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Use of an Alternating Inflatable Head Pad in Patients Undergoing Open Heart Surgery

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Study Design A
Data Collection B
Statistical Analysis C
Data Interpretation D
Manuscript Preparation E
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Background: Preoperative symptoms like occipital pressure ulcers and alopecia areata (AA) significantly lowered patient quality of life. Therefore, preoperative nursing was in need of investigation. This study aimed to compare effects of an alternating inflatable head pad and a gel pad on occurrence of postoperative pressure ulcers and AA in patients undergoing open heart surgery.

Material/Methods: This was a prospective study. We allocated randomly 120 patients undergoing surgery (3–7 h) in the Yantai Yuhuangding Hospital affiliated to Qingdao University, China from January to October 2015 to the control (gel head pad) or the experimental (alternating inflatable head pad) group (n=60 per group). The incidence and severity of occipital pressure ulcer were graded by the classification system of the European Pressure Ulcer Advisory Panel (EPUAP). The degree of occipital alopecia was measured by hair pull test. This study used the *t* test and chi-square analysis. All statistics were analyzed by SPSS 21.0.

Results: Compared with the control group, there was a significantly lower incidence and severity of occipital pressure ulcer and alopecia in the experimental group (9 cases/60 cases vs. 1 case/60 cases, $P < 0.01$). Moreover, multivariate analysis showed the risk of developing occipital pressure ulcer after surgery was also obviously lower in the experimental group (OR 1.449–120.798; $P < 0.005$). Hair pull test revealed that fewer patients in the experimental group had a hair loss over 10%.

Conclusions: The alternating inflatable head pad was effective in reducing the incidence and severity of occipital pressure ulcer and alopecia associated with surgery, which benefited the postoperative nursing and improved patient quality of life.

MeSH Keywords: **Alopecia Areata • Pressure Ulcer • Randomized Controlled Trial**

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Background

The onset of pressure ulcers is a common postoperative adverse event, with a high-risk population from all surgery patients ranging from 9.2% to 38% [1]. These ulcers frequently occur at the sacrum and coccyx (50.9%), heels (22.8%), and ischial tuberosities (10.5%), as well as various other sites (15.8%) [2]. In recent years, more and more researchers have shifted their attention to the pathogenesis of postoperative occipital skin pressure ulcer and alopecia and have made some progress, discovering that complex factors such as tissue tolerance for oxygen, temperature manipulation, vasoactive drugs, hypotensive periods, material used on the operating room table, frequency of repositioning, duration of immobilization, older age, low albumin levels, corticosteroid use, and many other conditions during surgery were strongly associated with this post-surgical ulcer [3,4]. Unfortunately, these complications not only increase postoperative pain and delay recovery, but also put higher economic burdens on patients. Since the application of early risk assessments, including the Braden [5], Norton [6], and Waterlow scales [7], play a crucial role in the prevention of intraoperative pressure ulcers, a series of appropriate prevention strategies based on these risk assessments can be implemented to reduce its incidence, including changing mattress material [8] and considering the intraoperative positioning of patients [9]. One evidence-based nursing recommendation for the requirements of specific patients in each operating theater indicated an astonishing figure, that approximately 95% of all pressure ulcers were indeed preventable [10].

Similarly, alopecia areata (AA) is a common and stressful disorder that results in hair loss from an autoimmune disorder [11–13]. AA is one of the most common human autoimmune disorders, with a lifetime risk of over 1.5% [13]. AA severity varies from patchy hair loss to total scalp and body hair loss [13,14]. A plethora of AA treatments have failed to show efficacy, especially in severe cases such as heart surgery. In addition, the relapse rates of AA are high. Sterols are commonly used to treat AA. For instance, intralesional or topical steroids were used for mild cases and systemic steroids or topical immunotherapy with diphenylcyclopropenone in severe cases [15–17]. Ongoing research has been conducted to investigate the mechanisms of AA onset [14]. Novel directions include biologics targeting immune response, as well as lasers and autologous platelet-rich plasma therapy [18–22]. It is hoped that these novel research outcomes can be rapidly translated into novel treatments for AA. However, in the meantime, the application of an appropriate head pad during surgeries could also reduce the pain and improve quality of life postoperatively.

