Section: Anaesthesiology

Original Research Article

A STUDY OF THE ROLE OF IMMERSIVE VIRTUAL REALITY ON ALLEVIATION OF PATIENT ANXIETY DURING ELECTIVE HAEMORRHOIDECTOMY UNDER REGIONAL ANAESTHESIA: A RANDOMIZED CLINICAL TRIAL

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ABSTRACT

Background: Regional anaesthesia has been the cornerstone for elective hemorrhoidectomy. Peri-operative anxiety is a common problem encountered in adults. Virtual Reality (VR) is a computer-generated environment with scenes and objects that appear to be real, making the user feel they are immersed in their surroundings. This study aims to understand the effects of VR on the peri-operative anxiety and variation in the intra-operative hemodynamic parameters of these patients.

Materials and Methods: After ethical committee approval, single-blinded randomised clinical study was conducted,after taking informed written consent on 32 Patients, aged 18 to 60 years, ASA I & II, undergoing elective hemorrhoidectomy after meeting inclusion and exclusion criteria . Study intervention: 32 patients are randomly divided into two groups. Group A- Non interventional Control group (n=16); Group B- Immersive virtual reality group (n=16). Anxiety of the patients was assessed 1 day prior to surgery and in the peri-operative period .Intra-op hemodynamics; patient's hemodynamic parameters are noted at 0,1,2,5,10,20,30,60,120,240 minutes..

Results: It was found that the anxiety scores among participants in the intervention group were lower than the anxiety scores of participants in the non-intervention group. The mean difference was found to be statistically significant in post 30 minutes stage(P = 0.001) and post operative stage(P=0.002). It was found that participants in the VR intervention group had statistically significantly lesser heart rate at 5,10,30 and at 60 minutes respectively. For all other time intervals, the heart rate was found to be comparable. It was observed that participants in the VR intervention group had lower systolic blood pressure than participants in the non-intervention group from 5 minutes to 120 minutes respectively. It was found that participants in the intervention group had lower diastolic blood pressure than participants in the non-intervention group at 10 minutes, 30 minutes, 60 minutes, 120 minutes, and 240 minutes respectively.

Conclusion: The study concluded that immersive virtual reality reduced patient anxiety in the peri-operative period and had lower gradual effect on the hemodynamics. The role of VR in hemodynamic stability of the patient in peri-operative period was significant in only few intervals and can be investigated further.

Keywords: Regional anaesthesia, Hemorrhoidectomy surgery, Virtual Reality, Peri-operative Anxiety, Hemodynamic Parameters.

INTRODUCTION

Regional anaesthesia has been the cornerstone for both elective and emergency hemorrhoidectomy surgeries as it avoids most of the potential risks of General anaesthesia and does not affect the patient's consciousness.[1] It is thus imperative that regional anaesthesia has become an indispensable weapon in the arsenal of anaesthesiologists to tackle post-operative pain and to provide for better patient care and outcomes at relatively lower costs. However, surgery and anaesthesia are often associated with increased patient stress and anxiety.[2]

Pre-operative anxiety is an important issue in pediatric anaesthesia ,affecting more than 50% of the children.[3] Peri-operative anxiety is a common problem encountered in adults also(32%).[4,5] The prospect of seeing and hearing everything in the peri-operative period, along with the type of surgery, perception of loss of control of surroundings, fear of post-operative pain and changes in body image influence the level of anxiety of patients.[6] High anxiety in turn leads to higher requirements of anaesthesia, use of sedative drugs, increased hospital stay and increased cost.[7]

Since time immemorial, different distraction techniques have been used to control fear and relieve the patient's anxiety,i.e: both pharmacological (sedatives) and non-pharmacological like distribution of pamphlets, listening to light music etc.[1]

Virtual Reality (VR) is a computer-generated environment with scenes and objects that appear to be real, making the user feel they are immersed in their surroundings. This environment is perceived through a device known as a Virtual Reality headset or helmet. VR use has expanded from the entertainment sector to the fields of medical education, rehabilitation, management of mental health and chronic pain.[8]

