Original Article

Incidence of Complications Associated with Reconditioned Halo-Vest Immobilization at Siriraj Hospital-Thailand's Largest National Tertiary Referral Center

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Background: Halo-vest is an effective and high-cost immobilization modality in patients that experience trauma of the cervical spine. To make this device available to more patients that may not be able to afford this modality, the authors refitted used halo-vests to create what has been termed reconditioned halo-vest (RHV). The rate of complications associated with the use of the RHV is not known.

Objective: To investigate the incidence of complications associated with RHV immobilization at Siriraj Hospital-Thailand's largest national tertiary referral center.

Materials and Methods: Cervical trauma patients treated with RHV immobilization at the Siriraj Spinal Unit during the February 1995 to December 2016 study period were included. A standardized chart and radiographic review protocol was developed to identify complications associated with the use of the RHV. Radiographs and patient records were retrospectively reviewed and analyzed.

Results: Seventy-one patients (52 men and 19 women) with an average age of 45 years (range: 16 to 86) were included. RHV immobilization was used as a definite treatment in 49 (69.0%) patients, and in conjunction with surgical intervention in 22 (31.0%) patients. The average period of RHV use was 69.8 days. No major complications (death or pneumonia) were observed in any study patient. Fourteen (19.7%) minor complications developed, including pin site loosening in 5 (7.0%) patients, infection in 5 (7.0%) patients, stress/depression in 2 (2.8%) patients, pressure sore under the body vest in 1 (1.4%) patient, and prolonged pin site pain in 1 (1.4%) patient.

Conclusion: RHV immobilization was shown to be a viable treatment modality in selected patients. Of the 71 patients that were treated with RHV immobilization for cervical trauma, there were no major complications and 14 minor complications, including pin site loosening and infection. The observed rate of complications in this study was low compared to the rates reported from many other studies.

Keywords: Incidence, Complications, Halo-vest immobilization, Cervical spine, Trauma

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The halo-vest orthosis, which was introduced in 1959 by Perry and Nickel[1-3], was developed to facilitate perioperative stabilization of the cervical spine in poliomyelitis patients. In contrast to immobilization equipment that is attached to the patient's bed, the halo-vest consists of immobilization hardware that is connected to a vest that is worn by the patient. Although these two methods are equally effective for immobilizing the cervical spine, the bed mounted version confines the patient to his/her bed. The halo-vest exerts the needed force to fully stabilize the cervical spine while allowing the patient some degree of bed-free mobility. The greater degree of cervical immobilization delivered by the halo-vest compared to other cervical orthotic devices[4-6] allows early mobilization of patients who would otherwise be confined to prolonged traction in bed[4,7-9]. The halo-vest is now widely used in patients with cervical spine injuries, infections, inflammatory diseases, and spinal tumors[10-16]. The halo-vest is used either as definitive treatment or in combination with surgical fusion. The high cost of the halo-vest limits its availability in low-resource settings and in patients that cannot afford this important, but expensive modality. In order to make this device available to more patients, the authors refitted used halo-vests to create what has been termed reconditioned halo-vest (RHV). The

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reconditioning process involves resterilization of the halo ring and pins, thorough cleaning of the plastic and metal vest structure, and the fitting and fixation of new cotton wool padding. Recent reports of complications associated with the use of halo fixation have stirred controversy, and they have some questioning its safety[17]. The rate of complications associated with the use of the RHV is not yet known. Accordingly, the aim of the present study was to investigate the incidence of complications associated with RHV immobilization at Siriraj Hospital Thailand's largest national tertiary referral center.

Materials and Methods

Cervical trauma patients treated with RHV immobilization at the Siriraj Spinal Unit of the Department of Orthopaedic Surgery, Faculty of Medicine Siriraj Hospital, Mahidol University during the February 1995 to December 2016 study period were included. Siriraj Hospital is 3,200-bed national tertiary referral center that is located in Bangkok, Thailand. A standardized chart and radiographic review protocol was developed to identify complications associated with the use of the RHV. Radiographs and patient records were retrospectively reviewed and analyzed. The protocol for the present study was approved by the Siriraj Institutional Review Board (SIRB) (COA No. 374/2560(EC1). The requirement for written informed consent was waived due to the retrospective nature of the present study.

