Virtual reality distraction decreases pain during daily dressing changes following haemorrhoid surgery

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Abstract
Objective: To investigate whether immersive virtual reality (VR) distraction could decrease pain during postoperative dressing changes.
Methods: This was a prospective, open-label randomized clinical trial that enrolled patients that had undergone haemorrhoidectomy. Patients were randomly assigned to one of two groups: a control group that received the standard pharmacological analgesic intervention during dressing change and a VR group that received VR distraction during dressing change plus standard pharmacological analgesic intervention. Pain scores and physiological measurements were collected before, during and after the first postoperative dressing change.
Results: A total of 182 patients were randomly assigned to the control and VR groups. The baseline characteristics of the VR and control groups were comparable. There was no significant difference in mean pain scores prior to and after the dressing change procedure between the two groups. The mean pain scores at the 5-, 10-, 15- and 20-min time-points during the first dressing change were significantly lower in the VR group compared with the control group. Heart rates and oxygen saturation were not significantly different between the two groups.
Conclusion: Immersive VR was effective as a pain distraction tool in combination with standard pharmacological analgesia during dressing change in patients that had undergone haemorrhoidectomy.
**Introduction**

Haemorrhoid disease is a common anorectal pathology manifesting with bleeding, excruciating pain, prolapse or perianal mass, and it has a considerable impact on quality of life and significant psychosocial implications.\(^1,2\) Surgery has been considered to be the most effective treatment for haemorrhoids for decades.\(^3\) Daily wound care, including dressing changes, is considered to be an important and effective part of a comprehensive postoperative treatment programme for haemorrhoids.\(^4,5\) However, the distressing pain resulting from daily dressing changes is often significant and severe in intensity, which adversely and seriously impacts on the quality of life and rehabilitation of patients with haemorrhoids following surgery.\(^6\) Therefore, postoperative pain management is a challenge for patients with haemorrhoids, which typically requires multiple modalities including oral analgesics, nonsteroidal anti-inflammatory drugs, local medications, sitz baths and other nonpharmacological techniques.\(^7,8\)

Oral or topical analgesic medications remain the primary treatments for postoperative pain.\(^9\) However, such medications not only reduce postoperative pain, but also have various negative side-effects. Severe dependence on analgesics can increase hospital stay and prolong wound healing.\(^10\) Moreover, pharmacological treatment alone often cannot fully eliminate all postoperative pain.\(^11\) Both the economic and psychological costs of just using pharmacological analgesic treatment for postoperative pain management have contributed to the need to identify a novel adjunctive analgesic approach that can combine conventional pain treatments to improve postoperative pain management, especially during daily wound dressing changes.\(^12,13\)

Virtual reality (VR) distraction is a psychology-based approach that is both immersive and engaging, which can divert attention away from painful feelings by immersing patients in a positive visual or auditory distraction environment generated by a computer.\(^14,15\) Generally, a VR system uses a microprocessing computer, a head-mounted three dimensional display and specialized built-in software to generate an immersive virtual environment.\(^16\) VR distraction is considered an effective pain treatment for patients undergoing various invasive procedures, such as dental surgery, urological endoscopies or burn wound dressing changes.\(^16–19\) However, to date, there are no data on the impact of VR on pain during postoperative daily wound care in patients after haemorrhoid surgery. In this study, VR sets were used to evaluate the effect of VR distraction on relieving pain during postoperative daily wound dressing changes in patients following surgery for haemorrhoids.

**Patients and methods**

**Patient population**

This prospective, open-label randomized study enrolled consecutive patients who underwent Milligan-Morgan haemorrhoidectomy in Three hospitals, respectively Huiqiao Medical Centre, Southern Hospital of Southern Medical University, Guangzhou, Guangdong Province, and Department of Health Care, Chinese PLA Southern
Theatre Command General Hospital, Guangzhou, Guangdong Province, China, and Dialysis Centre, York Central Hospital, Richmond Hill, Ontario, Canada, between 1 May 2016 and 1 May 2018. All patients met the following inclusion criteria: (i) aged over 18 years; (ii) able to communicate clearly without hearing impairment; (iii) Chinese speaking and reading/writing ability; (iv) an expected hospital stay > 7 days; (v) with post-operative wounds that required daily care and dressing changes. Patients with acute or chronic psychiatric illness, critical conditions requiring intensive care, physical impairments that precluded the use of VR sets, previous VR distraction therapy, a history of seizure disorders, drug addiction or abuse were excluded. Following haemorrhoidectomy, all patients received a standard postoperative treatment regimen including wound care, dressing changes, sitz baths and pharmacological medications including analgesics (flurbiprofen axetil; Beijing Tide Pharmaceutical, Beijing, China). This study commenced at the first dressing change after surgery. Prior to surgery, each patient was randomized using a computer-generated random number table to receive either routine dressing changes or dressing changes under VR distraction.

The study was approved by the Institutional Review Board of Southern Hospital of Southern Medical University (no. 20180291) and was retroactively registered in a registry of Guangdong Association of Clinical Trials (no. GACT190021019). The study was conducted according to the principles of the declaration of Helsinki and all enrolled patients were required to provide written informed consent.

