
First time of oral intake (min)	71.94	43.25	1163.37	82.70	< 0.05
Clear liquids (min)	246.95	31.39	1160.84	74.14	< 0.05
Semisolid (min)	531.16	143.27	2497.26	145.44	< 0.01
Solid (h)	35.92	13.11	64.66	5.74	< 0.01

\*Analyzed using student's t test

Ambulation attempt time	GROUP	Total	
	ERAS		
Within 6 h			
Ν	82	0	82
%	86.30%	0.00%	43.20%
6–12 h			
Ν	10	0	10
%	10.50%	0.00%	5.30%
12–24 h			
Ν	3	0	3
%	3.20%	0.00%	1.60%
More than 24 h			
Ν	0	95	95
%	0.00%	100.00%	50.00%
Total			
Ν	95	95	190
%	100.00%	100.00%	100.00%
	p value $< 0.001$		

 Table 5
 Comparison of mean duration to first ambulation attempt postoperatively

\*Analyzed using student's t test

 Table 6
 Comparison of mean duration of catheter removal time

Catheter removal time	GROUP	Total		
	ERAC	Traditional		
Within 6 h				
Ν	82	0	82	
%	86.30%	0.00%	43.20%	
6–12 h				
Ν	10	0	10	
%	10.50%	0.00%	5.30%	
12–24 h				
Ν	3	0	3	
%	3.20%	0.00%	1.60%	
More than 24 h				
Ν	0	95	95	
%	0.00%	100.00%	50.00%	
Total				
Ν	95	95	190	
%	100.00%	100.00%	100.00%	
	<i>p</i> value < 0.001			

\*Analyzed using student's t test

Similar findings were seen in studies done by Choudhary et al. [14] and Teigen et al. [15]

Recently, several studies have reported that early oral intake helps enhanced recovery after surgery compared with traditional method of resuming oral intake only after clinical signs of resolution of postoperative paralytic dysmotility [16]. The duration of first time of oral intake in our study was significantly lower in the ERAC group as compared to the traditional group ( $71.94 \pm 43.25$  vs  $1163.37 \pm 82.70$  min (*p* value 0.05). Similar results were obtained by Choudhary et al. [14] and Hedderson et al. [17] in their study.

Cochrane review has reported that early catheter removal after cesarean section showed decreased urinary tract infection and unchanged incidence of voiding dysfunction [18]. For these reasons, The Society for Obstetric Anesthesia and Perinatology guidelines recommend catheter removal at 6-12 h postpartum with protocol for managing post catheter retention [19]. In this study, in the ERAC group, catheter was removed within 6 h postoperatively in 86.3%; contrary to this, in the traditional group, catheter was removed after 24 h in all patients (*p* value < 0.001). Similar results were obtained by Choudhary et al. [14] and Hedderson et al. [17] in their study.

Early mobilization is an important intervention for improving postoperative pain, wound healing, prevention of DVT, reducing hospital stay and expediting recovery and return to normal activity [20]. Also, it enables new mothers for breast feeding and early oral intake [21]. In this study, patients in the ERAC group were mobilized within 6 h postoperatively in 86.3% contrary to the traditional group, where ambulation was attempted after 24 h in all patients (*p* value < 0.001).

Postoperative pain may be caused by postsurgical inflammation secondary to invasive stimulation and it markedly affects patient recovery and satisfaction; therefore, postoperative pain relief is important [22]. It was observed that 80% of ERAC patients required oral analgesic only till second day and 20% required oral analgesic on third day postoperative. On the other hand, 100% of the patients in the traditional group required oral analgesic till day 3 (p value < 0.01). The findings are similar to Kleinman et al. [23] where the implementation of ERAC resulted in a 38% reduction in total postoperative opioid consumption. Although no differences were noted in the study by Teigen et al. [15] in regard to postoperative narcotic requirement. Hospital length of stay (LOS) is a quality metric health systems use as a proxy of efficient hospital management. Reduction in LOS improves bed turnover, allowing hospitals to match demand with capacity for elective and emergent admissions, intensive care unit (ICU) care, and interhospital transfers [24]. In this study, the mean length of hospital stay was significantly lower for patients in the ERAC group as compared to those in the traditional group ( $68.8 \pm 1.9$  vs  $105.4 \pm 25.7$  h, p value < 0.001). Similar findings were seen by Choudhary et al. [14], Pravina and Tewary [25] and Tamang et al. [26]. The Obs OoR11 provides a valid, reliable and responsive global assessment of recovery after elective cesarean delivery. In this study, QoR 11 score was used at 24 and 48 h postoperatively and mean QoR score was significantly found higher for patients in the

ERAC group as compared to those in the traditional group  $(85.5 \pm 7.46 \text{ vs } 57.1 \pm 11.33, p \text{ value } < 0.01)$ . Similar results were obtained by Choudhary et al. [14]. To the best of our knowledge, no other study evaluated and compared QoR-11 score for ERAC and traditional protocol patients.

Postoperative adverse events are a common phenomenon which can occur after any surgical procedure, affecting patient's psychological, emotional and physical wellbeing as well as increases economic burden of both patient and hospital. In this study, 42.1% of the mothers in the ERAC group and 40% of mothers in the traditional group had adverse effects. The difference was not statistically significant. This is contrary to a study by Baluku et al. [27] where the difference was statistically significant. It was also observed in their study that ERAC group patients had significantly higher incidence of pruritis (8.9% in ERAC group compared to 1.5% in Traditional group, p value 0.023).

Surgical site infection is one of the common preventable complications after surgery, occurring in 2–4% of all patients, and remains a significant cause of morbidity and mortality after surgery [28]. The incidence of SSI was 3.2% in the ERAC group and 6.3% in the traditional group in this study. The difference was not statistically significant (pvalue = 0.49). Similar findings were noted by Tamang et al. [26] and Baluku et al. [27].

#### Limitations

Limitations of this study were:

- Randomization could not be conducted, as the decision to undergo ERAC or traditional protocol was made by the operating surgeon after discussing with the patients.
- The patients or the investigators could not be blinded to the protocol.

# Conclusion

The use of ERAC protocol at cesarean delivery significantly improves quality of recovery and length of hospital stay. These interventions may potentially reduce healthcare costs and decrease use of hospital resources. Successful implementation of ERAC protocol involves multidisciplinary team in collaboration with hospital administration with multimodal communication techniques. We recommend future multicentric and large sample studies to support our findings and to identify barriers in implementing ERAC.

#### Declarations

Conflict of interest There is no conflict of interest.

Ethical Approval Ethical clearance has been taken for the study.

**Informed Consent** Informed consent is being taken from all participants.

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