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Interest of Virtual Reality Distraction in the Management of Patients Benefiting from Oocyte Retrieval

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ABSTRACT

Introduction: Oocyte retrieval is a fundamental step in vitro fertilization (IVF). To date, no anesthetic technique has demonstrated superiority in terms of efficacy. The Virtual Reality (VR) distraction technique has been researched for its clinical applications. The main objective of this study was to reduce the need for sedation with the VR distraction during oocyte retrieval while maintaining satisfaction with the quality of care.

Materials and Method: We included 44 patients scheduled for oocyte retrieval in 2 groups: 22 patients in the distraction group via virtual reality (VR) and 22 patients in the control group. In the VR group, patients benefited from VR distraction with rescue sedation if necessary. In the control group, the patients benefited from routine sedation (propofol and remifentanil). The primary endpoint was propofol and remifentanil dose reductions with virtual reality distraction. The secondary endpoints were patient satisfaction, comfort, pain, and anxiety using validated questionnaires. Patient pain was measured using a visual analog scale (VAS). Patient comfort was measured using the Gloucester comfort scale. Patient satisfaction was evaluated with a Net Promoter Score (NPS). The State-Trait Anxiety Inventory (STAI) was used the measurement of patient anxiety.

Results: We observed a significant decrease in propofol (50.9 mg for the VR group versus 118.6 mg for the control group, P = 0.0013) and remifentanil (90.5 μ g in the VR group versus 135.65 μ g in the control group, P = 0.0047) with VR distraction. Both groups had similar comfort, pain, anxiety, and patient satisfaction with the procedure.

Conclusion: In our study, distraction by virtual reality reduced the need for sedation during oocyte retrieval while maintaining satisfaction with the quality of care with earlier recovery.

Abbreviations: IVF: In vitro Fertilization; VR: Virtual Reality; VAS: Visual Analog Scale; NPS: Net Promoter Score; STAI: State-Trait Anxiety Inventory; NIBP: Non-Invasive Blood Pressure; SpO2: Pulse Oximetry; ECG: Electrocardiogram; TCI: Target-Controlled-Infusion; Ce: Target Effect-Site Concentration; ASA: American Society of Anesthesiologists

Introduction

Oocyte retrieval guided by transvaginal ultrasound is a fundamental step in the in vitro fertilization (IVF), thas is performed on an outpatient basis. Oocyte retrieval has been associated with pain, discomfort, and anxiety [1,2]. To date, no anesthetic technique has demonstrated superiority in terms of efficacy, tolerance, or analgesia [1]. When analgesia with sedation and rapid recovery is desired, propofol and remifentanil are the agents of choice in the outpatient

setting because of their pharmacokinetic profiles [3,4]. However, drug sedation is accompanied by side effects such as nausea, vomiting, impaired breathing function, hemodynamic disorders, and other adverse effects [5]. The potential danger of these drugs being found in follicular fluid during embryo development remains unknown [6]. Therefore, several studies have examined non-pharmacological interventions to reduce anxiety and pain during oocyte retrieval [7,8]. Virtual reality (VR) distraction integrates visual and auditory cues generated by a computer to recreate the illusory perception of the

real physical world [9]. The distraction that comes with immersive virtual reality, induces an analgesic effect and is evaluated as a non-pharmacological means of alleviating acute procedural pain. She has also been shown to be effective in alleviating the perception of pain, anxiety, and general discomfort in both adults and children [9-14]. The main objective of this study was to reduce the need for sedation during oocyte retrieval while maintaining satisfaction with the quality of care.

Materials and Method

Study Design

This interventional, prospective, and randomized study was conducted at Erasmus Hospital, a university hospital in Brussels, Belgium, from 02/01/2022 to 04/11/2022. This study was approved by the local ethics committee (number P2021/574; December 17, 2021) and registered with ClinicalTrials.gov (NCT05244538).

People

Recruitment was performed through consultation with a gynecologist or anesthetist a few days before the intervention. After obtaining informed consent, the patients were randomized into two groups based on a computer-generated randomization list (QuickCalcs program; GraphPad Software Inc, La Jolla, San Diego, CA, USA). The inclusion criterion was an adult female patient scheduled for oocyte retrieval guided by transvaginal ultrasound.

