Schulterdystokie-Training mittels Virtual Reality: eine Pilot-Studie

(english title: „Training of shoulder dystocia using virtual reality: a pilot study“)

Study proposal

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1. Background

Simulation training has been well described through various fields of medical education, leading to improved patient safety, particularly with procedures that are either not regularly performed or more likely to occur in high stress environments and emergency situations [1].

In the field of obstetrics, situations like acute fetal distress, intra- and postpartum hemorrhage, as well as birth arrest in the second stage of labor, are exemplary settings when highly trained and qualified medical staff is needed to provide the best medical assistance and perinatal outcomes. Apart from that, multidisciplinary teamwork is of paramount importance in situations that necessitate fast clinical decision making [1]. To achieve the best outcomes, regular simulation trainings are required to achieve confidence with hands-on procedures, teamwork, and adapt to psychologically exceptional circumstances [1,2].

Throughout the last years, residency trainings significantly changed and trainings among all different specialties had to adapt to restriction of working hours and surgery numbers. Time for resident physicians to expand their practical skills became limited. Apart from that, the technological evolution has changed work modalities with residents spending up to half of their working hours in front of electronic medical charts and personal computers and not anymore with their patients. As a result, future generations of physicians might not have the same skills as today's physicians, e.g. to perform surgical procedures or handle critical clinical situations [3].

Thus, there is need to respond to these changes in terms of an adequate specialty training that is independent from working hours, taking advantage of new evolving technologies. Recent data suggest that virtual reality (VR) is feasible to practice surgical procedures and emergency scenarios anytime and anywhere in a safe,

repeatable, and reproducible way. VR has also been recognized as an effective teaching method for improving skills, theoretical knowledge, and clinical decision making [4,5].

A variety of VR simulation tools for training emergency medicine staff or disaster preparedness first responders exist. In particular, VirtSim [13], XVR [14], provide rich simulations to train specific techniques and procedures during emergency situations. However, existing solutions are mostly focused for training medical staff at emergency sites (as opposed to at the hospital site) and offer desktop-based VR training that lacks visual 3D immersion and navigation by free movement. Both factors decline the sense of presence or movement, which is essential to simulate stress and physical dynamics (fast reaction times are of crucial importance) of a realistic training for obstetrics emergency teams.

In the field of obstetrics, the situation of an acute shoulder dystocia intrapartum is one of the most frequent emergencies, which is associated with impaired neonatal outcomes. When the shoulder of the baby is stuck in the birth channel during the last phase of a vaginal cephalic delivery, specific maneuvers by medical staff are required to deliver the baby in a safe way and ensure its survival [6]. The definition of a shoulder dystocia is given in case of a prolongation of the head-to-body delivery-time of longer than 60 seconds [7]. Although the incidence of shoulder dystocia is relatively low (1.4%), its consequences are often fatal, being significantly associated with perinatal morbidity and mortality [6]. Apart from that, women who experience shoulder dystocia show higher risks of postpartum hemorrhage (PPH) and high-grade vaginal tears [7]. Risk factors of shoulder dystocia are any kind of diabetes, fetal macrosomia, history of previous shoulder dystocia and maternal obesity; however, most cases are

unpredictable [7]. According to guidelines of the Royal college of Obstetrics and Gynecology (RCOG), the retraction of the head to the vulva after head delivery ("turtle neck sign") is pathognomonic for shoulder dystocia [6], and should induce adequate management and maneuvers. Shoulder dystocia should be managed systemically as follows:

