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Biomechanical Properties of Glenohumeral Joint Capsule in Diabetic and non-Diabetic Patients with Adhesive Capsulitis

당뇨병이 있는 유착성 견관절낭염 환자에서 견관절낭의 생역학적 특성

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장 원 기

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in Clinical Medical Sciences

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Wonkee Chang, M.D.

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Biomechanical Properties of Glenohumeral Joint Capsule in Diabetic and non-Diabetic Patients with Adhesive Capsulitis

By

Wonkee Chang, M.D.

A Thesis Submitted in Partial Fulfillment of the Requirements for the Degree of Master of Science in Clinical Medical Sciences at the Seoul National University College of Medicine

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Approved by thesis committee:

Professor _____ Chairman

Professor _____ Vice Chairman

Professor _____

Abstract

Introduction: Diabetes mellitus (DM) is a well-known risk factor for the development of Adhesive capsulitis (AC) of the shoulder. However, the relationships between DM and the severity of the AC has not been fully established yet.

Objectives: To investigate whether DM incurs more severe AC, the differences in capsular stiffness were compared between DM and non-DM AC patients and the associations of DM parameters with capsular stiffness among DM patients were determined.

Design: Case series.

Setting: A tertiary university hospital outpatient clinic dedicated to intra-articular hydraulic distension (IHD).

Participants: A total of 114 patients (DM 24, non-DM 90) with AC who underwent IHD.

Methods: Pressure-volume profiles were obtained using a real-time pressure monitoring technique during IHD and the capsular stiffness (K_{cap}) was defined as the slope of elastic phase from the pressure-volume curve. Demographic, clinical and

DM parameters were collected by retrospective chart review.

Main Outcome Measurements: Comparison of averages was used to investigate whether there was difference of K_{cap} between DM and non-DM patients with AC. Multiple linear regression model was established to evaluate the association between K_{cap} and DM after adjusting for other covariates. Spearman rho test and Mann-Whitney test were used to analyze the relationship between K_{cap} and DM duration, HbA1c, time integrated HbA1c and insulin usage.

Results: The mean K_{cap} had no significant difference between DM and non-DM AC patients. (33.03 ± 20.63 versus 25.99 ± 14.08, $p=0.141$). Presence of DM was associated with higher K_{cap} after adjusting covariates(β=9.37, p=0.014). Duration of DM had positive correlation with K_{cap} (r=0.436, $p=0.048$) while HbA1c, time integrated HbA1c and insulin usage had no significant relationship with the capsular stiffness in the AC patients with DM.

Conclusions: Duration of DM was positively correlated with the capsular stiffness, suggesting longer duration of DM is associated with more severe AC in the patients with DM. There was no significant difference of capsular stiffness between AC patients with and without DM, however after adjusting covariates, presence of DM

was associated with higher capsular stiffness. Further prospective researches with larger numbers of subjects are required to delineate relationships between DM and the severity of AC.

Keywords: adhesive capsulitis, diabetes mellitus, IHD, biomechanical properties, capsular stiffness, DM duration

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I. Introduction

Adhesive capsulitis (AC) of shoulder is a condition characterized by a painful, gradual loss of both active and passive glenohumeral joint range of motion (ROM)[1, 2]. It is a self-limiting condition which lasts between 1 to 3 years untreated[3], and is known to affect patients' activities of daily living and the qualities of life.

Diabetes mellitus (DM) is a well-established risk factor for the development of AC along with age, female gender, thyroid disease, congestive heart disease and dyslipidemia[4-6]. A recent meta-analysis has revealed the patients with DM were five times more likely to have AC than those without DM[7]. However, the impact of DM on the severity of AC has not been studied thoroughly and remains unclear. Several literatures have reported the shoulder pain and the quality of life were poorer among AC patients with DM than the patients without DM[8, 9], while others demonstrated no significant difference in the disability or pain between the two groups[10, 11]. It has also been widely accepted that the duration and the severity of DM are related to the prevalence of AC among DM patients[12, 13], but the underlying mechanisms how DM affects AC have not been properly elucidated yet. Researches have speculated advanced glycosylation end product (AGE) accumulation, a long-

term complication of DM, as an important factor in developing AC in DM patients[14]. In-vitro studies have revealed incubation time and glucose concentration are responsible for the formation of AGE[15] and the accumulation of the AGE in the soft tissues results in decreased elasticity[16] . From these reports, we developed a hypothesis that higher blood glucose level might exacerbate capsular fibrosis to cause higher capsular stiffness.

