STUDY PROTOCOL

Title: VR Simulation and Basic Skills in THA

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Objectives

This prospective randomised trial aims to test if Virtual Reality (VR) simulation helps medical students who have no surgical experience acquire basic surgical skills in total hip arthroplasty (THA) by performing two dificult THA steps: the acetabular cup and femoral stem implantation in a specific position. This study hypothesised that VR training could help young doctors orient themselves in space and perform more accurate cup implantation in 60° inclination and femoral stem in 20° anteversion than a control group that had only video teaching from an expert. The primary outcome will be the a. the difference in the mean implanted cup inclination and femoral stem anteversion between the VR and control group b. the mean difference between the asked predefined and the actual implanted cup inclination or cup version between the VR and control groups. Secondary outcomes will be other differences in completing the task between groups a. the time needed to complete the task and b. the times asking for assistance c. the number of mistakes.

Background

All residents traditionally acquire new surgical skills by carefully studying technique guides, diligently watching procedure videos and working closely with a mentor[1,2]. However, according to a study, 96% of residents independently learned how to prepare for surgical procedures[3]. A recent study revealed that less than 80% of general surgery residents who have completed their training were competent in performing complex yet standard medical procedures on patients[4]. This emphasizes the importance of looking into additional training methods to fill the gap in surgical education[4].

There are currently a few surgical training methods, including reading surgical technique guides, using sawbones simulations, and performing cadaveric dissection[5-6]. However, each of these methods has its limitations[7-9]. Sawbones simulation is limited and not reusable, while cadaveric dissections are expensive, time-consuming and only provide little practice. Basic equipment knowledge is necessary to use technique guides, but practical exercises may not be possible.

Hence, it's crucial to integrate simulation into medicine, specifically in orthopaedics. VR technology has been evaluated as a training method for medical doctors or junior surgeons with promising results in their respective fields of expertise[6,10]. Although VR technology is advancing rapidly, there is still a limited number of high-level studies on how it can be used to train surgeons[6,10-12]. It is still being determined whether surgeons using VR gain advantages in identifying anatomical structures, understanding the steps involved in a procedure, improving their skills during dificult stages of a task, or more eficiently navigating themselves during surgery.

Methods

This study is a prospective randomised controlled trial with a specific design (*figure 1*) which is detailed below.

Recruitment

This prospective randomised trial was approved by our Institutional Review Board (70/2023-15/02/2023). Eligible study participants included undergraduate medical students at our university with no previous surgical experience willing to participate. Exclusion criteria included a. postgraduate medical students b. prior experience in THA or general surgery, c. undergraduate students unwilling to participate.

One month before the planned VR-THA surgery session, all eligible medical students were invited to an information session regarding the study through the university's social media. The 101 medical students who fulfilled the inclusion criteria were voluntarily enrolled, providing informed consent.

Pretest

Immediately after enrollment, medical students were asked to complete a multiple-choice pretest to quantify their baseline medical and procedural knowledge of hip arthritis and THA. All participants were unaware and unable to prepare for the pretest assessment, which allows the test scores to be considered an accurate measure of baseline knowledge.

Video teaching

All medical students were then asked to watch a detailed video explaining the basic anatomy of the hip joint, the fundamental pathophysiology of hip arthritis, and the THA steps. The video explained in detail the necessary steps and basic rules that the surgeon must understand to implant the acetabular cup and femoral stem in a proper position. The video was focused on practices and methods to understand the intraoperative landmarks to achieve a cup inclination of 30-60° and stem anteversion of 20° during implantation. All participants were free to watch the video two to three times to thoroughly understand the principles of the cup and femoral stem implantation.

Randomisation

All participants were then randomised in the VR or control group for cup and stem training and implantation by a computerised random number generator. In detail, each participant was randomised in the VR group for the cup or the stem implantation but in the control group for the other part of the THA. So, participants enrolled on the VR group for cup training were the control group for the femoral stem training and vice versa. In this way, each participant was asked to do one implantation following VR training and the other without VR training. Participants were privately notified of their randomisation assignment and asked not to disclose their designated cohort with any other study participant or research personnel. Only a research team member knew of the cohort assignments during this study. This study personnel did not participate in the evaluation and analysis of data.

VR training

As mentioned, each participant was randomised and did one implantation, either the acetabular cup or the femoral stem, following VR training and the other (stem or cup) without VR training, respectively. This method allowed us to evaluate and compare the performance of participants who received VR training versus those who did not within the same implantation. It also enables us to assess individual participants' performance in both scenarios (stem or cup), with and without VR training.

Before the VR-THA training, participants were asked to complete a survey evaluating their previous VR technology experience. All VR group participants were then asked to complete three consecutive VR sessions using the VR system (ORama VR, Geneva, Switzerland), performing cup or stem implantation based on their group.

Saw bone simulation

After completing VR training, all participants were asked to implant the cup at a 60° inclination in sawbones and the femoral stem at 20° of anteversion. As mentioned, they performed one implantation following VR training and the other without VR training.

The sawbones had been reamed and prepared appropriately to accommodate the metal prostheses from the students steadily. The students did not perform any reaming to the sawbones. The same saw bone was used for several implantations but was replaced with a new one when it could no longer handle the implant properly. The cup inclination and stem version were evaluated using specific goniometers and assessment of photographs taken during implantation. During implantation in sawbones, a study assistant was present and was instructed to intervene only if the study participants requested assistance or could not progress through the task.

