Long-term Results of Extracorporeal Shockwave Therapy and Core Decompression in Osteonecrosis of the Femoral Head with Eight- to Nine-Year Follow-up

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Background: This study analyzed the long-term outcomes of extracorporeal shockwave therapy (ESWT) and core decompression for early osteonecrosis of the femoral head (ONFH) with 8- to 9-year follow-up.

Methods: The study cohort consisted of 48 patients with 57 hips including 23 patients with 29 hips in the ESWT group and 25 patients with 28 hips in the surgical group. Patients in ESWT group received shockwave therapy to the affected hip. Patients in surgical group underwent core decompression and autogenous cancellous bone and allogenous fibular graft. The average length of follow-up was 103.5 ± 3.4 (ranged 93 - 106) months and 104.5 ± 4.3 (ranged 95 - 108) months for the ESWT and the surgical group, respectively. The evaluations included clinical assessment for pain and function, X-ray and MRI of the affected hips.

Results: The overall clinical results were 76% good or fair and 24% poor for the ESWT group; and 21% good or fair and 79% poor for the surgical group. THA was performed in 3% and 21% at one year, 10% and 32% at 2 years and 24% and 64% at 8 - 9 years for ESWT and the surgical group respectively. Significant differences in pain and Harris hip scores were observed at different time intervals favoring the ESWT group. There was a trend of decrease in the size of the lesion in the ESWT group when compared with the surgical group.

Conclusions: ESWT appears to be more effective than core decompression and bone grafting for early ONFH with 8- to 9-year long-term follow-up.

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Key words: core decompression, femoral head, osteonecrosis, shockwave

At a Glance Commentary

Scientific background of the subject

Core decompression with or without bone grafting is considered the gold standard for treatment of avascular necrosis of the femoral head of the hip joint. However, recent study reported that extracorporeal shockwave therapy is more effective than core decompression and bone grafting for avascular necrosis of the femoral head in short-term.

What this study adds to the field

This study showed that extracorporeal shockwave therapy is superior to core decompression and bone grafting with better clinical outcome in the treatment of hip with avascular necrosis of the femoral head with 8- to 9-year long-term follow-up. The advantages of shockwave include non-invasiveness, no surgery with no surgical risks and complications.

Treatment of osteonecrosis of the femoral head (ONFH) is disease stage dependent.[1-3] The natural course of the disease usually results in collapse of the femoral head and degenerative changes of the hip joint.[4,5] Conservative treatments are ineffective, and surgical intervention is usually indicated with the type of procedure varied according to the severity of the disease.[3,6,7] For early stages of ONFH, femoral head preserving procedures are recommended including core decompression, vascularized or nonvascularized bone graft, muscle pedicle graft,

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and rotational osteotomy.[8] Core decompression with or without bone grafting is considered the gold standard.[9-11] However, the outcomes are inconsistent, and many studies reported unsatisfactory results.[9,12,13]

Extracorporeal shockwave therapy (ESWT) is a noninvasive therapeutic modality in musculoskeletal disorders.[14,15] Our previous study showed that ESWT is more effective than core decompression with nonvascularized fibular grafting for early stage ONFH at 2-year follow-up.[16] The purpose of this study was extended to analyze the long-term clinical outcomes of the cohort of patients with 8- to 9-year follow-up.

METHODS

The inclusion criteria included patients with stage I or II or early stage III ONFH according to ARCO (Association Research Circulation Osseous) classification.[17] The exclusion criteria included patients with late stage III and stage IV lesions, patients taking immunosuppresing drugs, a history of current or remote infection, or skeletal immaturity. The cohort of the study population consisted of 23 patients (29 hips) in the ESWT group and 25 patients (28 hips) in the surgical group. Both groups showed similar demographic characteristics, duration and stage of the disease. Corticosteroid intake in two patients and history of alcohol abuse in 16 patients were noted in each group. Patients in the ESWT group received 6000 impulses of shockwaves at 28 KV (equivalent to 0.474 mJ/mm energy flux density) in a single session. In the surgical group, core decompression with autogenous cancellous and nonvascularized fibular allografting was performed. The technical details were described in previous report.[16] The treatments were performed between 2001 and 2002 and the average length of follow-up was 103.45 ± 3.43 months (range 93 - 106 months) and 104.54 ± 4.26 months (range 95 - 108 months) ($p = 0.073$) for the ESWT group and the surgical group, respectively.

