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Is virtual reality for acute pain reduction in adolescents undergoing burn wound care effective?

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A SELECTIVE EVIDENCE BASED MEDICINE REVIEW

In Partial Fulfillment of the Requirements For

The Degree of Master of Science

In

Health Sciences – Physician Assistant

Department of Physician Assistant Studies
Philadelphia College of Osteopathic Medicine
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ABSTRACT

OBJECTIVE: The objective of this selective EBM review is to determine whether or not the use of virtual reality (VR) is an effective method of pain reduction in adolescents undergoing burn wound care.

STUDY DESIGN: Includes a review of two English based randomized controlled trials, and one English based descriptive exploratory study. These studies were published in 2007-2014.

DATA SOURCES: Two randomized control trials (RCT's) and one exploratory study were found searching PubMed database. Both the random control trials and the exploratory study compare the use of virtual reality interventions against either medical management only or a combination of medical management and passive distraction techniques.

OUTCOMES MEASURED: Pain intensity was measured using APPT, Spielberger state-trait anxiety inventory for children, Pre-procedural questionnaire, Post-procedural questionnaire, VAS – visual analogue scale (self-reported), VAS – visual analogue scale (caregiver reported), FLACC – Faces, legs, activity, cry, consolability – nurse observations, Adolescent reactions, and Faces scale.

RESULTS: The RTC by Kipping, et al. showed no statistically significant improvement in pain intensity using virtual reality for adolescent burn care (P value=0.16 (dressing removal) and P value=0.40 (Dressing application)). The RTC by Jeffs, et al. showed no statistically significant improvement in pain intensity using virtual reality for adolescent burn care (P value=0.029). The exploratory study by Chan, et al. et al showed no statistically significant improvement in pain intensity using virtual reality for adolescent burn care (P value>0.05)

CONCLUSIONS: There was no clinically significant decrease in self-reported pain intensity with the use of VR during wound care in both the RTC by Kipping, et al. and RTC by Jeffs, et al. respectively. In the exploratory study by Chan, et al.; although not clinically significant, the VR intervention is more effective than simple distraction for pain reduction.

KEY WORDS: Virtual reality; adolescent; burn care pain management.

INTRODUCTION

A major burn is an injury with necrosis to epidermis and dermis resulting from thermal, chemical, electrical, or radiation exposure.¹ Burns are categorized into first, second, and third degree. First degree (superficial) burns damage the epidermis, rarely blister, and heal within 5-10 days. Second degree (superficial-dermal) burns damage the epidermis and upper layers of the dermis with wet/weeping clear blisters that heal in 2-3 weeks. Third degree (full thickness) burns damage all layers of skin and subcutaneous fat resulting in a leathery appearance; blisters are absent, and the wound will not heal without further debridement or possible skin grafting.¹ The evaluation of a burn should start with the cause and location of the burn. Providers should consider any concomitant trauma or risk for infection. Any burns “greater or equal to 15% of the total body surface area are associated with an increased risk of systemic morbidity and mortality;” if the burn is extensive it requires repeated painful burn wound dressing changes and debridement.¹

The prevalence of major burns is higher in children when compared to adults. Children account for 40%-50% of all severe burn injuries with 8.5 per 10,000 inhabitants less than 15 years old.¹ Regarding cost, burn injuries represent 1% of total injury incidence and 2% of the total cost of injuries each year, approximately \$7.5 billion.² Pediatric burn management encompasses 40-50% of the total cost which equates to \$3-3.75 billion a year. Fortunately, the number of health care visits for pediatric burn care have declined 41.9% from an estimated 20,014 visits in 1993 to 11,635 visits in 2006.²

The standard of care for pediatric wound management has been researched and established. Eighty-six percent of patients report significant pain with established wound care

management regimen.³ Secondary to ethical or litigious issues with carrying out research in this vulnerable population “few wound care products have been studied.”⁴

