

# Inhibition of Adhesion and Fibrosis Improves the Outcome of Epididymectomy as a Treatment for Chronic Epididymitis: a Multicenter, Randomized Controlled, Single-Blind Study

Jae Hoon Chung, Hong Sang Moon, Hong Yong Choi, Tae Yoong Jeong, U-Syn Ha, Jun Hyun Han, Jeong Man Cho, Tae Hyo Kim and Seung Wook Lee\*

From the Department of Urology, Hanyang University College of Medicine (JHC, HSM, HYC, SWL) and the Catholic University of Korea College of Medicine (USH), Seoul, Department of Urology, Myongji Hospital, College of Medicine, Kwandong University, Goyang (TYJ), Department of Urology, Hallym University Dongtan Sacred Heart Hospital, Hwaseong (JHH), Department of Urology, Eulji University School of Medicine, Daejeon (JMC), and Department of Urology, College of Medicine, Dong-A University College of Medicine, Busan (THK), Korea

## Abbreviations and Acronyms

CMC = carboxymethylcellulose  
HA = hyaluronic acid  
PVPS = post-vasectomy pain syndrome

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\* Correspondence: Department of Urology, Hanyang University Guri Hospital, 249-1, Gyun-dong, Guri 471-701, Korea (telephone: +82-31-560-2374; FAX: +82-31-560-2372; e-mail: swleepark@hanyang.ac.kr).

See Editorial on page 1624.

**Purpose:** We measured the effectiveness of inhibition of adhesion and fibrosis on patient outcomes after epididymectomy as a treatment for chronic epididymitis.

**Materials and Methods:** An initial cohort of 152 patients was treated conservatively for chronic epididymitis. Of these patients 43 did not respond to conservative treatment and following informed consent they were enrolled in the clinical trial. The patients were randomized into 2 groups so that 22 underwent epididymectomy with concurrent administration of the inhibitors of adhesion and fibrosis hyaluronic acid and carboxymethylcellulose (group 1), and 21 underwent epididymectomy only (group 2). Visual analog pain scores and patient satisfaction scores were obtained at postoperative weeks 4, 12 and 24.

**Results:** There were no postoperative complications such as wound infection or hematoma in either group. One patient was lost to followup from group 1 and 2 were lost from group 2. At postoperative week 24, 12 patients (57.1%) from group 1 and 3 (15.8%) from group 2 were pain-free, 6 (28.6%) from group 1 and 6 (31.6%) from group 2 exhibited limited pain relief, 2 (9.5%) from group 1 and 7 (36.8%) from group 2 exhibited no pain relief, and 1 (4.8%) from group 1 and 3 (15.8%) from group 2 exhibited recurrence of pain after initial resolution at earlier followup intervals ( $p = 0.028$ ).

**Conclusions:** Inhibition of adhesion and fibrosis after epididymectomy as a treatment for chronic epididymitis improves pain relief and patient satisfaction.

**Key Words:** epididymitis, fibrosis, tissue adhesions

CHRONIC epididymitis is epididymitis that ensues for more than 6 weeks. It is characterized by inflammation accompanied by pain, with variable epididymal pain, with or without induration, and testicular pain as the main presentations.<sup>1</sup> A prospective community based study revealed that approximately 1% of male subjects were diagnosed with chronic epididymitis.<sup>2</sup> The mainstay of treatment for chronic epididymitis is the admin-

istration of antibiotics together with anti-inflammatory agents and analgesics, scrotal support and nerve block as empirical treatments.<sup>2</sup> Epididymectomy may be considered after failure to respond to conservative management. However, it has therapeutic effectiveness for pain relief in only approximately 50% of patients.<sup>3,4</sup> The cause of such limited effectiveness has not been clearly identified. However, the occurrence of chronic scrotal

pain has also been noted after vasectomy. It has been reported that this post-vasectomy pain syndrome could be caused by interstitial fibrosis and extravasation of spermatozoa, induced by obstruction of the epididymal duct, and inflammation producing perineural fibrosis and adhesion.<sup>5</sup> Similarly, continuous scrotal pain after epididymectomy for chronic epididymitis may be due to perineural and interstitial fibrosis. Previous studies investigating the role of adhesion and fibrosis in causing continuous pain after epididymectomy for chronic epididymitis have not been identified.

