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Prophylactic Radiotherapy to Prevent the Recurrence of Heterotopic Ossification after Surgical Intervention of the Elbow

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Purpose: Heterotopic ossification is a well-known postoperative and post-traumatic complication of the elbow. We reviewed the treatment outcome for the use of low-dose radiation after surgical intervention of the elbow to prevent recurrence of heterotopic ossification (HO).

Materials and Methods: Forty-five patients with HO underwent surgical intervention and postoperative radiotherapy of the elbow. The median age of the patients was 29 years (16~75 years), and 27 of the patients were men and 18 were women. The occurrence of HO was mainly due to surgery after fracture (24/45) and traumatic injury (21/45). Limitation of the range of motion (ROM) was the most common symptom of the patients. Thirty-four patients received postoperative radiotherapy with a dose of 8 Gy in 2 fractions; 5 patients received a dose of 10 Gy in 5 fractions and 6 patients received a dose of 7 Gy in 1 fraction. Postoperative radiotherapy was given on the first two postoperative days for most of the patients. Sixteen patients were not given anti-inflammatory medication and 29 patients were given NSAIDs for 1~8 months.

Results: After a median follow-up period of 18 months (range 6~72 months), 41 patients showed clinical improvement and two patients did not show improvement. Assessment of the ROM showed a mean improvement from 0~135° to 60~145° (p=0.028), and assessment of the functional outcome according to MEPI was from (15~95) to (80~100) (p<0.0001). Two of the 34 patients that were followed-up with radiography had mild radiological recurrence of heterotopic ossification. No complications were observed after the radiotherapy.

Conclusion: These results suggested that low-dose radiation administered after surgical intervention is safe and effective to prevent the recurrence of HO in the elbow.

Key Words: Heterotopic ossification, Elbow, Radiotherapy

Introduction

Heterotopic ossification (HO) is defined as the formation of ectopic bone in nonosseous tissues. Although the mechanism of HO formation is unknown, it is thought that inappropriate differentiation of pluripotential mesenchymal cells or fibroblasts into osteoprogenitor or osteoblastic cells is the likely pathological process that results in the formation of HO.[1] The occurrence of HO is associated with direct local injury (dislocation, fracture and surgical procedures), brain or spinal cord injury, burns and genetic disorders.[2] HO is manifested on radiographs as late as 4~12 weeks after injury. Severe HO leads to limited or total loss of range of motion (ROM) and severe pain in the affected joints.

The incidence of HO at the hip after surgery, such as due to a total hip replacement arthroplasty, ranges from 36% to 62%.[3,4] Only a small number of studies have examined HO of the elbow and other sites.

Surgical excision is the most effective treatment for manifested HO, whereas a surgical procedure itself might be a potential cause of HO. Thus, treatment of HO should include prevention as well as the resection of HO.

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Although there is controversy regarding the best effective prophylactic methods for HO, both the use of nonsteroidal anti-inflammatory drugs (NSAIDs) and local radiation are well -documented, and widespread prophylactic regimens for HO.[5,6] Since the use of postoperative radiotherapy to prevent HO was introduced in 1981, numerous studies of prophylactic radiotherapy concerning the optimal dose, timing (preoperative vs. postoperative), and appropriate fractionation has been conducted for hip joints.[7~10] However, there are only limited studies concerning radiotherapy of elbow joints. Thus, we present our experience with postoperative radiotherapy for the prevention of HO after arthroplasty of the elbow.

The purpose of this study is to investigate the recurrence rate of heterotopic ossification and complication and to assess improvement of the ROM of the elbow joint and functional outcome after postoperative radiotherapy.