Immersive virtual reality creates a virtual environment that allows patients to interact and be immersed in the virtual world and apply them in real situations. Theoretically, inhibitory learning mechanisms emerge when anxiety supression is achieved by neurobiological adjustment of the pre frontal cortex, amygdala and hippocampus.[9,10] Virtual reality can alter several brain areas involved in pain pathways.[1]

Although VR has been shown to provide effective anxiolysis in minor procedures such as endoscopy and dressing changes,[11,12] there is still a need for investigation of VR's effective role in surgeries under regional anaesthesia . This study aims to understand the effects of VR on the peri-operative anxiety on these patients and also variation if any in the intra-operative hemodynamic parameters of these patients.

Objectives

To evaluate

1. The effect of Immersive virtual reality on alleviation of peri-operative anxiety of patients undergoing elective hemorrhoidectomy surgery under regional anaesthesia.
2. To evaluate the effect of Immersive virtual reality on changes in hemodynamic parameters (Heart rate, BP, SpO2) of patients undergoing elective elective hemorrhoidectomy surgery under regional anaesthesia.

MATERIALS AND METHODS

Approval of institutional ethics committee was taken prior to conducting the study. 32 patients scheduled for elective hemorrhoidectomy surgeries requiring regional anesthesia were enrolled in the study. Patients underwent a thorough pre anesthetic examination and were explained about the study, surgery and type of anesthesia and risks associated. Informed written consent was obtained on day prior to surgery for administration of anesthesia, separate consent was taken for the enrollment in the study.

The main variable in this study was the patient anxiety measured using Speilbergers State Trait Anxiety Inventory-6 questionarre,[13] with a Likert scale consisting of 4 values(1=not at all,2= somewhat,3=Moderately,4= very much) . The anxiety level of the patients will be measured 4 times:

1. baseline data measured 1 Day prior to the scheduled surgery
2. When the patient is in the pre-operative room
3. 30 minutes after anaesthesia administration and start of surgery
4. after the completion of surgical procedure in the recovery room

A score of >15 indicates the presence of anxiety which will be tabulated at each stage.

Inclusion Criteria

- Patients willing to give written informed consent
- ASA physical status I, II
- Patients aged 18-60 years
- Patients with educational qualification of SSLC (10th Grade) and above.

Exclusion Criteria

- Patients refusal of consent
- Patients with shock, major anaesthetic/surgical complications
- Patients who found that VR is damaged/error with device during the study
- Patients with history of epilepsy, psychiatry disorder, claustrophobia and visual disability

After confirmation of preoperative fasting status and baseline vital parameters (such as Heart rate, Blood pressure, Oxygen saturation), intravenous access was secured with 18G cannula. Patients were given Inj. Pantoprazole 40mg i.v, 30 minutes prior to surgery. The patients anxiety score was recorded before shifting to OT, and then standard ASA monitors were connected-pulse oximetery, non invasive blood pressure, ECG.

The patients were allocated to two groups randomly on the day of the study

A Group with No active intervention

B Group with Immersive Virtual Reality(IVR)
Coloading with crystalloid solutions (RL 10-15ml/kg) was done. Subarachnoid blockade was performed in left lateral position using 25G Quinke's spinal needle at L2-L3 or L3 - L4 interspace and 0.5% Bupivacaine (Heavy) drug(12-15mg) was deposited intrathecally. Patient was pre-oxygenated via face mask/nasal prongs. Once adequate blockade is obtained, the study was initiated for each of the two groups:
For group-A, No active intervention was given after administration of regional anaesthesia.
In case of the Group B, the group was given an IVR intervention (using JioDive VR Headset) for 30 minutes (meditational and nature based videos) with a 5 minutes rest period until the procedure was completed.
After the initiation of the study and appropriate positioning of the patient, the surgeon was allowed to start the surgery. Continous monitoring of ECG, NIBP, PR, SPO2 was done.
The patient's anxiety score was assessed at the end of 30 minutes and hemodynamic parameters were tabulated at 0,1,2,5,10,20,30,60,120 minutes and so on further and assessed. Post procedure all patients were monitored in the recovery room for 30 minutes and Anxiety score was re-assessed.