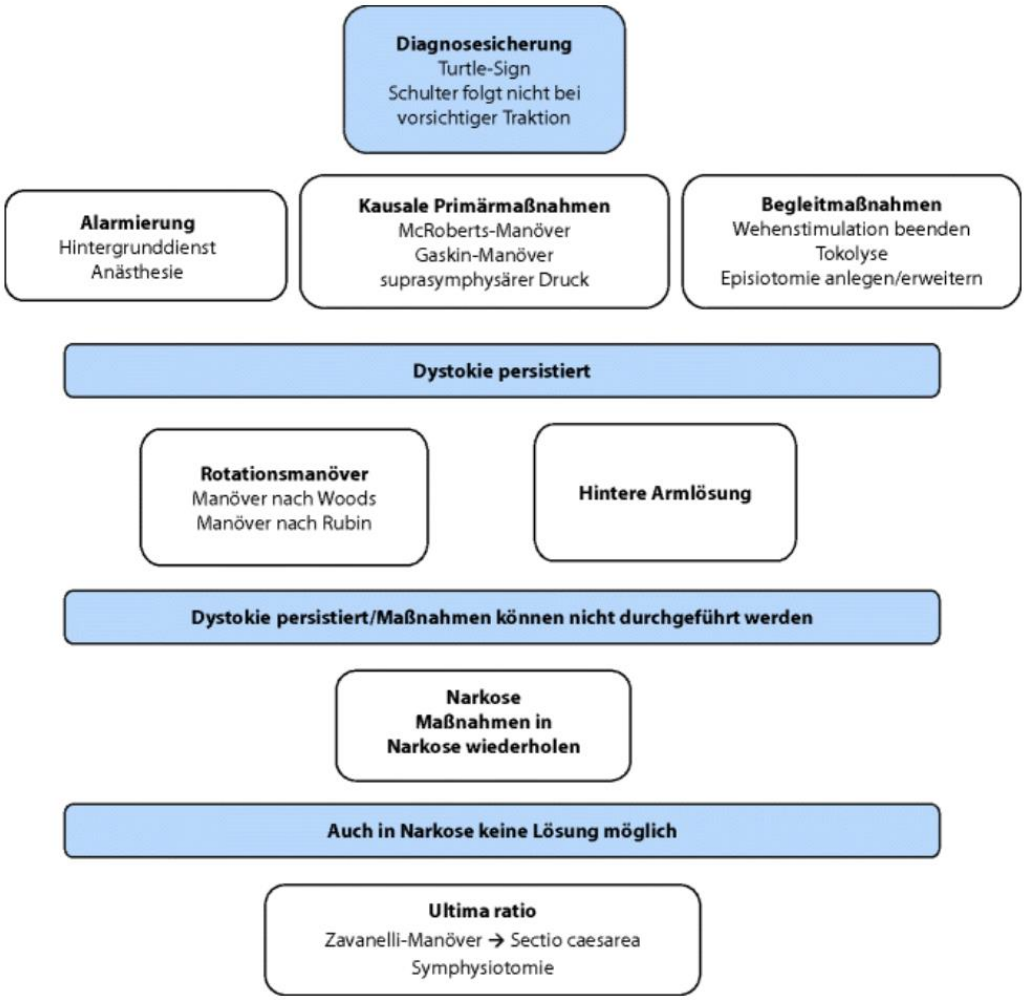

Figure 1: Algorithm for the management of shoulder dystocia [8].

The HELPERR mnemonic formula developed by the Advance life Support in obstetrics (ALSO) providers can be an useful tool during this emergency situation [9]. However, after a meticulous analysis of the present literature about management of shoulder dystocia, we decided to modify “HELPERR” into the “HELP-RER” mnemonic formula:

- H: ask for **H**elp
- E: consider **E**pisiotomy
- L: **L**egs hyperflexed (McRoberts Maneuver)
- P: apply supra**P**ubic **P**ressure to disimpact the anterior shoulder
- R: **R**oll the patient onto all fours (Gaskin Maneuver)
- E: **E**nter maneuvers (internal rotation)
- R: **R**emove the posterior arm

As reported in [8], internal rotations require advanced skills and should be performed by senior consultants. Given the high number of residents serving on the obstetrics wards, the Gaskin Maneuver could be pivotal in managing shoulder dystocia until qualified help comes. Hence, for our algorithm, we decided to anticipate the Gaskin Maneuver and to perform it, if the McRoberts Maneuver and the suprapubic pressure are unsuccessful. The last resort options include the fracture of the fetal clavicle, the Zavanelli maneuver and maternal symphysiotomy. After delivery, the baby should be examined for injury from neonatologists. Particular attention should be given to the evaluation of brachial plexus injury, clavicle fracture, pneumothorax and hypoxic brain damage [6]. Many cases require the transfer to the Neonatal Intensive Care Unit (NICU) and cardiopulmonary reanimation of the baby [7,10].

