Observational Study

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Lower limb immobilization device induced small setup errors in the radiotherapy

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Abstract The aim of this study was to design a lower limb immobilization device and investigate its clinical application in the radiotherapy of the lower limbs.

Around 38 patients who underwent lower limb radiotherapy using the designed immobilization device were included in this study. The setup errors were calculated by comparison of the portal images and the simulator films or digital reconstructed radiographs (DRRs).

From all 38 patients accomplished the radiotherapy using this device, 178 anteroposterior portal images and 178 lateral portal images were used for the analysis of the positional accuracy. Significant differences were observed in the setup error of the head–foot direction compared with the left–right direction ($t=3.404$, $P=.002$) and the anterior–posterior directions ($t=3.188$, $P=.003$). No statistical differences were identified in the setup error in the left–right direction and anterior–posterior direction ($t=0.497$, $P=.622$).

The use of the in-house designed lower limb immobilization device allowed for relatively small setup errors. Furthermore, it showed satisfactory accuracy and repeatability.

Abbreviations: DRRs = digital reconstructed radiographs, EPID = electronic portal imaging device, IGRT = imaging-guided radiotherapy, IMRT = intensity modulated radiation therapy, PVNS = pigmented villonodular synovitis.

Keywords: lower limb disease, lower limb immobilization device, radiotherapy, setup error

1. Introduction

Radiation therapy has been proven effective in cancer treatment.[1] Currently, many modern techniques are available for improving the accuracy of dose delivery to the tumor and the protection of organs at risk such as intensity modulated radiation therapy (IMRT) and imaging-guided radiotherapy (IGRT).[2,3] However, in order to achieve this task, the accurate and firm positioning of the patient has to be assured first.

Nowadays, several immobilization systems have been designed for radiotherapy simulation in order to guarantee the accuracy of radiotherapy. Among these devices, several masks have been developed such as head masks for head fixation, head-neck-shoulder masks for the cervical fixation, vacuum masks or thermoplastic masks for thoracic radiotherapy, as well as vacuum masks or abdominal plate for the radiotherapy for the abdominal and pelvic cancer, respectively.[4,5] However, to our best knowledge, not much attention has been given to the development of immobilization system for the radiation therapy on the lower extremities,[6] which is mainly due to the relatively lower percentage of malignancy incidence at this anatomic site. Nevertheless, there are many patients with primary malignant tumor, osseous metastasis, pigmented villonodular synovitis (PVNS) need to receive radiotherapy on the lower extremities. Lack of effective immobilization may impair the therapeutic outcome of radiotherapy. In this study, we designed an immobilization system for the lower limbs with an aim to improve the efficiency of the radiotherapy.

Editor: Ioannis Tsalafoutas.

The authors have no conflicts of interest to disclose.

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Medicine (2018) 97:15(e0384)

Received: 19 June 2017 / Received in final form: 14 March 2018 / Accepted: 21 March 2018

http://dx.doi.org/10.1097/MD.0000000000010384

2. Materials and methods

2.1. Description of the feet-immobilizing device

The device (width: 44 cm; height: 40 cm) was made of polymethyl methacrylate plastics and adjustable bolts. It was consisted of a main board, antiretroversion frame, as well as antianteversion frame linking a heel-immobilization column on each side (Fig. 1). Each heel-immobilization column was linked with an adjustable block. A recess was formed by adjusting the position of the block, which was used for the immobilization of one or both feet. An adjustable hole was provided in the upper and lower ends of the adjustable block. A protruding bolt that was fitting into the hole was set on the main board. The adjustable block could be fixed on the main board through modulating the bolts. A handle hole was set on the top of the recess of each heel-immobilization column. Feet-immobilization block was established on the top of the handle hole. A recess for the heel-immobilization was established on the top of the feet-immobilization block, to allow the use of lateral fields and/or lateral portal or set up images.

2.2. Clinical materials

Around 38 patients (male: 20, female: 18; mean age: 48.7 ± 18.1 years) were included in this study. These patients were diagnosed with chondrosarcoma (n = 2), liposarcoma (n = 2), pleomorphic

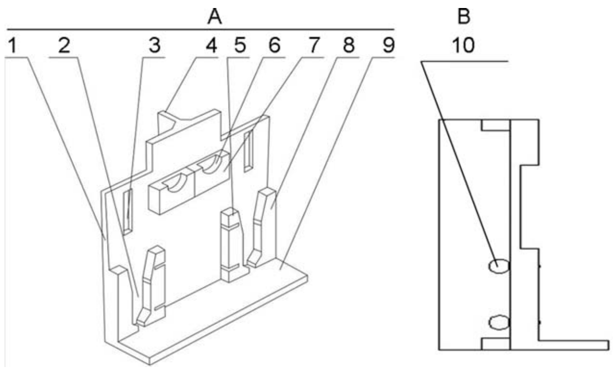

Figure 1. Schematic diagram of self-designed lower limb immobilization system for radiotherapy. (A) Overview of the system. 1: main block; 2: recess formed between the heel-immobilization column and the adjustable block; 3: handle hole; 4: antiretroversion frame; 5: adjustable block; 6: heel-immobilization recess; 7: feet-immobilization block; 8: heel-immobilization column; 9: antianteversion frame. (B). Lateral view of the system. 10: adjustable hole.