Place of Study

Major OT complex, BGS Global institute of medical sciences and hospital.

Sample Size

Based on the study conducted by Johan arifin, the estimated sample size was around 32, which was calculated at 90% confidence level, at the power of 80%, d2 is the allowable error of peri-operative patients anxiety in virtual reality and control group:
d^2 =effect size=0.9
$z_{(\alpha/2)}$=1.645 for 90% of the confidence interval[10% type 1 error]
$z_{(1-\beta)}$=0.842 for 80% power of the study

$$n = \frac{2(Z_{(\alpha/2)}+Z_{(\beta)})2}{d2}$$

The sample size was determined to be around 32(2x16).

RESULTS

Observation

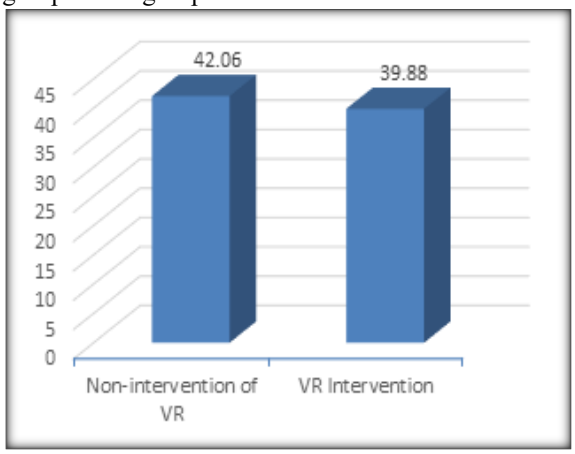
Speilbergers State Trait Anxiety Inventory-6 questionarre with a Likert scale consisting of 4 values (1=not at all,2= somewhat,3=Moderately,4= very much) .
THE 6 QUESTIONS OF THE QUESTIONARRE ARE:

1. I feel calm
2. I am tense
3. I feel upset
4. I am relaxed
5. I feel content
6. I am worried

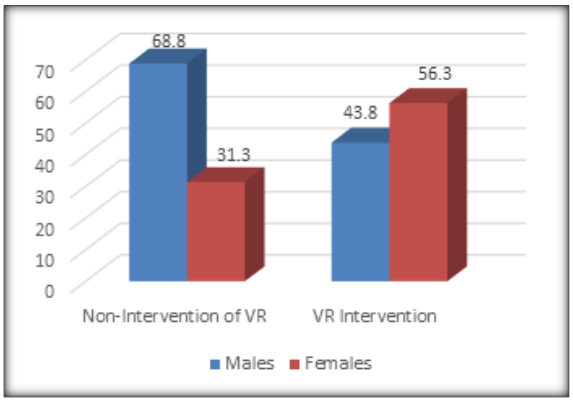
Reverse scoring of the positive items is done, (calm, relaxed, content) so 1=4, 2=3, 3=2 and 4=1
The anxiety level of the patients were measured 4 times:
A-baseline data measured 1 Day prior to the scheduled surgery
B-When the patient is in the pre-operative room
C- 30 minutes after anaesthesia induction and start of surgery
D- after the completion of surgical procedure in the recovery room
A score of >15 indicates the presence of anxiety in patients.

Results

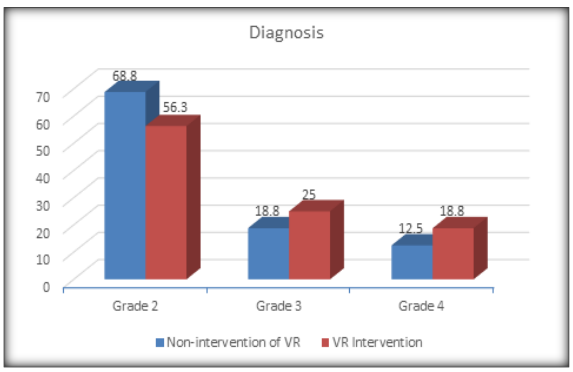
The study population consists of 32 patients who were divided into two groups of 16 patients each in group A and group B.