Follow-up examinations were scheduled at 6 and 12 months, and then once a year. The evaluation parameters included clinical assessment, plain X-ray and magnetic resonance image (MRI) of the affected hip. Clinical assessments included pain score and Harris hip score[18] for activities of daily living and work capacity. Radiographs of the affected hip were used to evaluate the size of the lesion, collapse of subchondral bone with crescent sign and degenerative changes of the hip joint. MR images were utilized to examine the size of the lesion, congruency of the femoral head, the presence of a crescent sign, bone marrow edema and degenerative changes of the hip joint.[19] Two radiologists who were blinded to the nature of the treatment evaluated the findings of X-rays and MRIs.

Statistical analysis

The pre- and post-treatment data within the same group were compared statistically using the Student *t* test. The data of shockwave group and surgical group were compared using Mann-Whitney "U" test. Statistical significance was set at $p < 0.05$. The primary end-point was the need for total hip arthroplasty (THA) during the course of treatment. The secondary end-point was the improvement in hip pain and function, and the tertiary end-point was the changes on image studies.

RESULTS

Overall clinical outcomes showed good or fair in 76% (22 of 29) and 21% (6 of 28), and poor in 24% (7 of 29) and 79% (22 of 28) for the ESWT group and the surgical group respectively. Three patients had had prior total hip arthroplasty on one hip and received shockwave treatment on the other hip. Two patients rated the shockwave side better and one patient scored equally on both hips.

THA was performed because of progression of the lesion except one for sepsis of the hip secondary to pneumonia and septicemia. The numbers of THA performed at different intervals are summarized in Table 1. The numbers of

THA increased with time in both groups. At the latest follow-up at 8 - 9 years, THA was performed in 24% (7 of 29) of the ESWT group and 64% (18 of 28) of the surgical group ($p = 0.002$). Three patients with 4 hips also received a second course of shockwave treatment, and three hips eventually underwent THA and one hip had improved after treatment.

The pain scores and Harris hip scores at different time intervals are summarized in Table 2. Pain score and Harris hip score significantly improved after treatment in the ESWT group at each interval ($p < 0.001$); however, the improvements in the surgical group were not significant ($p > 0.05$). The pain scores and Harris hip scores were comparable between the two groups before treatment ($p = 0.071, 0.066$), but the differences became statistically significant after treatment ($p < 0.001$). The majority of patients in the ESWT group reported considerable relief of hip pain at night and

Table 1: Numbers of total hip arthroplasty performed at different time intervals

	Pre-op	1 year	2 years	8-9 years
ESWT group				
Surviving hips	29	28	26	22
Numbers of THA	0	1 (3%)	3 (10%)	7 (24%)
Total	29	29	29	29
Surgical group				
Surviving hips	28	22	19	10
Numbers of THA	0	6 (21%)	9 (32%)	18 (64%)
Total	28	28	28	28
p-value	1.000	0.039	0.044	0.002