Table 1. Mayo Elbow Performance Index

Function	Points	Definition	Points
Pain	45	None	45
		Mild	30
		Moderate	15
		Severe	0
Motion	20	Arc $>100^{\circ}$	20
		Arc $50\sim100^{\circ}$	15
		Arc $<50^{\circ}$	5
Stability	10	Stable	10
		Moderate instability	5
		Gross instability	0
Function	25	Comb hair	5
		Feed	5
		Hygiene	5
		Shirt	5
		Shoe	5
Total	100		

Classification	Points*
Excellent	≥90
Good	75~89
Fair	60~74
Poor	<60

*summation of pain, motion, stability and function points

Materials and Methods

1. Patients

From May 1997 and Dec. 2005, a total of 45 patients were treated with arthroplasty for the elbow followed by prophylactic radiotherapy at the Seoul National University Hospital (SNUH). The inclusion criteria was as follows: clinical or expected HO, limited elbow ROM or symptoms, age >15 yrs, and complete radiotherapy after arthroplasty.

The patient population consisted of 27 male patients and 18 female patients with a mean age of 29 years (range 16~75 years). Stiffness was the most common pretreatment symptom (41/45 patients) and the ROM was 0~135°. The Mayo elbow performance index (MEPI) was used for the functional evaluation of the elbow and the mean MEPI was 65 (Table 1). The classification of Hastings and Graham of elbow ectopic ossification was used as the classification for the functional ROM (Table 2).[11] The IIC type (44%, 20/45) was the most common classification and IIA (31%, 14/45) was the second most common. The patient characteristics are shown in Table 3.

2. Treatment

Occurrence of HO was associated with both previous surgery due to fracture (24/45) and other events including trauma, dislocation and fracture (21/45). All 45 patients underwent arthroplasty followed by radiotherapy.

Postoperative radiotherapy was given on the first two postoperative days in most of the patients (41/45). Four

Table 2. Classification of Hastings and Graham for Elbow Ectopic Ossification

Class I	Radiographically evident elbow or forearm ectopic ossification without functional limitation
Class II*	Subtotal, functional, limitation of flexion and extension, pronation and supination, or both
Class III*	Ankylosis that eliminates either elbow flexion and extension, pronation and supination, or both

*Class II and III are subdivided into three types according to the plane(s) of limited motion. A: functional limitation in the flexion and extension plane, B: functional limitation in the pronation and supination plane, C: functional limitation of both planes

Table 3. Patient Characteristics

Characteristics	Number or range
Age	16~62 yrs (median: 26 yrs)
Sex	
Male	27
Female	18
Pretreatment symptom	
Pain	7
Stiffness	41
Sensory loss	7
Functional classification	
IIA	16
IIB	3
IIC	20
IIIA	3
IIIB	2
IIIC	1
Range of motion	0~135°
Functional score*	15~95 (median: 65)

*mayo elbow performance index

Table 4. Fractionation and the Surgery-radiotherapy Interval

Characteristic	Number of patients
Radiation dose (Gy)/fraction (fx)	
8 Gy/2 fx	34
10 Gy/5 fx	5
7 Gy/1 fx	6
Interval (surgery-radiotherapy)	
0 day	6
1 day	33
2 day	2
>3 day	4

patients received radiotherapy after 72 hours of surgery. The radiation therapy was performed with anteriorposterior/posteroanterior ports of 4/6 MV X-rays. Three main different regimens of radiotherapy were used, which were been modified with time. We initially used the regimen of 10 Gy in 5 fractions until 1997, which had also been used for hip cases[12] and the use o f a dose of 8 Gy in 2 fractions has been the main protocol since 1998. In this study, 34 patients received postoperative radiotherapy with a dose of 8 Gy in 2 fractions, 5 patients received a dose of 10 Gy in 5 fractions and 6 patients received a dose of 7 Gy in 1 fraction. The regimen of

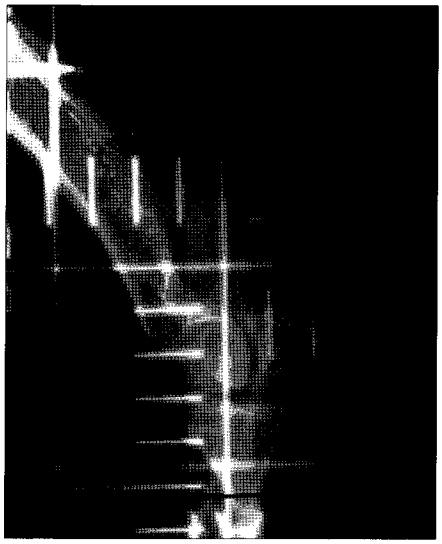

Fig. 1. Outline of a typical radiation treatment portal.