Virtual reality sets and dressing change procedures

In this study, an eMagin Z800 3DVISOR Head Mounted Display (eMagin Corporation, Hopewell Junction, NY, USA) with a 40° view field was used with an integrated audio system and a FastTrak control box (Hustler Turf Equipment, Hesston, KS, USA). The VR equipment was connected to a Dell 650 Precision computer (Dell, Round Rock, TX, USA). Immersive VR software, Snow World version 2.1 (Dell), running on a Dell 650 Precision computer was used to achieve the virtual distraction activity. Before surgery, all patients in the VR group received training on the VR equipment to ensure that they were fully familiarized with the VR sets and skilled in operating the software before the first postoperative dressing change. The standard dressing change procedure consisted of removing the dressings, cleaning and sterilizing the wound, wound assessment and covering the wound with a new dressing. For patients in the VR group, dressing changes proceeded after the patient fully immersed in the VR distraction. Patients in control group only received the standard dressing change procedure.

Outcome measures

Pain intensity during dressing change was considered as the primary outcome measure. A visual analogue scale (VAS) was used to measure the pain intensity. The VAS referred to a 10-cm visual scale representing a continuum with the ends marked ‘0 (no pain)’ and ‘10 (unbearable pain)’.

Patients were asked to mark the scale from 0 to 10 when they experienced the worst pain intensity. Physiological measurements, including heart rates and blood oxygen saturation (SaO2), were considered as the secondary outcome measures, which were monitored using a pulse oximeter. All VAS and physiological measures recorded for each patient were conducted by the same nurse who was present for the whole duration of the dressing change procedure. The VAS and physiological measures were also recorded at baseline before the dressing change.
change procedure. Subsequent VAS and physiological recordings were obtained at 5-min intervals until the completion of the dressing change. Post-dressing change VAS and physiological measurements were also recorded at 5 min after the completion of the dressing change. As patients usually suffer from the most severe pain during the first dressing change after invasive surgery, the VAS and physiological measurements were obtained at the first dressing change after surgery (postoperative day 2).

Statistical analyses

The sample size was based on data from a pilot study, in which the power of the test (1 – β) was set as 0.9 and the significance level (α) was 0.05. In a setting with a 20% dropout rate, the power calculation estimated that approximately 91 patients were required for each study group.

All statistical analyses were undertaken using IBM SPSS Statistics for Windows, Version 22.0 software (IBM Corp., Armonk, NY, USA). Normal distribution and homogeneity of variance of the data were evaluated. Continuous variables are presented as mean ± SD and were compared using an independent t-test. Categorical variables are presented as n of patients (%) and were compared using χ²-test. Repeated measures analysis of variance was used to compare the measurements over time between the two groups. A P-value < 0.05 was considered statistically significant.

Results

This study enrolled 182 patients (72 males, 110 females) that met the inclusion criteria. Of these, 91 patients were randomized to receive routine daily dressing changes (control group) and 91 patients were randomized to receive daily dressing changes under VR distraction (VR group). The flow chart for this study is presented in Figure 1. The baseline demographic and clinical characteristics of the patients are presented in Table 1. The mean ± SD age of the study cohort was 45.8 ± 12.6 years (range 18–65 years). The mean ± SD duration of haemorrhoids of the study cohort was 9.8 ± 1.8 years. A total of 159 patients had grade III haemorrhoids and 23 patients had grade IV haemorrhoids. There were no significant differences between the two groups in terms of baseline demographic and clinical characteristics.

There was no significant difference in the VAS pain scores between the two groups prior to the first dressing change at 0 min (mean ± SE 4.09 ± 1.42 [VR group] versus 4.17 ± 1.31 [control group]) (Figure 2). The mean ± SD duration of the first dressing change following surgery was 22.3 ± 1.2 min for the study cohort. During dressing changes, the mean ± SE VAS scores for the VR group were significantly lower than those of the control group at the 5-, 10-, 15- and 20-min time-points (P < 0.05 for all comparisons). Repeated measures analysis of variance showed that pain significantly decreased over time in the VR group compared with the control group (P < 0.01; Figure 2). The post-dressing change VAS pain scores did not differ significantly between the VR and control groups (mean ± SE 4.26 ± 1.31 versus 4.28 ± 1.33, respectively).