The exclusion criteria were:

- 1. Presence of psychiatric disorders
- 2. Presence of impaired visual acuity
- Presence of hearing abnormalities
- 4. Dementia
- 5. Limited French skills
- 6. Diagnosis of balance disorder or epilepsy
- 7. Claustrophobia
- 8. Stage 4 endometriosis

Protocol

All patients received oral premedication with 1 g of paracetamol (Prodafalgan, Bristol Myers, Squibb) and 10 mg butyl-hyoscine (Buscopan, Boehringer Ingelheim) as initially provided for in the institutional protocol. No anxiolytic premedication was administered. In the operating room, standard monitoring was applied: noninvasive blood pressure (NIBP), oxygen saturation via continuous pulse oximetry (SpO2), a 3-lead electrocardiogram (ECG), and supplemental oxygen (2 L/min) via nasal cannulas, also allowing monitoring of exhaled CO2 to be monitored (CapnoLine; Medline, Mundelein, Illinois, USA), and respiratory rate. Patients assigned to the VR group benefited from a 20-minute VR program (https://healthymind.fr/, Healthy Mind, Paris, France) via earphones

connected to a tablet Lenovo Android (Lenovo Tab M8, Lenovo, Bratislava, Slovakia). Patients watched a walk in the forest in virtual reality while listening to narratives designed to induce relaxation and meditation. If oocyte retrieval was not completed within 20 minutes, the patient looked again at the VR program. Remifentanil and propofol in mode target-controlled-infusion (TCI) were connected but stopped [15,16]. If the patient reported discomfort or wanted to stop watching the VR program, TCI remifentanil was started with a target effect-site concentration (Ce) of 1 ng/ml and adjusted in 0.5 ng/ml increments until the patient was comfortable. If the patient was still uncomfortable, after 1.5 ng/ml of remifentanil, TCI propofol was started with a Ce of 0.5 μ g/ml and adjusted in increments of 0.5 μ g/ml. The control group immediately benefited from an infusion of remifentanil and propofol, as reported by Coskun, et al. [4].

TCI remifentanil was started at a Ce of 1.5 ng/mL and TCI propofol at Ce of 1.5 µg/mL. The remifentanil concentration was adjusted in 0.5 ng/ml increments based on the hand sign. Propofol concentration was adjusted by a Ce of 0.5 μg/ml, in this case, is based on a 5-point scale as described by Hong, et al. [17] (1, completely awake and oriented; 2, sleepy; 3, eyes closed, quickly respond to commands verbal; 4, eyes closed, aroused only by mild physical stimulation; 5, the eyes closed, not aroused by mild physical stimulation). A lower sedation score, or equal to 3, was the target throughout the procedure. Protocol failure was defined as TCI remifentanil > 2.5 ng/ml or TCI propofol > 1.5 μg/ml. In the recovery room, the usual postoperative analgesia protocol at Erasmus Hospital was used, to know, diclofenac (Voltaren; Novartis Pharma, Switzerland) 75 mg if necessary every 12 h unless contraindicated, and intravenous titration of piritramide (Dipidolor; Janssen-Cilag, Beerse, Belgium) 2 mg every 5 minutes to keep VAS below 3/10.

Data Collection

Before starting the procedure, patients' pain, comfort, and state of anxiety in their daily lives and before the procedure were asked to assess. Data on participants' demographics (age and education) and medical history were collected. In the operating room, NIBP, SpO2, and respiratory rate values were recorded throughout the procedure. The total dose of remifentanil and propofol was recorded. The intervention time (time between inserting the speculum and removing the needle), operating room time (from when the gynecologist arrives until the patient leaves the operating room for the recovery room), the number of follicles punctured, and the number of oocytes collected was recorded. The occurrence of adverse effects was also noted. In the recovery room, the scores for pain, intraoperative comfort, postprocedural anxiety, satisfaction, sedation, length of stay, analgesic administration, and the occurrence of side effects such as nausea, and postoperative vomiting (PONV) were recorded by the anesthesiologist in charge of the alarm clock, which ignored patient assignment.

Outcome Measures

Primary Outcome Measure: The total doses of propofol (mg) and remifentanil (mcg) were recorded for each group. A decrease in

the doses of propofol and remifentanil in the VR group was expected to conclude the superiority of distraction in virtual reality.