sarcoma (n=1), synovial sarcoma (n=1), giant cell cancer (n=1), neurilemmosarcoma (n=2), myeloma (n=2), osteosarcoma (n=2), osteocytes hyperplasia (n=1), rhabdomyosarcoma (n=1), fibrosarcoma (n=1), malignant fibrohistiocytoma (n=3), bone metastatic cancer (n=6), and PVNS of the knee (n=13), respectively. Among these patients, radiation therapy was performed on the thighs (n=20), knees (n=13), and legs (n=5), respectively. Each patient signed the informed consent. The study protocols were approved by The Ethical Committee of Nanjing Medical University.

2.3. Treatment regimen

Nineteen patients diagnosed with PVNS of the knee or bone metastatic cancer received conventional radiotherapy. The patients were required to lie on their back wearing thin undergarments, and a pillow was placed to support the head. Both of the hands were crossed in front of the chest. The feet were placed onto the recess of the immobilization column, followed by modulating the adjustable block to immobilize the feet. The sites at the center of the scanning field at 0°, 90°, and 270° were subject to tattooing. Two-dimensional radiotherapy was performed to those with PVNS and bone metastatic cancer. Treatment plans were made by using a radiotherapy simulator (Simulix HQ, the Netherlands). The radiation field of PVNS patients included the knees and the designated area that was about 2 cm from the incision to the head and feet direction, while that for the patients with bone metastatic cancer was 1 to 2 cm from the bone metastatic lesions. The treatments were carried out in a linear accelerator (Primus-Plus, Siemens), using photon beams of 6 MV. Both anteroposterior and posteroanterior fields were used, with relative weights of 1:1. An anteroposterior simulator film and a lateral simulator film were obtained from each patient in the presence of a 140 cm space between x-ray source and surface of image intensifier. The radiotherapy dose for the patients with PVNS of the knee was 30 to 40 Gy/15 to 20 fractions, while that for the bone metastatic cancer patients was 40 Gy/20 fractions.

Nineteen patients diagnosed with soft tissue sarcoma received IMRT. Briefly, the body position (supine position) was similar with those received conventional radiotherapy. The feet were fixed in the recess of the immobilizing column. According to the requests of the portal image direction, the uninvolved foot was fixed in the heel-immobilizing recess at the bottom or on the top position (Figs. 2 and 3), followed by CT scan. The target areas were depicted by experiences clinicians on the radiotherapy, and the treatment regimen was established by physicians. The uninvolved limbs should not be subject to irradiation. The primary target volume was defined as an area of 2 to 5 cm to the tumor, and the radiation dose was 50 Gy/25 fractions. The secondary target volume was defined as an area of 5 to 10 cm to the tumor and the dose was 64 Gy/30 to 32 fractions. Treatment plans were generated by using a three-dimensional planning system (TPS, Pinnacle 3, version 9.3). TPS was used to generate the digitally reconstructed radiograph (DRR) images at the anteroposterior and lateral views.

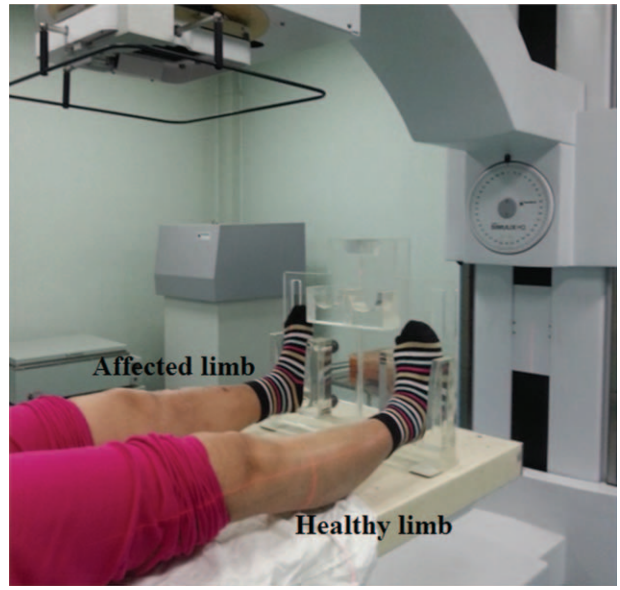

Figure 2. Application paradigm of the self-designed lower limb immobilization system.