7 Gy in 1 fraction was applied for patients that received treatment on a Friday, where the radiotherapy cases might be interrupted for two days as there is no radiotherapy schedule on the weekend. The radiation treatments are summarized in Table 4. Sixteen patients were not given anti-inflammatory medication and 29 were given NSAIDs for 1~8 months.

Radiation portals were rectangular with a size from 7×8 cm to 10×16 cm (median size: 8×12 cm) to cover the operative bed and suspected risk regions. Typical radiation portals are shown in Fig. 1. For radiation therapy, the elbow was routinely positioned in the prone position, and was flexed approximately 45°.

Thirty-four patients out of 45 were examined regularly during the first year with both a physical examination and radiography after treatment. We contacted 11 patients that were lost to the follow-up clinic by telephone after treatment to gather information regarding the range of motion and the functional outcomes.

Comparisons of the ROM of motion of the elbow and functional outcome were tested using the paired t-test. The significance level was defined as $p \leq 0.05$.

Results

At time of analysis, all 45 patients were evaluable and the mean follow-up period was 18 months (range, 6~72 months). All patients had had a limited ROM preoperatively. The ROM

was improved in 44 patients (pretreatment 0~135° vs. posttreatment 60~145°, p=0.028). There was no difference in the postoperative (120°) and preoperative (120°) ROM in one patient that underwent surgery due to osteomyelitis with severe pain. This patient also experienced mild recurrence of HO three months after surgery and radiotherapy.

Table 5 shows the results of functional outcome pre- and postoperatively. Functional outcome, according to MEPI, improved in 35 patients. There was no difference in the remaining 10 patients; 7 patients were classified as excellent and 3 patients were classified as good. The mean MEPI before treatment was 65 points (range, 15~95 points), which increased to 95 points (range, 80~100 points) after treatment ($p<0.001$).

Table 5. Results of the Functional Outcome between Pretreatment and Post-treatment

Pre \ Post	E*	G†	F‡	P§
E	8			
G	9	3		
F	3	7		
P	6	9		

*excellent, †good, ‡fair, §poor

At time of analysis, 34 patients were radiographically evaluable. Fig. 2 shows one example of a patient between pretreatment and post-treatment. There were two mild recurrences of HO as seen radiographically (6%, 2/34). One treatment failure had an experience of recurrence three months after treatment, as mentioned above, and the other treatment failure occurred six months later. The patients with recurrence were all classified as IIIB in the functional classification of Hastings and Graham (Table 2).

Stiffness is the most common pretreatment symptom and symptom improvement of stiffness was observed in most of the patients. Thirty-six out of 41 patients with preoperative stiffness had no symptom of stiffness after treatment and the remaining 5 patients had mild persistent stiffness. All patients with pretreatment stiffness were satisfied with the treatment results. There were 7 patients with pain and only one out of 7 patients continued to complain of pain after treatment. However, the relative symptom of sensory loss was difficult to recover, with 57% (4/7) improvement.

We could not assess the effect of administration of oral NSAIDs on the treatment outcome. There was variability in the prescription of oral NSAIDs according to orthopedic surgeons in regards to duration and drug dosage. The treatment results were not significantly different among

Pretreatment Post-treatment

Fig. 2. Comparison of radiography between pretreatment (A) and post-treatment (B).

different regimens of radiotherapy.

No complications were observed related to the radiation therapy. There was no evidence of delayed wound healing with infection.