Secondary Outcome Measures:

Patient Satisfaction: Patient satisfaction was assessed by the Net Promoter Score. The net promoter score (NPS) assesses the likelihood that patients will recommend the protocol from which they benefited. The score ranges from 0 (very unlikely) to 10 (very likely).

Patient Comfort: Patient comfort was measured using a five-point Gloucester comfort scale (1 = comfortable and 5 = severe discomfort).

Patient Pain: The patient's pain was assessed using a visual analog scale (VAS), which measures patients' pain before, during, and after the procedure:0, no pain; and 10, the most imaginable pain.

Patient Anxiety: The State-Trait Anxiety Inventory (STAI) was used to measure the anxiety of patients before and after the procedure. The 20-item STAI is widely used with scores ranging from 20 (no anxiety) to 80 (high anxiety).

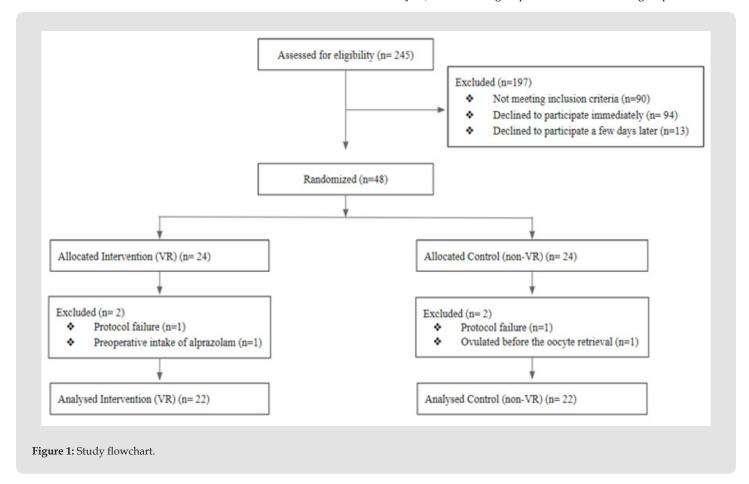
Statistical Analysis

Power analysis suggested that a minimum of 20 subjects per group would be needed to provide 80% power to test the hypothesis that the total dose of remifentanil and propofol would be halved with

virtual reality (VR) distraction. This analysis was based on the study by Coskun, et al. [4]. Given the dropout rate of 20%, 48 patients were estimated to be necessary. The Mann-Whitney Wilcoxon test was used to compare the quantitative variables between the two groups. Chisquare or Fisher's exact test (depending on the numbers) was used to compare the different groups according to the qualitative variables. Distributions were verified based on graphical representations. A $P \leq 0.05$ was considered statistically significant. The calculation was performed by a local statistician (independent of the study and blinded) using the SAS software (version 9.4).

Results

48 patients participated in this trial (Figure 1). A total of 245 patients were invited; 94 refused immediately during the consultation, and 13 withdrew a few days before the day of oocyte retrieval. Ninety patients were excluded before randomization (38 with limited proficiency in French, 12 with grade 4 endometriosis, one with claustrophobia, and 39 with visual acuity disorders). Informed consent was obtained for all 48 patients. After assignment, two patients in the VR (intervention) group and two patients in the non-VR (control) group were excluded (two patients were excluded due to protocol failure, one patient had already ovulated before the oocyte retrieval and one patient had taken the alprazolam before the oocyte retrieval). Consequently, 44 patients were included in the final analysis, 22 in the VR group and 22 in the non-VR group.



Basic Features

No significant differences were observed in the baseline characteristics between the two groups. The median age (34 years for the intervention group versus 35 years for the control group),

Table 1: The characteristics of the bases.

weight (median, 71 kg for the VR group versus 64.5 kg for the control group), height, BMI, the preoperative health status of patients (ASA score), religious belief, history of IVF, or hypnosis were comparable between the two groups. Similarly, the level of education did not differ significantly (Table 1).