Treatments

Plain radiographs were taken of the lateral, anteroposterior, and open-mouth views of the cervical spine. In some cases, those images were supplemented with swimmer's view images to review pathology of the cervico-thoracic junction of the spine. When a patient was found to have a fracture or dislocation that required cervical traction, Gardner-Wells tongs or a halo ring were applied for initial immobilization. Traction was started using ten pounds of weight with 5-pound incremental increases, as needed. During the reduction of dislocation procedure, a lateral radiograph was taken of the cervical spine to evaluate the effect of reduction until the reduction was accomplished. The maximum amount of traction weight used was 60 pounds without sign of cervical radiculopathy. In case of failure of reduction of cervical spine dislocation by conservative means, surgical intervention was required for reduction and fusion. If satisfactory alignment could be achieved with closed reduction, an RHV was applied at usually 2 to 3 days after admission. Placement and maintenance of the RHV was performed according to commonly accepted standards[18,19]. The four pins were tightened to a torque ranging from 6 inch-pounds (0.68 Nm) to a maximum of 8 inch-pounds (0.90 Nm.) It was previously reported that torque force should be less than 10 inch-pounds[20]. The ring was adjusted with lateral radiographs or fluoroscopy until satisfactory alignment was obtained. All patients were assigned a case-specific rehabilitation program. Ring alignment was rechecked at pre-established intervals during admission and before discharge. Lateral cervical radiographs were obtained during the follow-up period. In patients that required surgical treatment and halo immobilization, the RHV was applied immediately or within a few days after surgery. At the end of the treatment period, the halo ring was disconnected from the vest, and flexion and extension lateral cervical radiography was performed to evaluate the stability of the injured cervical spine. If there was no instability at the fracture or dislocation site and the patient was thought to require additional cervical support, the patient was placed in a Philadelphia collar for a couple weeks. Patients who had subluxation during RHV immobilization, patients who developed subluxation after removal of the RHV, and patients who developed progressive neurological deficit during RHV immobilization were scheduled to undergo surgical fusion.

Statistical analysis

Demographic and clinical characteristics were summarized using descriptive statistics. Categorical variables are shown as frequency and percentage, and continuous variables are given as number, mean $\pm$ standard deviation (SD), or median and range. SPSS Statistic version 18 (SPSS Inc., Chicago, IL, USA) was used to analysis the data.

Results

Seventy-one patients (52 men and 19 women) with an average age of 45 years (range: 16 to 86) were included. Patient demographic and clinical characteristics are shown in Table 1. RHV immobilization was used as a definite treatment in 49 (69.0%) patients, and in conjunction with surgical intervention in 22 (31.0%) patients. The average period of RHV use was 69.8 days. Regarding the types of fractures/

Table 1. demographic of 71 patients

Parameters	Mean $\pm$ SD, n (%) (n = 71)
Gender	
Male	52 (73.2)
Female	19 (26.8)
Age (year)	
Mean $\pm$ SD	44.6$\pm$17.2
Median (range)	43.5 (16 to 86)
Distribution of age	
11 to 20	7 (9.9)
21 to 30	11 (15.5)
31 to 40	11 (15.5)
41 to 50	18 (25.4)
51 to 60	8 (11.3)
61 to 70	10 (14.1)
71 to 80	5 (7.0)
>80	1 (1.4)
Mean range of halo immobilization (days)	
Mean $\pm$ SD	69.8$\pm$28.9
Median (range)	66 (9 to 143)
Types of treatment	
Halo immobilization alone	49 (69)
Surgery with halo immobilization	22 (31)

dislocations, old fracture of odontoid process associated with C1 to C2 instability was observed in 16 (22.5%) patients, sub-axial (C3 to C7) subluxation and dislocation in 14 (19.7%) patients, acute fracture of odontoid process in 12 (16.9%) patients, and hangman's fracture in 10 (14.1%) patients. No patients had pin penetration through the inner table of the skull, so there was no leakage of cerebrospinal fluid, epidural abscess formation, or meningitis.