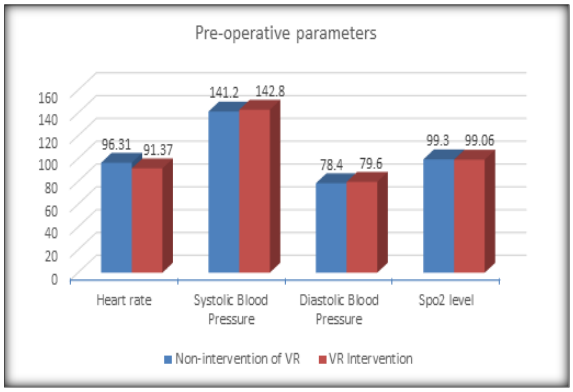
Graph 1: Age of study participants



Graph 2: Distribution according to gender



Graph 3: Distribution of participants according to diagnosis (hemorrhoids)



Graph 4: Mean pre-operative parameters

Pre-operative Heart rate

It was found that participants in the non-intervention group had a higher heart rate than participants in the intervention group. However, the mean difference was not statistically significant (P = 0.2).

Pre-operative Systolic Blood Pressure:

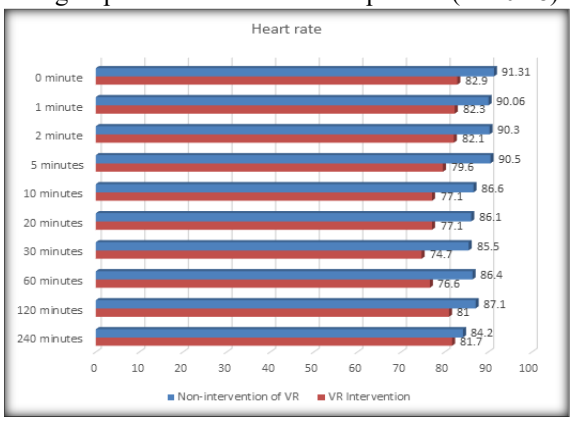
It was found that systolic blood pressure among participants in both groups was found to be comparable (P = 0.74).

Pre-operative Diastolic Blood Pressure

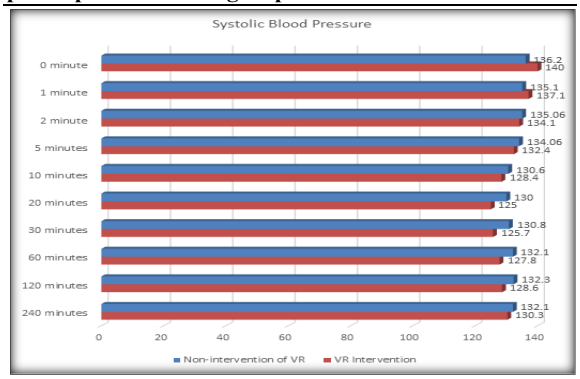
It was found that diastolic blood pressure among participants in both groups was found to be comparable (P = 0.77).

Pre-operative SPO2 level

It was found that SPO2 levels among participants in both groups were found to be comparable (P = 0.48).

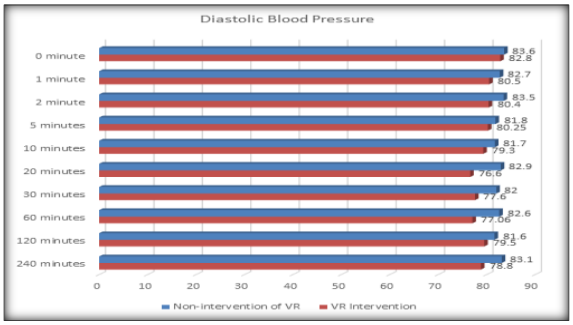


Graph 5: Mean intra-operative heart rate among participants between groups at different time intervals