The above maneuvers demonstrate how important adequate training is to ensure that health-care professionals are well trained and capable of responding to this critical care situation.

2. Rationale and primary objective

2.1. Rationale

Training of shoulder dystocia is feasible using a virtual reality (VR) technology.

2.2. Primary objectives

- To evaluate the score improvement, in managing shoulder dystocia using VR technology, in a cohort of health-care professionals (i.e., resident physicians in obstetrics, midwives, nurses), using the human factors skills for healthcare instrument (HuFSI) questionnaire, before and after the VR training [11].
- To correctly follow the modified HELP-RER checklist from the ALSO [9] during the VR training in comparison to conventional dummy-based simulation training, in a cohort of health-care professionals (i.e., resident physicians in obstetrics, midwives, nurses).
- To compare the amount of time for managing the simulated scenario in VR compared to conventional dummy-based simulation training.

2.3. Primary Endpoint

Score improvements within the validated questionnaire + HELP-RER checklist + time needed for managing the scenario after VR training will serve as the primary endpoint [11].

3. Study design

The study will follow a prospective case-control cross-over design and enroll 30 obstetrical health-care professionals (10 residents, 10 consultants and 10 midwives) at the Department of Obstetrics and Gynecology at the Comprehensive Center for Pediatrics (CCP), Medical University of Vienna (Vienna, Austria). Participants will be excluded if they are physically unable to conduct any of the training exercises or if they cannot use VR headsets. For the first part, the feasibility part of the study, health-care providers will accomplish the human factors skills for healthcare instrument (HuFSI), a validated questionnaire assessing healthcare providers confidence with specific human and technical skills. Pre- and post-course questionnaires will be collected before and after the VR training, as well as before and after the conventional dummy-based training, to prove feasibility of the method. The study group “VR training” will accomplish a conventional dummy-based training at the Department, while the control group “dummy-based” simulation training will accomplish a VR training. The questionnaire will be handed before and after this training as well in order to evaluate whether both methods, conventional dummy-based and VR training, are comparable. Each item of the validated questionnaire HuFSI will be presented as statement (e.g. “I am able to communicate effectively with a colleague with whom I disagree”) and rated with a 7-point Likert scale from (1) totally disagree, to (7) totally agree. In addition, trainers will notify whether the HELP-RER checklist will be consequently and efficiently processed from every single participant of both groups. 1 point will be assigned to each correctly performed step of the checklist. 1 point will be deducted, if one step of the checklist will be skipped (e.g. after calling for **H**elp the doctor will apply suprapubic

Pressure instead of consider an **E**pisiotomy). A maximal score of 7 can be achieved for the evaluation of the HELP-RER checklist. The amount of time needed to accomplish each scenario will be measured in minutes and seconds and compared before and after the training using both, the VR, and the conventional dummy-based method. As no information about the ideal time needed for the correct accomplishment of a shoulder dystocia scenario is officially provided, 1 point will be assigned to all participants, that conclude the scenario within the mean time needed from all participants. Participants, who will conclude the scenario after the mean time will collect 0 points.

In the second part of the study, the study group “VR training” will perform a dummy-based training, while the control group “dummy-based” will perform a virtual reality training. At the end of the study, scores of the study group will be compared to the scores of the control group.