Burns greater than 10% total body surface area require possible emergent airway protection and fluid resuscitation. Treatment includes topical agents like silver sulfadiazine, topical antimicrobials, and synthetic silver impregnated dressings when vitals are stable.¹ Burns greater than 20% TBSA require additional medications such as propranolol and oxandrolone to decrease the healing half-life and time spent in the intensive care unit. Extensive burns require early excision, debridement, and skin grafting.¹ Medical management for pain is typically used on an as needed basis in adjunct to non-pharmacological techniques. Unfortunately, “even with this multimodal approach, current pain management practices are still considered inadequate.”⁵

It is hypothesized that virtual reality (VR) may be an alternative to increased use of opioid/sedatives and the ineffective use of other types of passive distraction techniques (movies, music, standard video games, etc.) during extensive pediatric wound care management. Generally, VR interventions are based on the “gate control” theory of pain where the use of non-painful stimuli close the nerve “gates” thereby preventing pain sensations to the central nervous system.⁶ Ideally, the use of VR rather than increasing use of opioids avoids subsequent nausea, constipation, drowsiness, and lethargy.⁵ Research shows that the use of sedatives in pediatric populations has resulted in “more anxiety than the intended pharmacological effects.”⁷ This paper evaluates two single blinded randomized control trials, and a descriptive exploratory study, evaluating the efficacy of virtual reality for pain management during initial burn wound debridement.

OBJECTIVE

The objective of this selective evidenced based medicine review is “Is virtual reality for acute pain reduction in adolescents undergoing burn wound care effective?”

METHODS

Two single blind randomized control trials, and a descriptive exploratory study are included in this review. The population consisted of male and female adolescent burn patients between the ages of 7 and 17 years old. The interventions used are as follows; Snow world, Kaiser optics SR80a, SXGA resolution 1280-1024 Visual C++6.0/DirectX 7.0a SDK, 3D modelling tools (3D studio MAX and Rhinoceros), and eMagin Z800 3D Visor with head tracking and 2 high contrast SVGA resolution 800 x 600 16.7 million colours with a joystick hand control (LOGIK PC ATTACK 3). The outcome measured in all three studies was pain intensity. In the randomized control trial by Kipping, et al comparisons were made between the VR group, the standard distraction group (SDG) who had access to TV, stories, music, caregivers, or no distraction. In the randomized control trial by Jeffs, et al comparisons were made between a VR group, passive distraction group who watched a movie, and a typical care group with no distractions. In the exploratory study by Chan, et al comparisons were made between a virtual reality group and a group without VR (passive distraction technique not explicitly mentioned).

Key words used to discover the literature were "virtual reality" "adolescent", and "burn care pain management." All articles were written in English and published in peer reviewed journals. The studies were found using PubMed and selected based on their relevance to the clinical question and the use of patient oriented outcomes for outcome measurement. Inclusion criteria included studies that were either single blinded randomized control trials or a descriptive

exploratory study. Exclusions were made if the patients over the age of 18 years old, participants with cognitive impairment, and visual/hearing impairment. The statistics reported or used were P values and R². See Table 1 for demographics and characteristics of included studies.

Table 1 - Demographics and characteristics of included studies

Study	Type	# of patients	Age	Inclusion Criteria	Exclusion Criteria	W/D	Interventions
Kipping, 2012 (4)	RCT	41	11-17yo	Must be first conscious dressing change Must have total body surface area greater than 1% Attendance at SPABU or SPPBC Age 11-17	-Age over 18 -Cognitive impairment preventing the use of outcome measures. -Visual or hearing impairment -Wound location impacting the ability to use the VR device -Non-english speaking & child safety and protection	1	VR. eMagin Z800 3D Visor with head tracking and 2 high contrast SVGA resolution 800 x 600 16.7 million colours, joystick hand control (LOGIK PC ATTACK 3) Software game: Chicken Little – 11-13yo & Need for Speed – 15-17yo
Jeffer, 2014 (5)	RCT	28	10-17yo	Outpatient adolescent burn patients No history of motion sickness/seizure activity	-Over 18	2	Virtual Reality – Snow world, Kaiser optics SR80a, SXGA resolution 1280-1024 Bose Quiet comfort 3 headphones