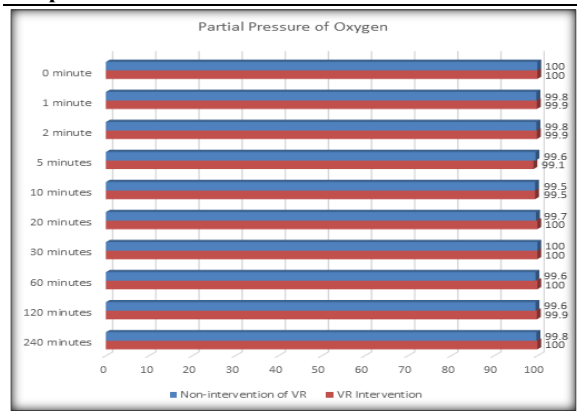


Graph 6: Mean intra-operative systolic blood pressure among participants between groups at different time intervals

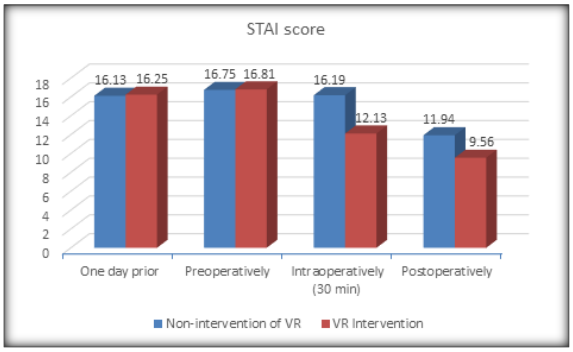
It was found that the systolic blood pressure among participants in both groups was found to be comparable (P > 0.05). Though, statistically not significant, it was observed that participants in the intervention group had lower systolic blood pressure than participants in the non-intervention group from 5 minutes to 120 minutes respectively.



Graph 7: ?



Graph 8: Mean intra-operative SPO2 level among participants between groups at different time intervals



Graph 9: Mean STAI score among participants between the groups at different time

One day Prior

It was found that the anxiety scores among participants between the groups were comparable (P = 0.74).

Preoperatively

It was found that the anxiety scores among participants between the groups were comparable (P = 0.82).

Intraoperatively (30 min)

It was found that the anxiety scores among participants in the intervention group were lower than the anxiety scores of participants in the non-intervention group. The mean difference was found to be statistically significant (P = 0.001).

Postoperatively

It was found that the anxiety scores among participants in the intervention group were lower than the anxiety scores of participants in the non-intervention group. The mean difference was found to be statistically significant (P = 0.002).

Table 1: Age of study participants

		Non-intervention of VR	VR Intervention
Age	Minimum	23	23
	Mean	42.06	39.88
	Maximum	58	56

Table 1.1: Comparison of mean age of participants between two groups

	Number	Mean	SD	t	P value
Non-Intervention of VR	16	42.06	11.6	0.58	P = 0.566
VR Intervention	16	39.88	9.55		NS

SD-standard deviation; NS-not significant using unpaired t-test

It was found that the ages of participants in both groups were comparable (P = 0.56)

Table 2: Distribution of participants according to gender

	Non-Intervention of VR	VR Intervention	Total	P value
	N (%)	N (%)	N	
Males	11 (68.8)	7 (43.8)	18	P = 0.28
Females	5 (31.3)	9 (56.3)	14	NS
Total	16 (100)	16 (100)	32	

N-number; %-percentage; NS-not significant using chi-square test

It was found that more males (68.8%) were in the non-intervention group and more females (56.3%) were in the intervention group. The distribution was not statistically significant (P = 0.28).

Table 3: Distribution of participants according to diagnosis (hemorrhoids)

	Non-intervention of VR	VR Intervention	Total	P value
	N (%)	N (%)	N	
Grade 2	11 (68.8)	9 (56.3)	20	P = 0.76
Grade 3	3 (18.8)	4 (25)	7	NS
Grade 4	2 (12.5)	3 (18.8)	5	
Total	16 (100)	16 (100)	32	

N-number; %-percentage; NS-not significant using chi-square test

It was found that participants in the non-intervention group had more grade 2 hemorrhoids when compared to the intervention group. In addition, participants in the intervention group had more cases of grades 3 and 4 respectively. The distribution was not significant (P = 0.76).

