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Can We Alleviate Pain Associated With The Peripheral Intravenous Catheterisation By Using Distraction Methods in Adults? A Randomised Controlled Trial

Study Protocol and Data Analysis

1. Aims

This study aimed to determine the effect of methods of distraction to mitigate pain associated with the PIC insertion procedure, thus improving patient satisfaction. Specifically, we examined such effect by playing 3D videos with virtual reality (VR) goggles and showing pictures to the patient containing distractive optical illusions. The study's hypotheses were as follows:

a. Pictures including optical illusion and 3D video display with VR goggles reduce pain associated with needle entry during the PIC procedure compared to the control group.

b. Pictures including optical illusion and 3D video display with VR goggles increase the satisfaction during the PIC procedure compared to the control group.

2. Study Design and Setting

The research was performed with a randomised controlled single-blind quasi-experimental study. It was conducted at the emergency unit of a training and research hospital in Ankara, Turkey, between January 18 and April 30, 2018. Before the PIC insertion, the patients were assigned to three groups.

Group-1 (Control): No intervention was made during PIC insertion.

Group-2 (Cards containing optical illusion pictures): Cards containing approximately six optical illusion pictures were shown to the patients and as a method of distraction during the PIC insertion procedure they were asked what they saw in these cards. Showing these cards

started at the beginning of the PIC insertion procedure and lasted approximately 2-3 minutes. (Seckel & Hofstadter, 2004).

Group-3 (3D Video): Underwater 3D audial videos were played with visual reality (VR) goggles during PIC insertion until the procedure was completed. This show, starting at the beginning of the procedure, lasted nearly 2-3 minutes. VR goggles were used for 3D video playing in the research. VR goggles were applied by means of smart phones. After mobile phone placement in the pull chamber at the front side of the VR goggle, it was attached by a headband. The distance between the mobile phone and the object was adjusted specifically for the patient, and patient comfort was taken into account.

3. Participants

The study sample consisted of 120 patients aged between 18 and 65 years old, who ranked 4 (less urgent) and 5 (non-urgent) based on Canadian Emergency Department Triage and who had no visual, audial, or lingual disabilities, and no mental disorder. Only those patients who planned to have PIC insertion and were suitable for having PIC insertion at their antecubital location using 20 Gauge (pink) cannula were eligible. Patients who applied to the emergency service for acute pain and had not used analgesics within 24 hours before applying to the emergency service or had previously experienced multiple PIC procedures, were excluded from the research scope. Patients who refused to participate in the study, who were not eligible for 20 G PIC insertion, who were not in the age range of 18-65 years, and who could not be inserted PIC at the first time (n=98) were excluded from the study (Figure 1). The CONSORT checklist was followed in reporting this study.

4. Sample Size Calculation

The sample size was estimated by using the Medicres E-picos program (https://www.e-picos.com/apps/power/sscm), and it was determined that a minimum of 117 patients were

needed [d (effect size/ effect width) =1.60, =0.05 =0.10, and power=0.95]. The study sample numbered 120 patients.

5. Randomisation

The randomisation method was used by layering according to gender. The patients were distributed into groups using the Medicres E-picos randomisation program (https://www.e-picos.com/apps/calculation/rapg). Three groups of 40 patients each were generated, and 120 patients were randomised into the control or experimental groups.

6. Data Collection Tools

The data were collected in the study scope by means of a data collection form consisting of the socio-demographic characteristics of the patients and the visual analog scale (VAS). VAS was used to evaluate pain caused by needle insertion. In the VAS of 10 cm length, "0" indicated no pain, and "10" indicated the severest pain. The scale between 1 and 10 was used to evaluate levels of satisfaction with the procedure. In this scale, "1" indicated the level of least satisfaction and "10" indicated the highest satisfaction level. The patients marked their pain and satisfaction levels on this scale.

7. PIC Insertion Procedure

The patient was seated in a position that suited the procedure. The arms were positioned below the heart level, when possible. An area in the antecubital location with no skin lesion was selected for PIC. The antecubital area and back of the hand are mostly preferred for the PIC. Because the antecubital vein, which is more commonly used in the PIC applications, has been reported to be less painful than the veins in the back of the hand in the literature, the PICs were all applied to the antecubital vein in the left arm. An autoguard shielded PEU-Vialon (BD-Venflon, Becton Dickinson) was used as an PIC. Lateral holding sections of the cannula were positioned horizontally. The tourniquet was attached to the patient's outfit at 5-12 cm above the selected vein. The patient was asked to open and close his/her hand and

make a fist. The veins in the arm used for application were monitored and palpated. The selected location was cleaned by antiseptic solution and 1-2 minutes were allowed for drying. The PIC was held as the blade of the needle was facing upward. A location approximately 3-5 cm below the point of insertion was pressed near the thumb of the empty hand to stabilize the vein, and the skin was stretched downwards. When the needle was inserted into the vein, the plastic portion was gently pushed through the inside of the vein. The tourniquet was undone and the catheter was fixed on the skin with a plaster. This application was completed within approximately 2-3 minutes. All of the PIC insertion procedures were performed by the same researcher. The other researcher, who did not know which patient was in which group, collected the data on the assessment of PIC procedure-associated pain and satisfaction levels immediately after PIC insertion using face-to-face interviews.

8. Ethical Consideration

A permit (number 18/7 and dated 10/16/2018) from the Ethical Committee of the hospital where the research was conducted was received, and the hospital's written permission was obtained. Moreover, the procedures to be carried out were explained to the patients prior to the procedure, and their written and oral consents were received.

9. Data Analysis

The collected data were analyzed by using the SPSS 21.0 package program. The variables determined by counting were shown in numbers and percentages, and the variables determined by measurements were shown as averages and standard deviations. T test and One way ANOVA were used in comparative statistics. A $p < 0.05$ level was accepted as an indication of significant difference in statistical decisions.

Figure-1.Diagram showing the flow of participants.