Chan, 2007 (7)	Descriptive exploratory study, cross over design	8	mean age 6.54yo	inpatient adolescent burn patients All patients who were enrolled in the study had experienced burns for the first time. All had dressing changes before the	-Over 18 -Burn to Dominate hand	0	Virtual Reality prototype: Visual C++6.0 and DirectX 7.0a SDK. 3D modelling tools (3D studio MAX and Rhinoceros) A visual display of an ice-cream factory ad auditory senses The sensation of cold (from an ice-cream factory) may engender the suggestion of pain relief from an experience of being burned.
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OUTCOMES MEASURED

Pain intensity was measured in all three studies utilizing POEMS for outcome measurement. Kipping et al. used the visual analog scale or VAS (self-reported & caregiver-reported), and the faces pain scale or FACES scale. In this review only VAS (self-reported) was considered. Jeffs, et al. used the adolescent pediatric pain tool or APPT, Spielberger state-trait anxiety inventory for children, pre-procedural questionnaire, and a post-procedural questionnaire. In this review only APPT (self-reported) was considered. Chan, et al. used the FACES scale (child required to choose a picture of a face with expressions of various graduations of pain with a scale rating from 0-100 before, during and after his/her dressing change).

RESULTS

Kipping, et al included 41 adolescent patients from 11 to 17 years old. Participants were selected from two inpatient tertiary hospitals including Stuart Pegg Paediatric Burn Center and Stuart Pegg Adult Burn Center. All patients had a TBSA greater than 1% without a previous conscious dressing change. This study was a single blinded randomized control trial until the intervention was implemented. After the patient received the treatment blinding was impossible.

The intervention assessed in this study was VR (eMagin Z800 3D Visor with head tracking and 2 high contrast SVGA resolution 800 x 600 16.7 million colours and joystick hand control (LOGIK PC ATTACK 3)), compared to the standard treatment group that received access to TV, stories, music, caregivers or no distraction in the treatment room. VAS and FACES scores were measured before randomization and procedure commencement (T1), after dressing removal (T2), and dressing application (T3). The results of the study were not converted into dichotomous data.

The authors used VAS (self-reported) mean change from baseline to determine treatment effect as shown in Table 2 below. During dressing removal patient VAS in the VR group was 2.9 (SD 2.3) with a P value of 0.16. During dressing application patient VAS in the VR group was 2.33 (SD 3.4) with a P value of 0.40. Therefore, there was no statistically significant decrease in self-reported pain (VAS) with the use of VR during wound care.

Table 2 - Adolescent self-report of pain VAS

	Dressing Removal	Dressing application
VR group	2.9	2.33
Standard group	4.2	3.8
P Value	0.16	0.40

Jeffs, et al. include 28 outpatient adolescent burn patients 10 to 17 years old with no history of motion sickness/seizure activity. This is a single blinded study; therefore, given the nature of the intervention the blinding of the study was broken after all pre-wound care assessments were complete. The intervention assessed in this study was VR (Snow world, Kaiser optics SR80a, SXGA resolution 1280-1024), compared to a passive distraction group who

watched a movie, and a typical care group with no distractions. APPT scores were measured before and after the procedure.

The authors used the APPT values to determine treatment effect size. The overall model variation explained by the covariates was 81.2%. The corrected for overfit $R^2 = 0.621$ and the estimated effect size = 1.25. The VR group reported less procedural pain than the passive distraction group with a P value = 0.029. The VR group also reported less procedural pain than the standard care group with a P value = 0.32. Therefore, this study shows no clinically significant decrease in self-reported pain (APPT) with the use of VR during wound care.