Table 4: Comparison of Mean pre-operative parameters

	Non-intervention of VR		VR Intervention		t	P value
	Mean	SD	Mean	SD		
Heart rate	96.13	10.4	91.3	10.8	1.3	P = 0.2 (NS)
Systolic Blood Pressure	141.2	9.6	142.8	16.9	-0.33	P = 0.74 (NS)
Diastolic Blood Pressure	78.4	12.4	79.6	11.4	-0.29	P = 0.77 (NS)
Spo2 level	99.3	1.2	99.06	1.25	0.709	P = 0.48 (NS)

SD-standard deviation; NS-not significant using unpaired t-test

Table 5: Comparison of mean intra-operative heart rate among participants between groups at different time intervals

	Non-intervention of VR		VR Intervention		t	P value
	Mean	SD	Mean	SD		
0 minute	91.31	11.44	82.9	17.2	1.6	P = 0.11
1 minute	90.06	8.7	82.3	16.7	1.62	P = 0.11
2 minutes	90.3	7.9	82.1	15.9	1.83	P = 0.07
5 minutes	90.5	6.3	79.6	15.9	2.5	P = 0.02*
10 minutes	86.6	8.3	77.1	16.7	2.04	P = 0.05*
20 minutes	86.1	7.6	77.1	16.3	2.01	P = 0.057
30 minutes	85.5	8.09	74.7	14.1	2.6	P = 0.014*
60 minutes	86.4	4.08	76.6	13.2	2.8	P = 0.012*
120 minutes	87.1	5.6	81	10.7	2.01	P = 0.056

240 minutes	84.2	7.6	81.7	11.8	0.7	P = 0.48

SD-standard deviation;

Statistically significant at *P < 0.05 using unpaired t-test

It was found that participants in the VR intervention group had statistically significantly lesser heart rate than participants in the non-intervention group at 5 minutes (P = 0.02), at 10 minutes (P = 0.05), at 30 minutes (P = 0.012), and at 60 minutes (P = 0.012) respectively. For all other time intervals, the heart rate was found to be comparable.

Table 6: Comparison of mean intra-operative systolic blood pressure among participants between groups at different time intervals

	Non-intervention of VR		VR Intervention		t	P value
	Mean	SD	Mean	SD		
0 minute	136.2	12.04	140	9.9	-0.96	P = 0.34 (NS)
1 minute	135.1	9.6	137.1	12.4	-0.492	P = 0.62 (NS)
2 minutes	135.06	9.7	134.1	11.2	0.235	P = 0.81 (NS)
5 minutes	134.06	8.2	132.4	10.7	0.48	P = 0.63 (NS)
10 minutes	130.6	3.7	128.4	11.5	0.72	P = 0.47 (NS)
20 minutes	130	8.5	125	9	1.613	P = 0.11 (NS)
30 minutes	130.8	6.55	125.7	11.4	1.53	P = 0.13 (NS)
60 minutes	132.1	6.9	127.8	14.3	1.08	P = 0.28 (NS)
120 minutes	132.3	7.2	128.6	11.9	1.05	P = 0.29 (NS)
240 minutes	132.1	7.1	130.3	9.6	0.6	P = 0.55 (NS)

SD-standard deviation;

NS-not significant and statistically significant at *P < 0.05 using unpaired t-test

Table 7: Comparison of mean intra-operative diastolic blood pressure among participants between groups at different time intervals

	Non-intervention of VR		VR Intervention		t	P value
	Mean	SD	Mean	SD		
0 minute	83.6	5.4	82.8	9.5	0.295	P = 0.77 (NS)
1 minute	82.7	5.5	80.5	8.8	0.84	P = 0.4 (NS)
2 minutes	83.5	5.57	80.4	8.8	1.17	P = 0.25 (NS)
5 minutes	81.8	5.1	80.25	8	0.65	P = 0.5 (NS)
10 minutes	81.7	5.2	79.3	8.2	0.96	P = 0.34 (NS)
20 minutes	82.9	5.3	76.6	8.3	2.5	P = 0.017*
30 minutes	82	5.2	77.6	7.8	1.85	P = 0.07 (NS)
60 minutes	82.6	6.4	77.06	10.5	1.8	P = 0.08 (NS)
120 minutes	81.6	4.8	79.5	10.5	0.75	P = 0.45 (NS)
240 minutes	83.1	6.2	78.8	7.04	1.8	P = 0.07 (NS)