Regarding complications, no major complications (death or pneumonia) were observed in any study patient. However, 14 (19.7%) minor complications developed, including pin site loosening in 5 (7.0%) patients, infection in 5 (7.0%) patients, anxiety in 2 (2.8%) patients, pressure sore under the body vest in 1 (1.4%) patient, and prolonged pin site pain in 1 (1.4%) patient (Table 2).

Of the 10 patients with hangman's fracture, 9 were successfully treated with RHV immobilization alone. The average duration of treatment was 68 days (range: 45 to 85). One case required a non-union anterior cervical discectomy and fusion (ACDF) at C2 to 3 with postoperative RHV immobilization for 88 days (Table 3).

Table 2. Level of injury (n = 71)

Level of injury	n (%)
Hangman fracture	10 (14.1)
Odontoid fracture	12 (16.9)
Old odontoid fracture + C1 to 2 subluxation	16 (22.5)
C1 arch fracture	3 (4.2)
C2 body fracture	3 (4.2)
C3 to C7 compression fracture	8 (11.3)
C3 to 7 subluxation or dislocation	14 (19.7)
C3 to 7 ruptured disc	4 (5.6)
T2 to 5 fracture	1 (1.4)

Table 3. Complications

Complications	n (%)
Pin loosing	5 (35.7)
Pin site infection	5 (35.7)
Pressure ulcer at body vest	1 (7.1)
Prolong pain at pin site	1 (7.1)
Anxiety	2 (14.3)

Table 4. Duration of RHV immobilization in 10 patients with hangman's fracture

Case	RHV duration (days)*	RHV only
1	76	Yes
2	52	Yes
3	61	Yes
4	85	Yes
5	45	Yes
6	85	Yes
7	47	Yes
8	77	Yes
9	82	Yes
10	88**	No

* The average number of RHV immobilization days among patients 1 to 9 is 68 days
** Non-union anterior cervical discectomy and fusion (ACDF)

Discussion

The key advantage of halo-vest immobilization is that the spine site can be immobilized while allowing the patient to ambulate freely. The halo-vest provided the greatest motion restriction at spinal levels inferior to the C2 vertebra, and the least amount of motion restriction above C2[6,21,22]. A potential limitation of the halo-vest is that movement of the cervical spine is still possible, even with a properly fitted vest. One study reported spinal movement in a halo device up to 31% of normal vertebral movement, which had the effect of impairing bone healing and fusion[6]. Other complications reported to be associated with the halo device include pin site infection, pin site loosening, pressure sore around the vest area, poor patient acceptance, and loss of reduction[8,17,23].

The success of halo immobilization is enhanced by patient understanding and acceptance. Therefore, both the patient and his/her family members must be thoroughly educated regarding the goals of therapy. Patient and family education and counseling reduces the incidence of adverse psychological effect, such as stress and depression. Once educated and then trained by physical therapy staff, most patients tolerate halo immobilization well.

The objective of this study was to investigate the major and minor adverse effects of RHV immobilization as a definitive treatment, and as an adjunct modality for postoperative external immobilization in patients that required non-secure internal fixation, such as posterior wiring and fusion.

Our findings revealed 9 of 10 hangman's fracture patients were treated successfully with the RHV alone. Grady, et al reported that hangman's fractures could be treated successfully using a Philadelphia collar[24]. Based on the experience of the authors of the present study, the short lever arm of the Philadelphia collar may render it unsuitable for safely immobilizing the upper cervical spine. Moreover, patients can remove the collar by themselves at any time. The authors of this study suggest the use of a Philadelphia collar only as a reminder to patients to limit their neck motion, and it is recommended not to use this collar in occiput, C1, or C2 fracture without surgery to provide internal stability.