During the dressing changes, both the VR and control groups had increasing heart rates compared with the baseline level (Figure 3). Repeated measures analysis of variance showed that heart rate significantly increased over time in the entire study cohort (P = 0.03). However, at each time-point during the dressing change procedure, there were no significant differences in heart rate between the two groups. There were no significant differences in SaO₂ between the two groups during the dressing change procedure (data not shown).
Table 1. Baseline demographic and clinical characteristics of eligible patients with haemorrhoids (n = 182) who underwent postoperative dressing changes with or without immersive virtual reality (VR) distraction.

| Characteristic                        | VR group n = 91 | Control group n = 91 |
|---------------------------------------|-----------------|----------------------|
| Age, years                            | 46.3 ± 11.8     | 45.2 ± 12.6          |
| Sex                                    |                 |                      |
| Male                                   | 34 (37.4)       | 38 (41.8)            |
| Female                                 | 57 (62.6)       | 53 (58.2)            |
| Haemorrhoid grade                      |                 |                      |
| III                                    | 78 (85.1)       | 81 (89.0)            |
| IV                                     | 13 (14.3)       | 10 (11.0)            |
| Duration of haemorrhoids, years        | 9.7 ± 1.8       | 10.2 ± 2.2           |
| VAS score at 4–6 h after surgery       | 7.8 ± 1.1       | 8.0 ± 1.2            |
| Duration of first dressing change, min | 21.2 ± 3.8      | 20.4 ± 4.1           |

Data presented as mean ± SD or n of patients (%). 
No significant between-group differences (P ≥ 0.05); continuous variables were compared using an independent t-test and categorical variables were compared using χ²-test. 
VAS, visual analogue scale.
Discussion

This current study prospectively analysed the effect of VR on pain alleviation during the first postoperative dressing change in patients with haemorrhoids. Patients that received the first postoperative dressing change under immersive VR distraction had a significantly lower mean VAS pain score compared with the control group that received a routine dressing change procedure. Furthermore, pain significantly decreased over time in the VR group compared with the control group. This current study has demonstrated that immersive VR can reduce pain intensity during dressing changes in patients that have received standard pharmacological analgesic treatment.
which suggests that VR could be a useful adjunct to pharmacological analgesia.

Severe pain associated with wound dressing changes has been a constant challenge for patients undergoing invasive surgery, especially for anorectal diseases. Pharmacological analgesics including opioids remain the primary treatment of choice in such patients, but they usually offer inadequate pain control during wound dressing changes. It has long been known that the perception of pain requires the attention of the mind. Considering the limited capacity of an individual's mind, it is conceivable that diverting the patient's attention away from the painful feelings to some other positive visual or auditory distraction during wound dressing changes could effectively alleviate pain. As a type of distraction technique, VR is uniquely characterized by being both immersive and engaging, integrating many sensory experiences and thus capturing a greater degree of the person's attention. Virtual reality has been shown to be a useful interventional tool in conjunction with pharmacological analgesia and its efficacy has been successfully confirmed in various groups of patients that experience pain during dressing changes. In this current study, immersive VR in combination with pharmacological analgesia significantly decreased the pain intensity during postoperative dressing change compared with routine dressing change in the control group. The results of this current study were consistent with a previous randomized controlled trial. The pain alleviation effect of VR was more significant during the dressing change procedure compared with that of before or after the dressing change, suggesting that the efficacy of VR distraction on pain is more effective while patients have more intense pain.

Physiological measurements during the dressing change procedure demonstrated no significant differences between the VR and control groups. It has been demonstrated that heart rate is not significantly associated with pain scores during painful procedures. Moreover, the mean SaO2 values at all of the time-points were not significantly different in the VR and control groups. SaO2 is associated with respiratory function, which would not be influenced by pain during wound dressing changes. None of the patients in this current study had any psychological factor that affected SaO2.

The VR headset used in the current study was an early version with a relatively narrow field of view, which limited the amount of peripheral vision that could be stimulated. A VR headset with a wider field of view might have even stronger analgesic effects. The immersive VR software, Snow World version 2.1 (2003), used in this current study was developed for medical and pain applications in general and has been shown to be effective in pain alleviation. The components of the VR system used in the current study were inexpensive and easy to use, which may not be the best choice for pain alleviation in this patient population, but the efficacy was promising. With the ongoing improvements in the hardware and software, the application of VR in pain alleviation for patients that have undergone invasive procedures is likely to increase in the future.

This current study had a number of limitations. First, the single-centre design may limit the generalizability of the results. A large-scale, multicentre, prospective study should be conducted to confirm the findings and obtain more definite evidence. Secondly, the use of VR headsets made it impossible to use a blinded design. A double-blind design would be the ideal research method to evaluate the effectiveness of an intervention. Thirdly, the application of VR in postoperative pain management is still limited in China.
The VR headsets used in this study were not dedicated medical devices, so may not provide the best intervention for patients that have undergone haemorrhoid surgery. A more professional medical VR system that delivers specialized VR environments might be required for optimal pain management during dressing changes.

Pain alleviation is an important part of the postoperative care of patients that have undergone haemorrhoid surgery. According to results of this current study, immersive VR distraction can improve pain intensity during dressing changes in patients that had received a standard pharmacological analgesic treatment, suggesting that VR can serve as a useful adjunct to pharmacological analgesia. The results of this current study support the use of immersive VR distraction to reduce pain during invasive nursing procedures.

In conclusion, this current study found that application of immersive VR distraction in combination with standard pharmacological analgesics significantly improved pain alleviation during dressing changes in patients that had undergone haemorrhoidectomy when compared with standard pharmacological analgesic treatment alone. The results of this study suggest that VR distraction is a useful adjunct to pharmacological analgesia for pain relief during wound dressing change.

Declaration of conflicting interest
The authors declare that there are no conflicts of interest.

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