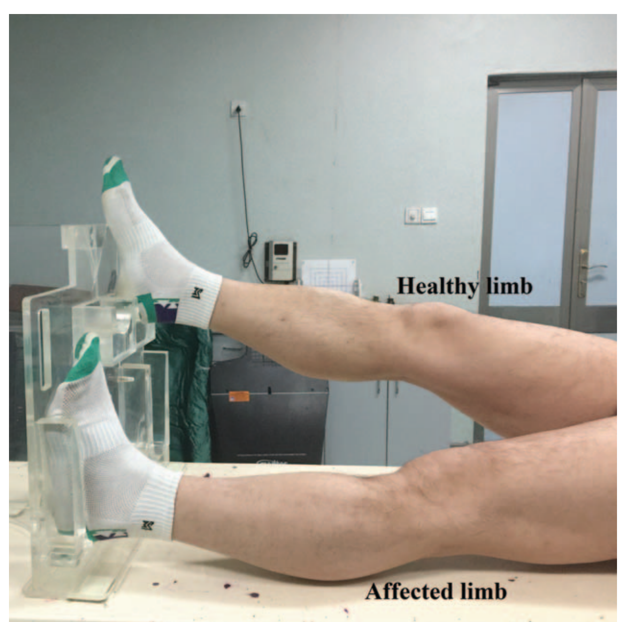

Figure 3. Application paradigm of the upper heel immobilization.

Prior to the treatment, repositioning adjustments were carried out to the patient limbs on the linear accelerator couch, in order to assure that the patient positioning was in agreement with simulator films or DRR films. Subsequently, the electronic portal imaging device (EPID) of 6 MV x-ray energy bundled with Siemens linear accelerator was used for the anteroposterior and lateral projection in the presence of a 140 cm between x-ray source and surface of EPID. Such a set of portal images was performed once per week before treatment for all patients.

2.4. Determination of setup error

The setup error refers to the difference between the actual treatment position and the reference position. For the left and right directions, a positive value was assigned for the direction at the right of the origin, while a negative value was assigned for the direction at the left side. For the head and feet directions, a positive value was assigned for the position near the feet, and a negative value was assigned for the position near the head. Finally, a positive value was assigned for the position at the front of the origin, and a negative value was assigned for the position behind the origin. Then a comparison was performed to the portal image and the simulator films or digital reconstructed radiographs (DRRs). The determination was performed by 2 independent radiotherapy oncologists, and the differences of the results were <1 mm. A value of 0 was considered as appropriate setup, while the setup error was calculated based on the determined values.

Three patients that were randomly selected to undergo immobilization using vacuum pad serving as control, including 2 with lesions at the knee joint and 1 at the leg. On this basis, we compared the setup errors in those underwent immobilization using vacuum pad and feet-immobilizing device, respectively.

2.5. Statistical analysis

SPSS 19.0 software was used for the data analysis. Student's t-test was performed for the group comparison. $P < .05$ was considered to be statistically significant.

3. Results

Nineteen patients with PVNS and osseous metastasis received conventional two-dimensional radiotherapy with a mean duration of 3.6 weeks. From these patients, 68 pairs of an anteroposterior and a lateral portal image were collected. Thus, 68 left–right, 68 anteroposterior and 136 head–foot direction setup errors were obtained, after comparison with the respective simulator films. Nineteen patients with soft tissue sarcoma received three-dimensional radiotherapy with a mean duration of 5.8 weeks. From these patients, 110 pairs of an anteroposterior and a lateral portal image were collected. Thus, 110 left–right, 110 anteroposterior and 220 head–foot direction setup errors were obtained, after comparison with the respective DRR images. In total, 178 left–right direction setup errors, 178 anteroposterior setup errors, and 356 head–foot direction setup errors were obtained and analyzed as shown in Table 1.

Table 1

Setup errors at different directions in the patients.

Direction	Film number	Mean ± SD, mm	Maximum	Minimum
Left–right	178	0.47 ± 2.62	−3	3
Head–feet	356	2.16 ± 2.25	−2	5
Anterior–posterior	178	0.18 ± 2.64	−3	4

SD = standard deviation.

Compared with the left–right direction, significant differences were noticed in the setup error of the head–foot direction (t=3.404, P=.002). Besides, significant differences were noticed in the head–foot direction when comparing with the anterior–posterior direction (t=3.188, P=.003). Whereas, no statistical differences were identified in the setup error in the left–right direction and anterior–posterior direction (t=0.497, P=.622). The shifting in the left–right direction and anterior–posterior direction was smaller, while that of the head–foot direction was larger, which was represented by obvious shifting to one side.