Upon completion of the VR-THAs, participants completed a survey focused on their interest in using VR simulations for surgical skills training and assessing potential negative consequences.

Power Analysis

After reviewing eight recent RCT studies on virtual reality simulation training, it was found that each study had an average of 14 to 28 participants and an effect size of 0.80 to 0.90. Previous studies have utilised specific scores to evaluate the impact of trauma or arthroplasty simulator training on actual performance in real-world scenarios. These evaluations were different from our measurements. To assess the necessary sample size for our study, we based on the first ten measurements of cup angle implantation from our medical students; the mean cup angle was 50.40 with a standard deviation of 18^0. To detect a difference of 20 degrees of implantation between two groups with a standard deviation of 18 degrees and with a two-sided alpha of 0.05 and power of 80%, at least 26 students were required in its group.

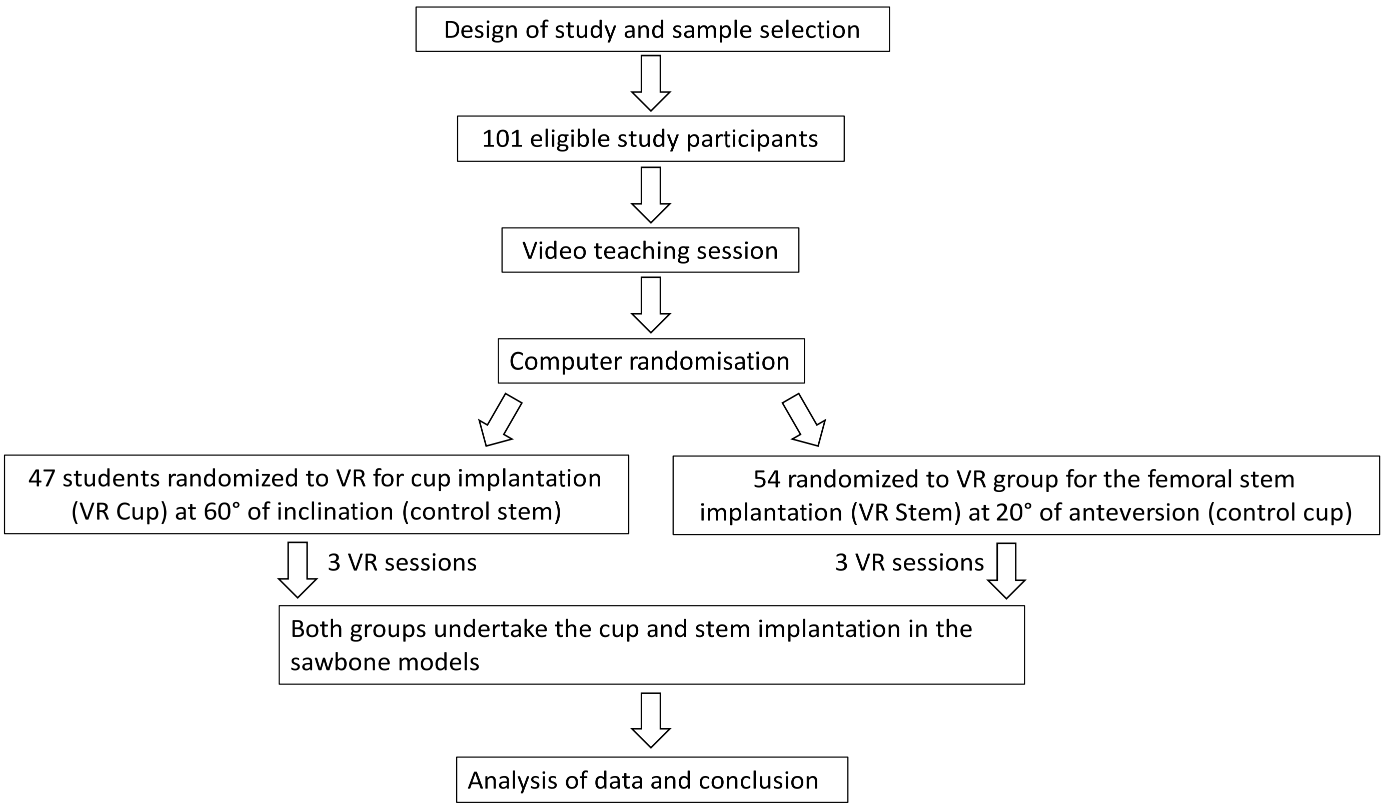

Figure 1, Study Design

Statistical Analysis Plan (SAP)

The primary outcome was the mean implanted cup inclination and femoral stem anteversion difference between the VR and control groups. Other outcomes considered between groups included: a) the duration required to complete the task, b) the frequency of requesting assistance, and c) the number of errors made.

We used standard statistical methods to gather descriptive statistics. We conducted the Kolmogorov-Smirnov and Shapiro-Wilk tests to check whether the data followed a normal distribution. Our statistical tests were two-tailed, and we set the alpha level at 0.05. For continuous variables that were normally distributed, we used the two-sided independent sample t-test, while for those that weren't normally distributed, we used the Mann-Whitney U-test. We compared categorical data using the chi-square test. To determine if using VR had an impact on a student's task performance, a paired t-test was conducted to compare their outcomes with and without VR. We performed all statistical analyses using SPSS software (IBM, version 27.0).

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