Discussion

Although low-dose irradiation is a well-known method and has been examined in numerous studies for prophylaxis of HO in the hip, it has been described infrequently for other sites including the elbow.[7~10,12] The role of radiotherapy for the prophylaxis of HO at the elbow remains anecdotal because of no prospective randomized trials. However, it was reported that dislocation combined with a fracture (20~33%), and surgical procedures (57%) were highly related to the occurrence of HO at the elbow and patients that had a history of HO are at a high risk of recurrence after excision of HO.[13,14] For these reasons, patients with a history of HO at the elbow have been treated with excision of the HO followed by low-dose radiation at SNUH. We reviewed 45 patients with HO at the elbow that underwent surgery and low-dose radiation to define the role of prophylactic radiotherapy.

Our study confirmed that surgery and low-dose irradiation of the elbow was a safe modality to prevent the recurrence of HO and radiological progression. There were two mild recurrence cases (6%, 2/34) of HO with no functional significance. The recurrence rate was thought to be low in consideration of the occurrence rate of HO after a surgical procedure in patients with a previous HO, and this result is comparable to results of other studies with recurrence rates of 0~27%.[15~17] We could not find any differences between the two recurrence cases and other patients without a recurrence except for functional classification. The Hastings and Graham classification system focuses primarily on functional limitation with consideration of the anatomic basis of HO distribution (Table 5).[2] The recurrence cases were all classified as IIIB. As there were only a small number of cases, our study could not analyze the relationship with treatment failure and classification.

Radiotherapy factors (total dose, fractionation and timing) and the timing of surgery in this study were similar to the factors of other studies, in which radiotherapy was given postoperatively with a total dose of 6~10 Gy.[16,17] However, those studies included a small number of patients or did not assess functional outcomes. As recurrence of HO causes a limited ROM and functional impairment, functional assessment is necessary to estimate treatment effectiveness. We conducted an analysis of functional outcome using the MEPI and ROM, and confirmed that most of the patients benefited clinically for functional outcome and for the range of motion after surgery and low-dose irradiation.

There are no definite principles of the radiation treatment scheme for the optimal dose, timing (preoperative vs. postoperative and early vs. delay) and fractionation. Since Coventry et al. reported that HO were treated successfully with 20 Gy/10 fractions postoperatively, the total radiation dose has diminished from 20 Gy to 10 Gy to 6~8 Gy, and the number of fractions similarly has diminished from 10 fractions to 5 fractions to 1 fraction, as reported in numerous studies.[18,19] Padgett et al. reported on a prospective, randomized, pilot study comparing the use of 5 Gy in 2 fractions versus 10 Gy in 5 fractions for the radiation treatment of the prevention of HO in hip arthroplasty and concluded that a dose of 5 Gy appears to be as effective as a dose of 10 Gy.[20] Recently, it was reported for an osteogenesis model system in rats that fractionated radiation has to be preferred to a dose-equivalent single-dose, especially considering that fewer side effects were noted with the fractionated radiation.[21] However, the use of a single-dose such as 6~7 Gy is widely used in consideration of the convenience and economy in a clinical situation. Accordingly, further clinical studies are needed to evaluate the superiority between the use of fractionated and single-dose in respect to efficacy and side effects.

At SNUH, the protocol of radiotherapy was changed, with 10 Gy in 5 fractions used until 1997, and a protocol of 8 Gy in 2 fractions used since 1997. All of these radiation schedules seem to have been effective and safe. Generally, preoperative radiotherapy, recently less often used, has shown the same results as compared with postoperative radiotherapy.[9] Some investigators have suggested the use of preoperative radiotherapy for reasons of minimizing patient discomfort and optimizing radiation staff resource utilization.[9,22] However, there are some shortcomings in the use of preoperative radiotherapy. Radiation must be administered within 4 hours before surgery and the radiation field cannot be determined to cover the surgical bed and seeding areas.