In this study, only 3 cases were included in the control group. The setup error for these patients was 5 mm, 7 mm, and 10 mm, respectively, which were significantly higher than those of the foot-immobilization system. Meanwhile, the setup errors were larger than those of the previous setup errors of the same case, which were all featured by external rotation of feet. Therefore, taking the ethical issues into consideration, we had to terminate the study as the setup errors in the vacuum pad group were too large.

4. Discussion

Not much attention has been paid on the development of immobilization system for the radiation therapy on the lower extremities as most of the studies have been focusing on the development of immobilization system on the head, neck, abdomen, and chest for the radiotherapy. In this study, we designed a homemade feet-immobilization system with satisfactory setup accuracy and repeatability.

Thermoplastic head mask or head-neck mask has been commonly used for the immobilization in the radiotherapy with less setup error.[7,8] Vacuum pad is commonly used for the immobilization of patients with thoracic and abdominal cancer. However, it may modify the build-up effects of the high-energy x-ray due to absorption, which then induced shifting of the maximal dose points to the skin surface or even extracutaneous region.[9] For patients receiving surgical clips inserted into the tumor bed, the setup errors were reported to be associated with the ptosis and shape of breast, muscle tone and relaxation of skin when raising the arms, trunk slide induced by gravity, changes of upper limb function of the involved side after surgery, particularly the shifting of the target area induced by respiratory movement.[10] In a previous study, application of vacuum pad for the immobilization was more suitable as it showed satisfactory reliability and repeatability.[11] Catton et al[12] showed the designed leg immobilization device contributed to the accuracy of the lateral field in the abdominal radiotherapy. Similarly, Mubata et al[13] reported restriction on the body shifting may be associated with the reduction of the setup errors.

Currently, the foot immobilization during radiotherapy is mainly depending on the vacuum pad, foam pad, and reticulate masks, as well as the T-shape sole fixation. To our best knowledge, the vacuum pad, foam pad and reticulate masks were designed according to the physiological curves of the lower limbs for the immobilization, which prevented the movement of the limbs. However, the errors generated by the intorsion and abduction of the feet were inevitable. For the T-shape sole fixation, the shoes were fixed on the T-shape frame, and the feet were fixed in the shoes during the setup. On this occasion, the movement of the feet could be controlled. However, horizontal portals were not available due to irradiation of the unaffected lower limbs during the T-shape fixation. To solve these problems, in this study, a homemade foot-fixing system was designed for the radiotherapy of the limbs. The internal backup at the bottom could contribute to the feet fixation in the recess through modulating the directions to the left or right. The hale-fixing recess on the top of the device contributed to the elevation of the healthy limbs, in order to prevent the healthy limbs from irradiation in the presence of horizontal portals.

Compared with the immobilization system used above, our devices showed the following advantages: the device showed satisfactory accuracy and repeatability; contributing to the multiple angle irradiation in the presence of elevating the unaffected limbs; the device triggered no discomfort or poor compliance during the application of the facility; it decreased the setup errors induced by body position shifting, especially the trunk shifting.[14] Our data showed the setup error in the head–foot direction was significantly larger than those of the anterior–posterior direction and the left–right direction, respectively, which was manifested as severe shifting to one side of the feet. This is mainly associated with the fact that ankle joint angle (>90°) under a relaxation condition. Meanwhile, when the feet were placed in the recess of the device, the soles were closely contacted with the main board, which may result in the space between the heel and the board. On this occasion, the patients would subconsciously step on the board, which then triggered the shifting downwards.

The patient received immobilization using vacuum pad showed larger setup errors than those received immobilization using our designed device. Patients showed feet external rotation may be related to the relaxation of the mental status when receiving the second fraction of the radiotherapy compared with the first fraction. On this basis, the feet showed extorsion involuntarily, which resulted in obvious external rotation. Vacuum pad could contribute to the heal fixation, but it may trigger the generation of errors of extorsion and/or intorsion as it is not effective for the feet immobilization. Taking the ethical issues into consideration, we had to terminate the study as the setup errors in the vacuum pad group were too large. The third case chose to receive the feet immobilization for radiotherapy since week 2, and then the obtained setup errors were smaller than that of the vacuum pad.

In conclusion, the in-house designed feet-immobilization system for the radiotherapy showed satisfactory setup accuracy and repeatability. Meanwhile, it contributed to the multiple angle portals. The device deserves further application in clinical practice.

Author contributions

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Validation: Zhiqiang Sun, Jianlin Wang, Suping Sun, Jian Wang.
Visualization: Jianlin Wang, Jian Wang.
Writing – original draft: Yuting Lu.
Writing – review & editing: Jian Wang.

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