Variables	Intervention (VR) (n=22)	Control (Non-VR) (n=22)	p-value
Age (years)	34.50(27-41)	35.50(31-39)	0.8322*
Weight (kg)	71(60-77)	64.5 (58-78)	0.6300*
Size (cm)	165.5(163-168)	165.5(162-169)	0.8871*
BMI kg/m2	25.7(21.5-29)	24.85(21.7-29)	1.0000*
ASA score, %(n)			0.5174***
1	72.73(16)	63.64(14)	
2	27.27(6)	36.36(8)	
Religious belief(Yes) %	50(11)	50(11)	1.0000***
History of IVF**(Yes) %	54.55 (12)	54.55(12)	1.0000***
History of hypnosis (Yes)%	27.27(6)	13.64(3)	0.4566**
Education level, %(n)			0.8417 **
Primary school	0 (0)	4.55(1)	
Lower vocational education	4.55(1)	4.55(1)	
Upper general secondary school	31.82(7)	22.73(5)	
Higher professional education	9.09(2)	18.18(4)	
University	54.55(12)	50(11)	

Note: Values are expressed as medians (interquartile ranges) or numbers (%).

p-values are the results of:

 $kg \ (kilogram) \ cm \ (centimeters) \ m^2 \ (square \ meter) \ BMI \ (body \ mass \ index) \ ASA \ (American Society \ of \ Anesthesiologists) \ IVF \ (in \ vitro \ fertilization) \ (body \ mass \ index) \ ASA \ (American Society \ of \ Anesthesiologists) \ IVF \ (in \ vitro \ fertilization) \ (body \ mass \ index) \ ASA \ (American Society \ of \ Anesthesiologists) \ IVF \ (in \ vitro \ fertilization) \ (body \ mass \ index) \ ASA \ (American Society \ of \ Anesthesiologists) \ IVF \ (in \ vitro \ fertilization) \ (body \ mass \ index) \ ASA \ (american Society \ of \ Anesthesiologists) \ ASA \ (american Society \ of \ Anesthesiologists) \ ASA \ (american Society \ of \ Anesthesiologists) \ ASA \ (american Society \ of \ Anesthesiologists) \ ASA \ (american Society \ of \ Anesthesiologists) \ ASA \ (american Society \ of \ Anesthesiologists) \ ASA \ (american Society \ of \ Anesthesiologists) \ ASA \ (american Society \ of \ Anesthesiologists) \ ASA \ (american Society \ of \ Anesthesiologists) \ ASA \ (american Society \ of \ Anesthesiologists) \ ASA \ (american Society \ of \ Anesthesiologists) \ ASA \ (american Society \ of \ Anesthesiologists) \ ASA \ (american Society \ of \ Anesthesiologists) \ ASA \ (american Society \ of \ Anesthesiologists) \ ASA \ (american Society \ of \ Anesthesiologists) \ ASA \ (american Society \ of \ Anesthesiologists) \ ASA \ (american Society \ of \ Anesthesiologists) \ ASA \ (american Society \ of \ Anesthesiologists) \ ASA \ (american Society \ of \ Anesthesiologists) \ ASA \ (american Society \ of \ Anesthesiologists) \ ASA \ (american Society \ of \ Anesthesiologists) \ ASA \ (american Society \ of \ Anesthesiologists) \ ASA \ (american Society \ of \ Anesthesiologists) \ ASA \ (american Society \ of \ Anesthesiologists) \ ASA \ (american Society \ of \ Anesthesiologists) \ ASA \ (american Society \ of \ Anesthesiologists) \ ASA \ (american Society \ of \ Anesthesiologists) \ ASA \ (american Society \ of \ Anesthesiologists) \ ASA \ (american Society \ of \ Anesthesiol$

Features of the Procedure

There were no differences in the procedural characteristics. The time of the intervention (medians of 12 min for the two groups), the times of the operating room, and the number of follicles and oocytes collected were comparable between the two groups. There was no

significant difference in intraoperative side effects (it should be noted that three patients in the control group had an episode of apnea, of which two patients had oxygen desaturation with the need for mask ventilation compared with no patients in the intervention group) (Table 2).

Table 2: Characteristics of the procedure.

Variables	Intervention (VR) (n=22)	Control (Non-VR) (n=22)	p-value
Intervention time (min)	12(10-19)	12(10-20)	0.8691*
Operating room time (min)	21.5(14-30)	21(19-27)	0.4238*
Numbers of follicles	7.5(4-14)	7(4-12)	0.9437*
Number of oocytes	4(2-10)	5(2-8)	0.9343*
Apnea, %(n)	0(0)	13.64(3)	0.2326**
Desaturation, % (n)	0(0)	9.09(2)	0.4884**
Mask ventilation, %(n)	0(0)	9.09(2)	0.4884**

Note: Values are expressed as medians (interquartile ranges) or numbers (%).

p-values are the results of: *Mann-Whitney U test for continuous variables

^{*}Mann-Whitney U test for continuous variables.