Recently synthetic physical barriers such as hyaluronic acid/carboxymethylcellulose have been developed to supplement the damaged natural barrier. HA/CMC is a liquid-type synthetic physical sol-gel barrier with a viscosity ranging from 2,500 to 3,500 cP.<sup>6</sup> Therefore, we evaluated the effectiveness of inhibiting adhesion and fibrosis, achieved via the application of HA/CMC to the operative site, on pain and satisfaction scores after epididymectomy for chronic epididymitis.

### Subjects and Study Design

An initial cohort of 152 patients was diagnosed with chronic epididymitis. Patients visiting outpatient clinics and complaining of unilateral epididymal pain persisting for more than 6 weeks were given a physical examination. Urinalysis was also performed and a urethral swab was taken. Scrotal ultrasonography was performed for patients with localized epididymal pain and tenderness but no urinary tract infection. Patients with a clinical and radiological diagnosis of unilateral chronic epididymitis were subsequently treated with a 4-week course of antibiotics (500 mg levofloxacin once daily) and nonsteroidal anti-inflammatory drugs (200 mg ibuprofen 3 times a day).<sup>2,7</sup> Patients showing no improvement in pain stopped taking the medication and received a spermatic cord block (10 ml 1% lidocaine without epinephrine).<sup>8</sup> The 43 patients who did not have resolution of pain symptoms despite these conservative measures were enrolled in the surgical study after fully informed consent, and satisfaction of the inclusion and exclusion criteria. Inclusion criteria were clinical symptoms of continuous epididymal pain for more than 6 weeks and diagnosis of chronic epididymitis by scrotal ultrasonography, no pain relief after 6 weeks of conservative treatment, and willingness to participate in the study. The exclusion criteria were urinary tract infection, bilateral epididymal pain, prostatitis, chronic pelvic pain syndrome, previous vasectomy, previous scrotal surgery, and the presence of concurrent diseases such as an epididymal cyst or a granuloma, both of which can cause scrotal pain.

Six hospitals participated in this prospective, randomized, single blind controlled study. Full approval was obtained from the relevant institutional review boards. Patients were randomly divided into 2 groups by simple block method into the experimental group (group 1, 22 subjects with post-epididymectomy application of HA/CMC) or the control group (group 2, 21 subjects without post-epididymectomy application of HA/CMC). The primary end point was pain score (visual analog pain scale) at postoperative week 24. The secondary end point was patient satisfaction (Likert scale) at postoperative week 24. Information regarding duration of illness and medical history were collected at enrollment (V0). Pain and satisfaction scores were recorded 4 (V1), 12 (V2) and 24 weeks (V3) after the operation.

### Surgical Technique

The surgery was performed with the patient under general or spinal anesthesia with the testis and tunica vaginalis exposed by vertical incision. A sharp dissection was conducted starting from the apex after epididymal head traction using the traction suture followed by isolated ligation of the efferent tubule. The epididymal tail was separated from the body with a stay suture, and the specimen was clamped, divided and ligated with Ellis forceps. After careful bleeding control, the testes were recovered to the scrotum. For patients in the experimental group 3 gm HA/CMC (Guardix-sol®, Hanmi Medicare, Seoul, Korea) were applied to the operative site including the spermatic cord. The dartos layer was sutured to the skin after confirmation that there was no bleeding. No patient required a drain.

### Hyaluronic Acid and Carboxymethylcellulose

HA is an anionic polysaccharide, and is an active ingredient of extracellular matrix and a high level polymer. HA exhibits hydrotropism, nonimmune properties and viscoelasticity. HA coats and lubricates the mucosa surface, inhibiting fibrosis and adhesion after the operation.<sup>9</sup> CMC is also an anionic polysaccharide and an inducer of more hydrophilically modified celluloses from the carboxymethylated glucosidic hydroxyl base. These properties have led to the wide use of CMC as an excipient, thickening agent, lubricant and stabilizer of pharmaceutical, cosmetic and food products.<sup>10</sup>

### Assessment of Efficacy and Safety

At 4, 12 and 24 weeks after the operation, pain scores were recorded using the visual analog pain scale (0—no pain, to 10—extreme pain) and patient satisfaction scores were recorded using a Likert scale (0—extremely satisfied, to 3—extremely dissatisfied). The

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