Open heart surgery (OHS) is an extraordinary life event that is associated with feelings of hope and fear among patients and relatives. All involved are in need of attention from health care professionals (HCPs) to preserve their well-being in the best

possible way. An alternating pressure air mattresses (APAMs) could decrease the incidence of pressure lesions via repositioning to reduce the duration of direct pressure and shearing force [23]. In consideration of the effects of pressure on the development of pressure ulcers, various pressure-relieving instruments have been applied to improve intraoperative conditions, including the use of dry, viscoelastic, and polymer overlays [24] and a 4-cm thermoactive viscoelastic foam pad on the operating table [25]. APAMs have been used to prevent pressure ulcers in mechanically ventilated critical care patients. However, strategies for the prevention of occipital pressure ulcers related to surgery have not yet been widely reported.

With the aim of alleviating intraoperative lesions and prevent postoperative pressure ulcers and AA, in 2013 an APAM used for head support during surgery was designed by us (WeXuan Co., China). An inflatable pad with air cells spanning the central region of the pad is extended one-dimensionally relative to the air cells in the head region of the mattress. This alternating inflatable head pad is separated into 4 equal sections (A, B, C, and D), each of which can be inflated in an alternating pattern every 30 min during surgery to maintain intermittent contact with the patient's head, providing steady support.

In this study, we have identified an efficient pressure-relieving instrument with the ability to provide stability, pressure reduction, and pressure redistribution for the patient's head during surgery. We also compared the effectiveness of our alternating inflatable head pad with a gel pad in the prevention of postoperative occipital hair loss and pressure ulcers in patients undergoing open heart surgery.

Material and Methods

Design

In this prospective study, the development of occipital pressure ulcers and the degree of occipital hair loss were recorded as a part of a quality-improvement initiative. A total of 120 patients undergoing surgery (duration 3–7 h) between January and October 2015 were randomized into the experimental or control group using a random number generator. The randomization code was placed in a sealed envelope. Patients and circulating nurses were blind to the group assignment until the patient entered the operating room. The alternating inflatable head pad (WeXuan Co.) was used in the experimental group, while the gel head pad was used in the control group with patients being repositioned every hour during surgery (n=60 per group). Both groups followed identical repositioning protocols.

This study was carried out in the 22-bed Surgery Department of Yuhuangding Hospital affiliated to Qingdao University in

Yantai, China, where 400 surgeries are performed each year on average.

Participants

Patients were consecutively recruited from the Department of Cardiovascular Surgery at the above hospital according to the following inclusion criteria: scheduled for surgery with cardiopulmonary bypass, age >18 years, and average duration of surgical procedure >4 h. The following exclusion criteria were applied: the presence of occipital pressure ulcer and alopecia before surgery, and laboratory data showing albumin lower than <30 g/L. This study was approved by the Ethics Committee of Yantai Yuhuangding Hospital affiliated to Qingdao University. The demand for written consent was waived. Relevant data were generated and collected into 2 databases in a data decoupling procedure, which adhered to data protection legislation and maintained individual privacy.

Treatment

In both groups, operating room tables were covered with a moisture-retaining disposable sheet and a cotton sheet. In the control group, the gel head pad was placed in position after the induction of general anesthesia. During the surgery, the patients' head was raised once per hour for 1–3 min. In the experimental group, the alternative inflatable head pad (with a maximum height of 5–6 cm) was positioned under the patient's head and each section was inflated sequentially every 30 min over the course of the operation. Both groups received routine postoperative medical skin care in the Intensive Care Unit (ICU) and alternating pressure air mattresses (APAMs) were used.