^{**}Fisher exact test for categorized variables.

^{***}Chi-square test for categorized variables.

^{**}Fisher exact test for categorized variables. Min (minute)

Post-Operative Data

There was no significant difference in postoperative nausea between the 2 groups (one patient in the VR group, and 0 patients in the control group). No other adverse effects were observed. The need for diclofenac postoperatively was statistically higher in the control group (10 control patients versus three intervention group patients); however, we did not observe a significant difference in patients in the intervention group). The Aldrete score in the immediate postoperative period was significantly higher in the intervention group [10] compared to in the control group [9]. However, 10 minutes after the procedure, all patients had a maximum Aldrete recovery score of 10. The median time in the recovery room was significantly shorter in the intervention group (26 min) than in the control group (44 min) (Table 3).

opioid analgesic need (three patients in the control group versus two

Table 3: Postoperative data.

Variables	Intervention (VR) (n=22)	Control (Non-VR) (n=22)	p-value
Postoperative nausea, %(n)	4.55(1)	0(0)	1.0000**
Aldrete score at 0 min	10(10-10)	9(9-10)	0.0006*
Aldrete score at 10 min	10(10-10)	10(10-10)	1.0000*
Postoperative diclofenac , %(n)	13.64(3)	45.45(10)	0.0207***
Postoperative piritramide, %(n)	9.09(2)	13.64(3)	1.0000**
Recovery room time (min)	26(17-34)	44(36-59)	0.0002*

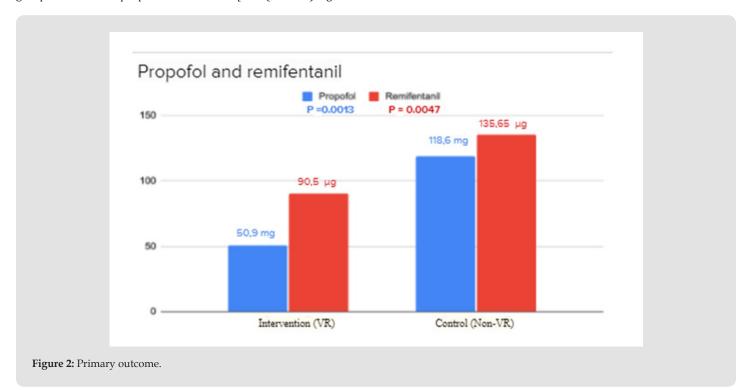
Note: Values are expressed as median (interquartile range) or number (%). p-values are the results of:

Min (minute)

Anesthetics Administered

Regarding our main objective, we noted a significant decrease in anesthetics administered in the VR group compared to the control group. A decrease of propofol administered [50.9 (0-110.5) mg for the

VR group against 118.6 (99-133) mg for the control group; P-value 0.0013] and remifentanil [90.5 (43.7-126) μ g for the VR group versus 135.65 (96.7-170) μ g for the control group; P-value 0.0047] (Figure 2).



^{*}Mann-Whitney U test for continuous variables.

^{**}Fisher exact test for categorized variables.

^{***}Chi-square test for categorized variables.

Patient Satisfaction, Pain, Anxiety, and Comfort

No differences were observed between the two groups in terms of patient satisfaction. The satisfaction score was high in both 2 groups (the median score was 9 out of 10 in both groups). The pain scores before (0 in both groups) and during the procedure (an average pain score of 2 in both groups and a peak pain score of 5 in the VR group versus 4.5 in the control group) were similar between the two groups.

Table 4: Secondary outcome.

The Gloucester comfort scale did not reveal a significant difference in the comfort of patients between the two groups before and during the procedure (21 patients [95%] in the control group were considered comfortable during the intervention, compared to 17 patients [77%] in the intervention group), and baseline and current anxiety state (State-Trait Anxiety Inventory TRAIT-STATE) were comparable across the groups (Table 4).