SD-standard deviation;

NS-not significant and statistically significant at *P < 0.05 using unpaired t-test

It was found that at 20 minutes, participants in the intervention group had lower diastolic blood pressure than participants in the non-intervention group which was statistically significant (P = 0.017). In addition, though not statistically significant, it was found that participants in the intervention group had lower diastolic blood pressure than participants in the non-intervention group at 10 minutes, 30 minutes, 60 minutes, 120 minutes, and 240 minutes respectively.

Table 8: Comparison of Mean intra-operative SPO2 level among participants between groups at different time intervals

	Non-intervention of VR		VR Intervention		t	P value
	Mean	SD	Mean	SD		
0 minute	100	0	100	0	-	-
1 minute	99.8	0.34	99.9	0.25	-0.591	P = 0.56 (NS)
2 minutes	99.8	0.34	99.9	0.5	1.26	P = 0.56 (NS)
5 minutes	99.6	0.8	99.1	1.3	0.21	P = 0.21 (NS)
10 minutes	99.5	0.72	99.5	0.89	-2.23	P = 0.83 (NS)
20 minutes	99.7	0.44	100	0	-2.61	P = 0.033*
30 minutes	100	0	100	0	-	-
60 minutes	99.6	0.47	100	0	-2.6	P = 0.014*
120 minutes	99.6	0.61	99.9	0.25	-1.8	P = 0.07 (NS)
240 minutes	99.8	0.4	100	0	-1.8	P = 0.08 (NS)

SD-standard deviation;

NS-not significant and statistically significant at *P < 0.05 using unpaired t-test

It was found that the partial pressure of oxygen among participants was comparable at all time intervals between the groups except at 20 minutes and 60 minutes. In addition, participants in the

intervention group had 100% SPO2 level when compared to participants in the non-intervention group at 20 minutes (P = 0.033) and 60 minutes (P = 0.014) respectively which was statistically significant.

Table 9: Comparison of mean STAI score among participants between the groups at different time

	Non-intervention of VR		VR Intervention		t	P value
	Mean	SD	Mean	SD		
One day prior	16.13	1.02	16.25	1.1	-0.33	P = 0.74 (NS)
Preoperatively	16.75	0.93	16.81	0.65	-0.22	P = 0.82 (NS)
Intraoperatively (30 min)	16.19	0.91	12.13	0.22	7.9	P = 0.001**
Postoperatively	11.94	2.2	9.56	1.7	3.3	P = 0.002**

SD-standard deviation;
NS-not significant and statistically significant at *P < 0.05 using unpaired t-test

DISCUSSION

Virtual reality is one such advanced technology where in patients are immersed in a simulated environment which helps scale down anxiety when they are confined to stressful hospital environment.. Immersive Virtual Reality(IVR) uses computer generated auditory and visual stimuli to create an illusionary presence or the perception of virtual objects in the physical world. The greater the illusion the patient feels, the greater the degree of immersion and distraction, resulting in reduced patient anxiety[2] IVR is a non-pharmacological therapy. As a distraction technique, IVR has the potential to reduce anxiety in patients undergoing surgery.

The study conducted by us intended to evaluate the role of Immersive virtual reality against no other intervention such as sedatives or benzodiazepines. We had enrolled 32 patients in our study and all of them agreed to participate in our study. Some patients were aware about IVR technology and some were educated about it. In few patients, reassuarance about the intervention helped play a key role for their consent to participate in the study. Patients were offered consent forms and anxiety questionarre forms in both English and local language(kannada) to defer any linguistic barrier for the study. The patients on the day of surgery were randomly allowed to choose a number from 1-32 with odd numbered ones receiving no intervention and even numbered patients recieving IVR. No patient expressed any discomfort/dissatisfaction during or after the procedure.