Data collection and evaluation

Participants were followed up on for 48 h postoperatively. Any occipital pressure ulcers were graded according to the classification system recommended by the European Pressure Ulcer Advisory Panel (EPUAP 2005) by trained researchers and 3 nurses with 10 years of experience in providing medical care for patients after surgery. The reliability of the classification of pressure ulcers between researchers and nursing staff ranged from $\kappa=0.89$ (95%CI 0.83–0.97) to $\kappa=0.93$ (95% CI 0.90–0.97). The classification was performed as follows: Grade I, non-blanchable erythema; Grade II, partial-thickness skin loss or damage involving the epidermis and/or blisters and shallow ulcer; Grade III, full-thickness skin loss, involving damage or necrosis of the epidermis and/or dermis; Grade IV, full-thickness skin loss, involving damage or necrosis of the epidermis, and/or dermis extending to underlying muscle, bone, tendon, or capsule.

Postoperative occipital alopecia was evaluated via hair pull test [26], in which approximately 50% of occipital hairs were

grasped between the thumb and index finger and pulled before individual separated hairs were counted [27]. Personnel underwent a standardized training process before administering this classification standard test. The reliability of the classification of the hair pull test between researchers and nursing staff ranged from $\kappa=0.87$ (96%CI 0.81–0.96) to $\kappa=0.91$ (93%CI 0.89–0.95). The incidence and severity of pressure ulcers and the amount of hair loss were recorded for both groups.

Validity and reliability

Three nurses were selected and trained for corrected nursing. The classification of the incidence and severity of pressure ulcers was scored according to the EPUAP and the degree of AA was determined by hair pull test. Researchers assessed the patients' skin each day after the operation. Any doubt about pressure ulcer and hair loss was appraised independently by 3 nurses to achieve consensus.

Statistical analysis

Normally distributed continuous variables were analyzed using *t* tests, and χ^2 tests were used for categorical variables. Logistic regression analysis was performed to evaluate the difference in the incidence of pressure ulcers between the control and experimental groups. All analyses were performed with the SPSS 21.0 software package (IBM Corporation, California, USA). $P<0.05$ was considered to indicate statistical significance.

Results

There were 120 surgery patients (74 males and 46 females) eligible for this study (60 patients each in the experimental and control group). The mean age of the cohort was 56 years (range: 34.5 to 66). The mean operative duration was 214.37 min (range, 174.62 to 252.72 min). Sex, age, length of operation, Braden score on admission, body mass index, diabetes mellitus, and types of operation were investigated, and we found no significant differences between the control and experimental groups ($P>0.05$, Table 1).

The occurrence and grade of postoperative pressure ulcers are listed in Table 2. Pressure ulcers were identified after surgery in one patient of the experimental group and 9 patients of the control group. Among these pressure ulcers, 3 were classified as Grades I and II immediately after the surgical procedure, and 6 were identified on the first day post-surgery. The remaining 3 pressure ulcers were determined on the second postoperative day.

Table 3 compares pressure ulcer and occipital hair loss between the control group and the experimental group. The

Table 1. Baseline characteristics of recruited patients.

Characteristics	Control group (n=60)	Experimental group (n=60)	t or χ^2	P
Sex, n (%)				
Male	36 (60.0)	38 (63.3)	0.14	0.85
Female	24 (40.0)	22 (36.7)		
Age (mean \pm SD y)	56.67 \pm 10.39	55.32 \pm 9.84	0.73	0.47
Length of operation (mean \pm SD min)	213.68 \pm 39.06	215.05 \pm 33.92	-0.20	0.84
Braden score on admission (mean \pm SD)	11.72 \pm 1.53	12.033 \pm 1.48	-1.15	0.25
Body mass index (mean \pm SD)	19.89 \pm 2.27	20.63 \pm 2.63	-1.31	0.19
Diabetes mellitus				
Yes, n (%)	14 (23.3)	15 (25.0)	0.45	0.83
No, n (%)	46 (76.7)	45 (75.0)		
Operation, n (%)				
MVR	14 (23.3)	14 (23.3)		
AVR	12 (20.0)	12 (20.0)		
DVR	15 (25.0)	13 (21.7)	0.31	0.99
CABG	11 (18.3)	13 (21.7)		
Bentall's	8 (13.3)	8 (13.3)		

MVR – mitral valve replacements; AVR – aortic valve replacements; DVR – double valve replacements; CABG – coronary artery bypass surgery. Braden score, a score >16 indicates low risk; 15–16 indicates mild risk; 12–14 indicates moderate risk; \leq 11 indicates high risk.