Regarding complications, we found no major complications and 14 minor complications in the present study. The minor complications included pin site loosening (5 patients), infection (5 patients), stress/depression (2 patients), pressure sore under the body vest (1 patient), and prolonged pin site pain (1 patient). Moreover, we observed no increased risk of complication using RHV immobilization in older (>65 years) cervical spine trauma

patients. Joost J, et al studied 239 patients treated with halo-vest immobilization, and they found twenty-six major, seventy-two intermediate, and 121 minor complications[25]. They also reported that 14 (6%) patients died during treatment, although only one death was directly related to halo immobilization, and three may have been directly related to immobilization. Moreover, 12 of their patients (5%) acquired pneumonia during halo-vest immobilization. A study by Glaser, et al in 245 patients found that pneumonia caused death in 1 patient, loss of reduction or progression of the spinal deformity following orthotic in 23 patients, pin-track infection in 13 patients, and cerebrospinal fluid leakage from a halo pinhole in 1 patient[17]. Bransford RJ, et al reported the most common complications to be pin site infection (11%) and instability (11%)[26]. Another study reported a pressure ulcer at the scapula that was caused by halo immobilization[27].

The present study included ten older adults (>65 years) with halo vest immobilization, and no death or pneumonia. This finding is consistent with that of Joost, et al who reported that patients older than sixty-five years did not have an increased risk of pneumonia or halo-vest-related mortality[25]. Garfin, et al[28] reported on complications in 179 patients, but the number of deaths and the pneumonia rate were not reported in their study. In the same year, Glaser, *et al* reported on complications associated with halo-vest immobilization in 245 trauma patients[17]. Only one death was reported in the present study. In contrast, Majercik, et al recently reported that pneumonia developed in 21 (47%) of 45 elderly patients managed with halo-vest immobilization[29]. Eighteen (40%) of those elderly patients died, and 14 of those deaths were the result of pneumonia. In contrast to the study of Joost, et al[25] only three (4%) of seventy-nine elderly patients had pneumonia develop, and six elderly patents (8%) died without termination of life support. As these results, no significant risk factors related to these outcomes could be identified in the elderly patients. Therefore, the indications for halo-vest immobilization in elderly patients should be assessed on a case-by-case basis.

Consistent with the findings of Chan, et al[23], the results of the present study revealed no mortality or pneumonia during RHV immobilization. However and in contrast, fatality rates among patients with halo immobilization of 0.5%[17], 3.7%[30], 6%[25], and 6.5%[31] have been reported. No deaths were directly related to halo fixation itself; however, the halo device may have complicated resuscitation efforts[30]. An advocate having appropriate release tools located near patients in halo fixation was recommended.

As previously described, we found a 90% success rate for treatment of hangman's fracture with RHV alone. The other hangman's fracture patient had an old fracture with non-union that required surgery (ACDF C2-3) before postoperative application of the RHV for 88 days. Early halo immobilization after traction reduction of type II and IIA hangman's fractures is an effective method of management[32]. Cheung, et al reported successful halo immobilization treatment in all of their 11 hangman's fracture patients[31].

The authors believe that improvements in technique as well as experience and awareness in both prevention and the management of complications may have contributed to a lower rate of complications that comparable to the complications rate reported from many studies[33-36].

Limitations

The mentionable limitation of the present study is its retrospective design, which renders it vulnerable to missing or incomplete data. However, adverse events, whether they be major or minor, are meticulously recorded at our spinal unit, so the data presented here should be regarded as being both complete and accurate.

Conclusion

RHV immobilization was shown to be a viable treatment modality in selected patients. Of the 71 patients that were treated with RHV immobilization for cervical trauma, there were no major complications and 14 minor complications, including pin site loosening and infection. The observed rate of complications in the present study was low compared to the rates reported from many other studies.

What is already known on this topic?

Halo-vest is an effective and high-cost immobilization modality in patients that experience trauma of the cervical spine. However, the high cost of this treatment may put it out of reach of some patients. Accordingly, the authors refitted used halo-vests to create what has been termed *reconditioned halo-vest* (RHV). However, the rate of complications associated with the use of the RHV is not known.

What this study adds?

RHV immobilization was shown to be a viable treatment modality in selected patients. Of the 71 patients that were treated with RHV immobilization for cervical trauma during 1995 to 2016, there were no major complications and 14 minor complications, including pin site loosening and infection. The observed rate of complications in this study was low compared to the rates reported from many other studies.

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Potential conflicts of interest

The authors declare no conflicts of interest.

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