In our study it was found that the anxiety scores among participants in the intervention group were lower than the anxiety scores of participants in the non-intervention group. The mean difference was found to be statistically significant in post 30 minutes stage (P = 0.001) and post operative stage(P=0.002). It was found that participants in the VR intervention group had significantly lesser heart rate at 5,10,30,60 minutes respectively. It was observed that participants in the VR intervention group had lower systolic blood pressure from 5 minutes to 120 minutes (statistically not significant) and had lower diastolic blood pressure than participants in the non-intervention group at 10 minutes, 30 minutes, 60 minutes, 120 minutes, and 240 minutes respectively and statistically significant at 20 minute interval. It was found that the partial pressure of oxygen among participants was comparable at most time intervals between the groups was not statistically significant except at 20 and 60 minute intervals.

In the study conducted by Johan arifin et. Al,[2] a total of 30 participants had participated in a similar study to observe the effects to allievate anxiety in patients posted for lower limb surgeries with virtual reality vis a vis iv midazolam , they found that a significant reduction in perioperative anxiety levels was observed in the VR group compared to the control group. The patient satisfaction level was also significantly higher in the VR group than in the control group (P = 0.024). Both groups had no significant difference in monitored vital signs, side effects, and surgeon satisfaction.

In a similar study conducted by Camille alterre et al,[1] in 2020 on 100 patients(VR-PERLA Study) receiving upper limb regional anaesthesia where 50 patients received VR intervention and , primary outcome was patient self-rated satisfaction score evaluated right after surgery. Secondary outcomes included 2-month patient-reported satisfaction score, perioperative self-rated anxiety and intraoperative hemodynamic changes. Compared to former standard care, VR distraction was associated with significantly higher postoperative satisfaction scores. Patient median intraoperative anxiety score was lower in the VR group, compared to Standard Care group and occurrence of intraoperative hemodynamic changes was also lessened in the VR group. The present findings suggest that VR distraction program in the operating room could effectively improve patient satisfaction with anxiety-reduction and hemodynamic benefits.

In a study conducted by ryu et al,[4] in 2017,69 children were given a VR tour of the operating theatre before anaesthesia to determine whether a pre-operative VR tour could reduce pre-operative anxiety, and it was found that 35 children in the VR group had significantly lower anxiety score than those in the control group. During anaesthesia, the VR group had better induction compliance and procedure behavioural score. Thus concluding that a pre-operative VR tour/counselling will be effective .

In a study conducted by Vazquez et al,[5] in 2016 on the use of VR in patients undergoing diagnostic upper

GI endoscopy reported that visceral responses during oesophageal, stomach, and duodenum endoscopy were reduced using VR. Overall pain was significantly lower in the VR group than the control group with a moderate effect size. Physician stress was also reduced in the VR group, allowing greater accuracy and a shorter procedure time, thus concluding that VR therapy considerably reduces the need for medication, effectively lowering costs for public health institutions and decreasing patient complications and recovery time.

Thus the results are indicative of VR's impact on reducing peri-operative patient anxiety. VR has a significant potential impact on medical practice especially as a non-pharmacological therapy. Therefore the application of VR can be a non-pharmacological solution that provides many benefits for healthcare system. It could reduce the use of sedation and opioids, the side effects of drugs, postoperative recovery time, and health care costs

Limitations of Our Study

The limitations of our study are

1. Patient satisfaction score, surgeon satisfaction score and post-operative follow up was not conducted in our study.
2. The study population was only limited to patients undergoing elective hemorrhoidectomy surgeries
3. The sample size for the study population could have been higher for better implementation of the VR intervention for various surgeries under regional anaesthesia.

CONCLUSION

The current study concluded that immersive virtual reality is an effective tool in alleviation of patient anxiety in the peri-operative period. The role of VR in hemodynamic stability of the patient in peri-operative period can be investigated further.

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