Table 2. The occurrence and grade of pressure ulcer.

Postoperative day	Control group (n=60)		Experimental group (n=60)	
	Grade I	Grade II	Grade I	Grade II
0	1	2	0	0
1	2	3	1	0
2	0	1	0	0
Total	3	6	1	0

Table 3. Comparison of the pressure ulcer and the occipital alopecia between the control group and experimental group.

	Control group (n=60)	Experimental group (n=60)	χ^2	P
Pressure ulcer n (%)	9 (15.0%)	1 (1.7%)	6.982	0.008*
Grade I, n (%)	3 (5.0%)	1 (1.7%)	1.034	0.3091
Grade II, n (%)	6 (10.0%)	0 (0.0%)	6.316	0.027*
Hair loss \geq 10%, n (%)	36 (60.0%)	5 (8.3%)	35.604	<0.001*
Alopecia areata, n (%)	6 (10.0%)	0 (0.0%)	6.316	0.027*

* Significant differences.

Table 4. The binary logistic regression with pressure ulcer as the dependent variable and risk factors as independent variables.

	n	B(SE)	P	OR (95%CI)
Patients recruited	120			
Sex		2.450 (1.505)	0.104	(0.607, 221.237)
Prevention pad		6.111 (2.747)	0.026*	(1.449–120.798)
Length of operation		0.108 (0.039)	0.005*	(1.032, 1.202)
Age		−0.052 (0.119)	0.660	(0.752, 1.198)
BMI		−0.294 (0.319)	0.356	(0.399, 1.391)
MVR		6.114 (3.707)	0.276	(0.316, 646657.431)
AVR		7.018 (3.758)	0.099	(0.706, 1765923.125)
DVR		1.147 (2.281)	0.062	(0.036, 275.323)
CABG		0.350 (2.010)	0.615	(0.028, 72.953)

BMI – body mass index; MVR – mitral valve replacements; AVR – aortic valve replacements; DVR – double valve replacements; CABG – coronary artery bypass surgery.

total postoperative pressure ulcer incidence was 8.3% (control group: 15% (9/60); experimental group: 1.7% (1/60)). Chi-square analysis showed a significantly reduced incidence of pressure ulcer in the experimental group ($P=0.008$, χ^2 -value, 6.98, degrees of freedom (df, 1)). In terms of the severity of pressure ulcer, significantly more Grade II pressure ulcers were identified in the control group, at 10% (6/60) vs. 0% (0/60) in the control and experimental groups, respectively ($P=0.027$). Furthermore, the incidence of hair loss ($\geq 10\%$ in the hair pull test) was also significantly higher in the control group compared with the experimental group, at 60% (36/60) vs. 8.3% (5/60), respectively ($P=0.000$). For occipital AA 48 h after surgery, the incidence was notably higher in the control group, at 10% (6/60) vs. 0% (0/60), ($P=0.027$). The results of this study fully demonstrate that the condition of hair loss and the localized alopecia after open heart surgery with OPB were worse in the control group than in the experimental group, with clear statistical significance (all $P<0.05$).