Variables	Intervention (VR) (n=22)	Control (Non-VR) (n=22)	p-value
NPS (patient satisfaction)	9(9-10)	9(9-10)	0.9074*
Preoperative VAS	0(0-1)	0(0-1)	0.5190*
Mean intraoperative VAS	2(1-3)	2.(1-2)	0.2422*
Peak intraoperative VAS	5(4-6)	4.5(4-5)	0.2238*
Preoperative Gloucester comfort scale, %(n)			0.1324**
Comfortable	68.18 (15)	90.91 (20)	
Minimal	27.27(6)	9.09(2)	
Mild	4.55(1)	0(0)	
Intraoperative Gloucester comfort scale, %(n)			0.2172**
Comfortable	77.27(17)	95.45(21)	
Minimal	13.64(3)	4.55(1)	
Mild	4.55(1)	0(0)	
Moderate	4.55(1)	0(0)	
TRAIT	35,5(29-44)	30(25-36)	0.0928*
Preoperative STATE	31(25-36)	29.5(24-36)	0.6890*
Postoperative STATE	23.5(21-26)	21.50(20-24)	0.1581*

Note: Values are expressed as medians (interquartile ranges) or numbers (%).

 $\ensuremath{\text{p-values}}$ are the results of :

NPS: Net promoter score, visual analog scale (VAS), State-Trait Anxiety Inventory-TRAIT (evaluates the level of anxiety in general), State-Trait Anxiety Inventory-STATE(evaluates the level of anxiety in stressful situations).

Discussion

We conducted a randomized controlled trial comparing virtual reality distraction and drug sedation in patients who benefited from oocyte retrieval guided by transvaginal ultrasound. The reduction in the need for sedation administered during oocyte retrieval in the group with a virtual reality headset was statistically significant while maintaining satisfaction with the quality of care and earlier patient recovery. All the patients in the intervention group used a VR headset throughout the procedure. Three patients in the VR group did not require rescue sedation. Most patients (20/22) rated the use of the VR headsets as positive. Five patients indicated that they preferred to select the VR content. Two patients complained about the quality of the images, which may have been more realistic. In two trials on virtual reality in severe burn victims, the authors suggested solving this problem by developing a better personalized virtual reality system instead of ready-made virtual reality sets [18,19].

Our results corroborate those of other studies, which suggest that virtual reality is an effective anxiolytic and analgesic that does not compromise patient care or satisfaction patients [9-14,20-22]. However, to our knowledge, this study is the first to evaluate VR distraction in patients undergoing transvaginal ultrasound-guided oocyte retrieval. A strategy that integrates virtual reality into an oocyte retrieval workflow is also likely to offer systemic cost savings. This can be attributed to the decrease in the cost of medications, and the reduction in the time and resources required in the recovery room. Future studies are warranted to explore other potential applications of VR distraction in the perioperative period through other personalized anesthesia concepts. Our study has some limitations. First, the sample size was calculated based on the primary objective. Secondary outcome measures were not considered in the calculation of the sample size. Second, our study was a single-center trial; therefore, its external validity may be limited. Third, the anesthesiologists and patients were not blinded to the assignment of groups; although we

^{*}Mann-Whitney U test for continuous variables

^{**}Fisher exact test for categorized variables.

have a protocol in place, this could have affected the choice and dose of sedatives. Fourth, we used a single VR program (walking in the forest), without leaving the choice of VR content to the patient. It is possible that offering patients a greater choice of VR programs could lead to greater benefits. To achieve the maximum immersive effect, VR content should provide a targeted distraction that is specific to the procedure.

Conclusion

Our results indicate that virtual reality distraction helps decrease the need for sedation administered during oocyte retrieval while maintaining satisfaction with the quality of care with earlier recovery. Future studies are warranted to assess the possible substitution of sedation by virtual reality through other programs in a personalized anesthesia concept.

Funding

This study was not financed by any external funds.

Conflicts of Interest

No conflict of interest.

Key Points

Question

Can virtual reality distraction help us in the care of patients undergoing oocyte retrieval?

Findings

We observed that distraction by virtual reality reduced the need for sedation during oocyte retrieval while maintaining satisfaction with the quality of care with earlier recovery.

Meaning

Virtual reality distraction can be used effectively during oocyte retrieval.

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