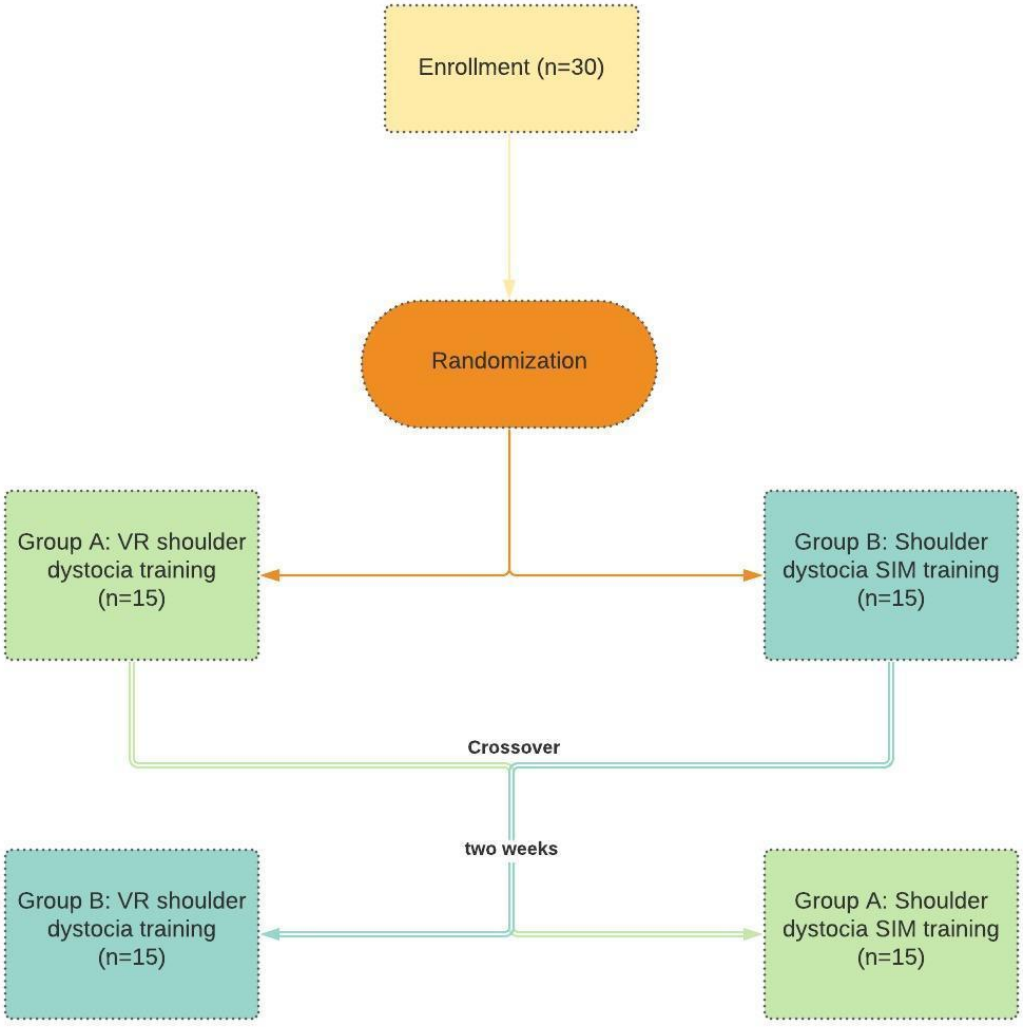

Figure 2: Flowchart of the crossover study design

Both study groups will undertake the same scenario (shoulder dystocia), but in different settings. Whereas the control group will perform a traditional simulation training first, followed by a VR training, the intervention group will perform a VR training first, followed by a traditional simulation training and scores will be analyzed in each training and compared between groups.

3.1. Virtual reality training

Within our shoulder dystocia VR training, 3D immersion as well as navigation by free movement and haptic will play an important role. This part will conclude the first scenario, that will take 5 to 6 minutes. All virtual reality trainings will be performed at the Comprehensive Center for Pediatrics Simulation Training Center at the Medical University of Vienna. All study participants will wear a PICO Neo 2 VR headset (*PICO Interactive, San Francisco, CA, USA*). This headset features a state-of-the-art 845 Snapdragon processor, 4k resolution at a 75 hertz refresh rate and built-in eye-tracking technology (https://www.pico-interactive.com/us/neo2.html). One of the main advantages of this device is its stand-alone feature as there is no need to plug it into a computer or to use any additional sensors, while still offering the option to connect wirelessly to external devices for live view. We will use a neonatal emergency VR scenario within the IMED platform (Soma Reality GmbH, Vienna, Austria). This platform has been created for medical VR trainings, particularly in German language. The virtual scenario will take place in a recreated obstetric unit which looks exactly the same as the real setting. The participant can move freely either in the virtual room or in the simulation room and can select any equipment or medication that is needed. If the participant does not select the correct action, or takes too long to decide, an auditory reminder will be given by a member of the study team. The objective of the scenario is to analyze the status of the patient and to recognize and solve the problem of should dystocia.