For the multivariate logistic regression analysis, the dependent variable was the occurrence of occipital pressure ulcer and the initial model included 10 independent variables, including sex, type of head pad, age, BMI, length of operation, and type of operation. Sex was included because it indicates a host of biological characteristics. Age, length of operation, and BMI were all considered since these indexes were statistically significant in the univariate analysis. As the method of ulcer prevention and the investigated variable, the type of pad was close to the level of statistical significance in the univariate analysis and was also included. These factors were cross-checked against a logarithmic model in which each column was evaluated as a continuous variable, with no correlation extant between these predictor variables and the occurrence

of pressure ulcer. Table 4 displays the parameter estimates, standard errors, odds ratios (OR) with 95% confidence intervals (95% CI), and P -values calculated for each variable. The type of ulcer prevention pad (OR range, 1.449–120.798; $P<0.005$) was a significant variable when the probability of head pressure ulcer development was estimated. The length of surgery was also shown to be a significant factor. All other variables were evaluated as well but showed no significant value in predicting the development of occipital pressure ulcer after surgery. These data further suggest that the risk of developing occipital pressure ulcer after surgery was higher in patients using the gel head pad compared with the population using the alternating inflatable head pad.

Discussion

The purpose of this study was to provide credible evidence in assessing the effectiveness of the alternating inflatable head pad in preventing and lowering the severity of occipital pressure ulcer, hair loss, and AA after surgery. The results show that the percentage of patients who suffered from pressure ulcers on occipital skin after open heart surgery in the experimental group was 1.7%, markedly lower than that in the control group. Furthermore, the experimental group had better results in the degree of hair loss and progression to AA than in the control group.

Vigilant surgeon and nursing attention is essential among patients who undergo open heart surgery, enhancing the quality of care and contributing to the recovery. According to extant literature, pressure ulcers are caused by intense pressure or pronounced pressure gradients which are unrelieved for

prolonged periods of time, resulting in local ischemic damage [2]. Since extracorporeal circulation can lead to hypothermia and reduce the level of hemoglobin and serum albumin, complicated surgery performed over several hours with inadequate padding and incorrect positioning can cause serious and long-term injury, which has even led to cases of litigation in the past [28]. Therefore, finding new methods to limit the incidence of intraoperative pressure ulcers is imperative. In this experiment, the position of the occiput was changed every 30 min during the surgical procedure to eliminate occipital breakdown. However, the change in head position in the process of surgery is typically difficult to accomplish and increases the workload for nursing staff. In this study, we found that the alternating pressure air pad was superior to the gel head pad in reducing the incidence and severity of occipital pressure lesions after prolonged surgery. This outstanding effectiveness was achieved by relieving or releasing the local pressure at regular intervals, which improved the blood circulation to occipital skin during the operation. Furthermore, the device efficiently reduced the requirement of patient repositioning by theater nurses. It is widely understood that the hair loss in such patients is related to several factors, such as thin subcutaneous adipose tissue, lack of adequate protection during operation, and long-term local compression [29]. The exertion of pressure on skin can cause local diminution of the blood supply and nutritional deficiency in hair follicles. As a result, patients can develop local occipital trichomadesis after surgery, which significantly affects patient quality of life. In this study, we compared the effects of using an alternating inflatable pad to adjust the compression of occipital skin with that of a gel head pad during surgery. Postoperative pressure ulcers were monitored, and alopecia and injury to hair follicles were also evaluated via the hair pull test. Our results indicate that the alternating inflatable pad can provide a relatively better strategy to address the problems caused by hemodynamic derangement in the occipital region, leading to lower incidence and severity of pressure ulcers, as well as limiting hair loss and localized occipital alopecia.

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Limitations

The present study was subject to several limitations. First, due to database restrictions, our results may be biased. Next, our analysis only represented the experience of a single academically affiliated hospital; therefore, the results might not be fully generalizable to other settings or hospitals. Moreover, there exists no in-depth study investigating the mechanical robustness of the devices tested or the effects of other conditions, such as the pressure, duration, and gradient of inflation, influencing the effectiveness of the alternating inflatable pad. Last but not least, effectiveness of alternating inflatable head pad use in other diseases and symptoms remain to be investigated in future studies.

Conclusions

This quasi-experimental study demonstrated that an alternating pressure air pad was more effective than a gel pad in preventing pressure ulcers and hair loss in open heart surgery. Further investigations with a more robust experimental design, more relative factors considered, more subjects, and more research institutes involved should be performed to fully evaluate this device and its potential applications.

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Conflict of interest

None.

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