There is controversy about the preferred treatment between the use of local radiation therapy and the use of oral NSAIDs for prophylaxis against HO. In two randomized studies, although Burd et al. concluded that there was no significant difference in efficacy between two prophylactic regimens, Kolbl et al. showed that radiotherapy is more effective than the use of NSAIDs.[5,23] Recently, a meta-analysis of randomized trials was reported that although the absolute differences may be small, postoperative radiotherapy is on average more effective than the use of NSAIDs in preventing HO after major hip procedures.[24] As both methods are known to be equally effective, decisions regarding the treatment of the individual patients should be based on medical and economic considerations. Radiotherapy has advantages over the use of NSAIDs for the reasons of complications and patient compliance. While NSAIDs may cause gastric ulcerations or other complications such as decreased platelet function and renal toxicity, the use of radiotherapy has little acute toxicity. In addition, as radiotherapy is conducted during hospitalization, patient compliance with the treatment is good. Disadvantages of radiotherapy include the necessity of transferring the indicated patient to the treatment facility. An radiation-induced malignancy is a long-term complication of radiation therapy for other benign or malignant conditions. The average latent period between radiation treatment and development of a sarcoma has been reported to be 4 to 30 years, with average of 12.5 years.[25] However, considering that no radiation-induced malignant lesions at doses of less than 30 Gy have been seen and prophylactic radiotherapy doses are less than 10 Gy, the possibility of this late complication is thought to be very low.[26]

There are several limitations to this study. First, sixteen patients were not given anti-inflammatory medication and 29 patientswere given NSAIDs during 1~8 months. As the orthopedic surgeons prescribed the NSAIDs, respectively, the administration of an NSAID was variable in dosage, duration of treatment and type of drug. Our study could not determine the effect of NSAIDs on the results of treatment. This might suggest caution in interpretation of treatment outcomes of this study. Second, this study could not present the recurrent rate of HO without radiotherapy, as there was no data from a control group. Third, 11 patients with unavailable follow-up radiographs were excluded in the analysis of the radiographical recurrence rates.

In conclusion, these results suggested that low-dose radiation after surgical intervention is safe and effective to prevent the recurrence of HO and to improve functional outcome in the elbow. Further studies providing results from a control group should be systematically investigated to define the risk group in which prophylactic radiotherapy of the elbow is indicated.

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국문초록

주관절에서 이소성 골형성의 재발방지를 위한 예방적 방사선 치료

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목 적: 주관절의 이소성 골형성은 수술이나 외상 후에 발생하는 흔한 합병증으로 알려져 있다. 본 연구는 주관절에서 발생하는 이소성 골형성의 재발 방지를 위해 예방적 방사선 치료를 시행한 환자들을 대상으로 후향적 분석을 시행하였다.

대상 및 방법: 주관절에 이소성 골형성으로 진단된 45명의 환자가 수술 후 방사선 치료를 시행 받았다. 이소성 골형성의 주된 원인은 골절과 외상이었고 수술 전 주된 증상은 가동관절범위의 제한이었다. 방사선 치료는 대부분의 환자에서 수술 후 2일 안에 시작하였고 1일 조사선량을 4 Gy씩 2회에 걸쳐 총 8 Gy를 조사하였다. 29명의 환자에서 1~8개월 동안 NSAID를 투약 받았다.

결 과: 치료 후(60~145°) 측정한 가동관절범위에서 치료 전(0~135°)보다 통계적으로 유의한 향상을 보였고($p=0.028$), MEPI를 이용한 기능지수 평가에서도 치료 전(15~90)보다 치료 후(80~100)에서 통계적으로 유의하게 증가하였다. 추적 관찰 시 방사선 사진의 판독이 가능했던 34명의 환자 중 2명에서 경미한 이소성 골형성의 재발이 있는 것으로 나타났다. 치료 후 합병증은 관찰되지 않았다.

결 론: 주관절의 이소성 골형성의 경우 수술 후 예방적 방사선 치료를 시행하는 것은 재발 방지를 위해 유용한 치료로 선택될 수 있고, 향후 더 많은 환자를 대상으로 연구가 진행되어야 할 것으로 생각된다.

핵심용어: 이소성 골형성, 주관절, 방사선 치료