The exploratory study by Chan, et al. included 8 inpatient adolescent burn patients mean age 6.54 years old. All of the patients who were enrolled in the study had experienced burns for the first time. All had dressing changes before the implementation of the VR, therefore they all had anxiety secondary to the anticipated pain. The intervention measured in this study was VR (Visual C++6.0 and DirectX 7.0a SDK. 3D modelling tools (3D studio MAX and Rhinoceros) compared to a group without VR. This study was a descriptive exploratory study where a “crossover design was used, and the experimental group served as its own control. The order in which the treatments were administered was carried out by simple number randomizations.”⁶ FACES score was measured before, during, and after dressing change.

The authors used mean change from baseline of FACES score (self-reported). The group with VR was 38.13 (SD 12.02) and the group without VR was 53.75 (SD 11.80). The P value > 0.05 during dressing removal. The P value >0.05 during dressing application. Therefore, this study shows there was no clinically significant decrease in self-reported pain with the use of VR during wound care.

DISCUSSION

Research about VR for pain management has been ongoing since 1996 for burn related injuries.⁸ Investigations for the use of VR for analgesia in other settings like dental procedures, post-operative pain, and general wound debridement, are underway. Unfortunately, off-shelf/non-customized VR interventions do not appear to be a viable solution to pain management during burn wound care in the pediatric population at this time. The studies conducted above did not find statistically significant improvement in pain intensity with the addition of VR during the initial appointment for pediatric burn wound care. This suggests that “savings made on purchasing an off-shelf system, will not result in meaningful or effective reductions in pain.”⁴

A specific limitation cited by Kipping et al. study was the use of a non-customized VR system. Inferences were made that the lack of “motivational relevance” hindered the effectiveness of this non-customized VR intervention.⁹ The authors again cited gate control theory and suggested that a more immersive VR system should be the focus of further research and investigations. Additionally, the authors highlighted the need for further research regarding multiple or consecutive dressing changes rather than just focusing on the initial dressing change/management. Of note, there was a downward trend in mean pain scores in the Kipping et al. study illustrating at least a moderate association between immersive distraction techniques and pain reduction during pediatric burn wound care.

Limitations cited by Jeffs et al. and Chan et al. were the use of a small or convenient sample size from a single burn care center site. The authors expressed concern that the interventional effects can not translate with great significance to an inpatient center with more extensive burns. Similar to Kipping et al., multiple or consecutive dressing changes were not addressed and cited as a significant limitation.

Blinding of staff/participants was cited as a limitation in all three studies due to the given the nature of the distraction intervention. No significant patent, US availability, or insurance issues were mentioned in any of the studies highlighted in this review. Contraindications for the use of VR are as shown above in Table 1 regarding cognitive impairment, visual/hearing impairment, and wound location given the physical constraints of the VR device.

CONCLUSION

The results of the two RTC's and the descriptive exploratory study under review suggest that the use of an off-shelf or non-customized VR system does not significantly decrease pain intensity during pediatric burn wound care management. Although not statistically significant, the VR intervention is more effective than simple distraction for pain reduction in all three studies. This suggests the need for future research opportunities exploring how to make the VR system more immersive and affordable thereby increasing the "motivational relevance" and decreasing pain intensity. Additionally, a future study would need to utilize a larger sample size which was cited as a limitation from one of the RTC's and the descriptive exploratory study. Once research shows statistical significance using VR for pain management, investigation needs to be expanded beyond the initial wound care appointment. For VR to become clinically feasible, it would be important to establish efficacy over multiple or consecutive wound care appointments given the nature of burn wound healing. With all of these factors considered, VR should not be disregarded in the pediatric population for pain control during pediatric wound care management just yet. Rather, more investigation should be focused on how to adjust the equipment with appropriate financial considerations to avoid overuse of sedatives and opioids in the venerable pediatric population.

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