Table 2: Pain scores and Harris hip scores at different time intervals

	Pre-Op.	1 year	2 years	8-9 years
Pain score (VAS)				
ESWT group	(N=29)	(N=28)	(N=26)	(N=22)
p -value-1	4.3±2.8 (2-9)	0.8±1.2 (0-5)	0.4±0.6 (0-2)	1.1±1.4 (0-4)
Surgical group	(N=28)	< 0.001	< 0.001	< 0.001
p-value-1	5.1±1.0 (4-9)	(N=22)	(N=19)	(N=10)
p-value-2	0.071	4.9±1.4 (3-7)	4.7±1.6 (3-7)	4.9±1.4 (3-7)
		0.658<0.001	0.539<0.001	0.798<0.001
Harris hip score				
ESWT group	78.7±13.5	93.5±8.5	97.5±2.9	93.8±9.5
p-value-1	(57-98)	(57-100)	(93-100)	(75-100)
Surgical group	74.6±4.7	< 0.001	< 0.001	< 0.001
p-value-1	(62-88)	75.0±5.4	76.8±5.6	75.0±6.7
p-value-2	0.066	(68-89)	(68-89)	(65-83)
		0.774<0.001	0.110<0.001	0.138<0.001

p-value-1: Comparison of data at each time interval with the preoperative data; *p*-value-2: Comparison of ESWT group and surgical group.

Table 3: The size of the lesion on X-ray and MRI

	Pre-op	1 year	2 years	8-9 years
ESWT group	(N=29)	(N= 28)	(N= 26)	(N = 22)
Size of lesion	21±41	30±20	30±20	26±18
p-value-1	(1-73)	(1-67)	(1-65)	(1-60)
		0.258	0.369	0.343
Surgical group.	(N=28)	(N=22)	(N=20)	(N=10)
Size of lesion	40±23	42±15	41±27	41±4.0
p-value-1	(11-87)	(42-52)	(45-64)	(35-43)
p-value-2	0.092	0.357	0.169	0.722<0.001
		0.003	0.040	

The size of the lesion was presented in percentage of the size of the femoral head.

p-value-1: Comparison of data at each time interval with the preoperative data; *p*-value-2: Comparison of ESWT group and surgical group.

Figure 1: Before ESWT, MR image of the hip showed a moderate sized osteonecrotic lesion of femoral head (A). The size of the lesion has reduced after ESWT (B).

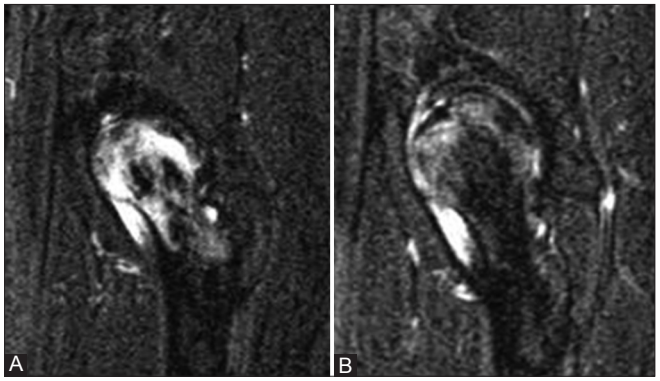

Figure 2: Extensive bone marrow edema of the hip was noted before ESWT (A). Bone marrow edema of the hip drastically reduced after ESWT (B).

better hip motion in activity of daily living and at work.

The changes in the sizes of the lesions on X-rays and MRIs after treatment are summarized in Table 3. In the patients with ONFH, the necrotic areas were estimated on a high resolution monitor (Barco view, MGD 521MK II, Kortrijk, Belgium) via the PACS system (Centricity Workstation, version 3.0, General Electric Medical Systems, Milwaukee, Wis.). The percentage of infarcted femoral head volume (IFHV) was measured by IFHV divided by total femoral head volume. The changes in the size of the lesion at different time intervals showed no significant difference as compared to the size before treatment in both groups ($p > 0.05$). When the two groups were compared each other, there was a trend of decrease in the size of the lesion [Figure 1] and reduction of bone marrow edema [Figure 2] after ESWT as compared to the surgical group ($p < 0.05$).