3.2. Case scenario:

A 35-year-old female, G1 P0, 160 cm, 85 kg, who has a spontaneous rupture of membranes and regular contractions in gestational week 40+2, presents at the

delivery room. She reports an uneventful pregnancy, except for gestational diabetes (treated with lifestyle-modification). According to the last fetal biometry, performed at 36+0 weeks of gestation, the fetal weight was estimated to be at the 70. percentile. At 7 cm of cervical dilatation, oxytocin infusion is started. The delivery is assisted by an experienced midwife and a ob/gyn resident physician. After the delivery of the head, they observe the typical “turtle sign” thereby defining a shoulder dystocia. The resident physician immediately stops the oxytocin infusion and calls for help **(H).** An episiotomy **(E)** is performed. Subsequently, he/she performs three times of the McRoberts Manoeuvre **(L)**. A second midwife tries to deliver the baby’s shoulder, which is however unsuccessful. The suprapubic pressure manoeuvre **(P)** is also unsuccessful. After two minutes, the obstetric team urges the patient to roll onto all four **(R)** in order to allow the delivery of the posterior shoulder. During the Gaskin Manoeuvre, a highly experienced consultant physician arrives and together with the midwife, they roll the patient on her back in order to perform a Wood Manoeuvre **(E)**. Now, the baby’s shoulder can be delivered, and the baby is subsequently transferred to the neonatology ward after immediate cord-clamping. During the scenario, a study team member will be present to assist with any technical issues but will not interfere with the exercise or provide content-related assistance in any way.

3.3. Sample size

In order to evaluate a 20% score increasement within the two trainings modalities, a sample size calculation will be performed.

4. Statistical methods

Statistical analysis will be performed using the SPSS and Excel software. Data will be calculated and graphed as mean plus/minus standard deviation (SD) or median and interquartile ranges. Continuous variable (age of experience, number of managed deliveries, etc.) will be summarized by mean ± SD and categorical variables by counts and percentages. Bar and column charts as well as box plots will be used to graphically represent the metric variables. The Student's t-test will be used in order to represent the magnitude of effect of the VR-SIM Training on the outcomes. The results will be graphically reported by box plots. Dichotomous variables will be analyzed using the Chi-squared test or the Bernard's exact test. Student's t-test for unpaired comparisons will be used to compare mean values (SD) between groups. Rank based procedures will be used as an alternative for strongly skewed distributed variables. P-values of 0.05 or lower (two-sided) will be considered statistically significant. However, p-values will be interpreted in an explorative manner aiming to generate new hypotheses. Therefore, no adjustment of multiple testing will be performed.

5. Ethical aspects

5.1. Risks

There is no additional risk that arises for the study participants. Personal data of the study participants will be protected by anonymization and storage at a password secured server at the Department of Obstetrics and feto-maternal Medicine, Medical University of Vienna (Vienna, Austria). Data will be only be accessible by the principal investigator of the study.

5.2. Declaration of Helsinki

The guidelines of both the Declaration of Helsinki (1964) and the Good Clinical Practice (GCP) will be followed. Approval of the local ethics committee is obligatory prior to the start of this study.

5.3. Publication of data

The results of the study will be published within an adequate timeframe.

5.4. Changes of the study protocol

If changes of the study protocol should occur, they will be documented carefully. If significant changes should be necessary, the ethic commission will be contacted and asked for permission. The study protocol will be published and available on clinicaltrials.gov (pending).

5.5. Quality assurance and data security

The principal investigator of this study will be regularly informed about the progress of the study and will be instructed immediately in cases of problems and uncertainties. Statistical analyses will be based on the allocation of continuously registered individual numbers, which are indirectly personalized and can only be decoded by the principal investigator. Data will be anonymized and protected as explained above; collection, storing, transmission and utilization of data shall be carried out exclusively in compliance with the valid national and the relevant international regulations. The guidelines for Good Scientific Practice specify the respective procedures.

5.6. Qualification of authorship

Persons who substantially contributed to the project (i.e., active intellectual, and practical or procedural participation) will be qualified for authorship.

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