The classifications of the disease stages showed stage I in 3, stage II in 10 and stage III in 16 before treatment, and stage I in 4, stage II in 6 and stage III in 19 after treatment for the ESWT group. Three hips with stage II lesion before treatment became stage IIIa in 2 and stage IIIb in 1 after

treatment. In surgical group, there were 2 stage I, 17 stage II and 9 stage III before treatment, and 0 stage I, 2 stage II and 27 stage III after treatment.

Complications

In the ESWT group, there were no systemic or neurovascular complications or device-related problems. Local complications included ecchymosis and mild swelling at the treatment site in 14 hips (48%), and these problems spontaneously dissolved within a few days with ice pack and observation. For the surgical group, there was no infection, no perforation of the articular cartilage of the femoral head or graft migration. Donor site pain was noted in 16 cases (57%).

DISCUSSION

Core decompression with or without bone graft is commonly employed for early stages of ONFH. However, many studies have reported poor outcomes.[9,13,16] The current study showed that ESWT is more effective than core decompression with bone grafting for early stage ONFH at 8- to 9-year long-term follow-up. The primary end-point showed that the numbers of THA at different time intervals were significantly less in the ESWT group as compared to the surgical group ($p < 0.001$). It appears that ESWT can retard or slow down the progression and prevent the collapse of femoral head affected by early ONFH. The secondary end-point showed that significant improvements in hip pain and function were noted in the ESWT group as compared to the surgical group. The results of the current study were comparable to or better than other reported series.[20,21] ESWT appeared to be superior to core decompression and bone grafting for hips affected by early stages of ONFH in long-term follow-up.

The exact mechanism of shockwave therapy is not fully understood. Previous studies postulated that shockwaves induces hyperalgesia by increasing the painful levels of stimulation and promoted bone healing by microfracture.[22] Other studies demonstrated that shockwave therapy stimulates the ingrowth of neovascularization and upregulation of angiogenic growth factors including endothelial nitric oxide synthase (eNOS), vessel endothelial growth factor (VEGF) and proliferating cell nuclear antigen (PCNA) in tendon, bone and tendon-bone interface.[23,24] In animal experiment in rabbits, ESWT showed increases in temporal and spatial expression of BMP-2 and upregulation of VEGF in subchondral bone of the osteonecrotic femoral head.[25,26] Recent studies demonstrated that ESWT-treated hip with ONFH showed significant increases in neoangiogenesis, cell proliferation, bone remodeling and regeneration of the femoral head. It appears that application of shockwave results in regenerative effects in hips with ONFH.[27] The increased vascularity and bone remodeling do not necessarily assure bone resorption, loss of mechanical integrity and actually predispose to subchondral fracture and failure of the disease. Therefore, ESWT is best applied in hips with early stages of ONFH before the crescent sign develops. This study demonstrated that shockwave therapy relieved hip pain and improved hip function in long-term follow-up. X-rays and MRIs showed a trend of regression of the lesions. It is reasonable to believe that shockwave therapy may produce an analgesic effect, restoration of the pathophysiology and retardation of collapse of the femoral head affected by early osteonecrosis.

There are limitations noted in this study. Although this study may represent the longest follow-up of ESWT in ONFH, it is limited by virtue of small numbers of patient population that may cause bias in statistical analysis. This study only compared the outcomes between ESWT and core decompression with bone grafting for early ONFH. There is no head to head study comparing ESWT with other methods including conservative treatment, osteotomy, gene therapy and growth factors. Furthermore, this study did not stratify patients with corticosteroid or alcohol-related ONFH from patients with idiopathic ONFH. Previous study showed that ESWT was effective in corticosteroid related ONFH in patients with systemic lupus erythematosus.[28,29] Lastly, the study did not compare the functional outcomes of ESWT and hip replacement in ONFH despite prior report showing more favorable functional outcomes with ESWT.[30]

In conclusion, ESWT appears to be more effective than core decompression and bone grafting for hips affected by early stages of ONFH with 8- to 9-year long-term follow-up.

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