Intra-articular hydraulic distension (IHD) of the glenohumeral joint is a widely used non-operative treatment option for treating AC[17, 18], and its therapeutic effect has been well-proven in the literatures[19, 20]. To improve the therapeutic effect of IHD, we have developed a real-time intra-articular pressure monitoring technique[21], which has also allowed us to obtain the real-time intra-articular pressure-volume (P-V) data, from which biomechanical properties including capsular stiffness of the glenohumeral joint were quantitatively calculated[22-26]. Since IHD was adopted in our frozen shoulder clinic, approximately 500 IHD procedures have been undertaken. Before prospective researches are planned and executed, we delved into accumulated IHD data to explore the hypothesis.

In this study, we aimed to test the hypothesis that DM may affect the severity of AC by increasing capsular stiffness of the glenohumeral joint. For the purpose, we

compared capsular stiffness of AC patients with and without DM. In addition, the relationship of capsular stiffness with exposure to higher blood glucose level determined by duration of DM, blood levels of HbA1c, time integrated HbA1c levels, and insulin usage status.

II. Methods

Study Participants

A total of 194 patients' medical data and P-V profiles who underwent IHD procedure at the outpatient clinic for adhesive capsulitis from October 2009 to January 2011 were retrospectively reviewed. From the patients who underwent multiple IHD procedures, only the P-V profiles from the first IHD were included in the study. AC was diagnosed when the passive shoulder ROM of the affected shoulder was limited in the external rotation (ER) with 1 or more directions[27]. Limitation of shoulder ROM was defined as passive shoulder ROMs measured by goniometer as following; abduction < 80°, flexion < 130°, internal rotation level L1 and below and external rotation < 30 ° or scratch test level C7 and above[22, 25].

Patients were excluded when they had previous history of trauma or major surgery (n=33), breast cancer (n=12) or full-thickness tear (n=2) on the affected shoulder. Patients who did not reach phase 2 during the IHD procedure (n=9) and patients with irregular P-V profiles which were not analyzable (n=24) were also excluded from the study. In final, 114 patients were included in the study analyzation and of them, 24 patients had DM. Initial analysis was done with 114 patients and there was

significant difference of age between DM and non-DM group. To minimize the effect of age and gender on the capsular stiffness, we selected non-DM group using propensity-score matching technique. A logistic regression model was created to derive a propensity score with age and gender as independent variables. A DM group patient was matched with 2 non-DM patient (1:2 matching). In final, 72 (DM n=24, non-DM n=48) patients' data were analyzed. Among DM patients, HbA1c within 3 months of IHD procedure, DM duration, time integrated HbA1c which was defined as the value of HbA1c integrated by time period throughout the entire medical record and finally, type of medication (Insulin usage status) were obtained from the medical record review. The study was approved by the institutional review board of Seoul National University Hospital.

Clinical Evaluation

All patients went through passive ROM measurement and sonographic evaluation prior to the IHD procedure by the senior author (S.G.C). Passive ROMs were measured with goniometer while the patient was sitting upright on a stool. Abduction, flexion and external rotation ROMs were measured with the goniometer and the sum of the ROMs (ROM_sum) was defined as the summation of the

degrees of ROMs in 3 directions. Scratch tests were used to evaluate the external and internal rotation ROMs which were measured as the lowest and the highest anatomy reached with the thumb and the middle finger, respectively.

The sonographic evaluation on the affected shoulder was performed after ROM measurement. Specific findings including long biceps tendon sheath swelling, rotator cuff tear, calcification, subacromial and subdeltoid bursa swelling were assessed to exclude other pathologic diseases of the shoulder.

IHD procedure

IHD procedures were performed by the senior author (S.G.C.) at the outpatient clinic in the following setting. The subject was sitting on a stool with the arm resting on the thigh to have fully relaxed during the procedure. A 22-gauge spinal needle was connected to a pressure sensor and a 50-mL syringe via a 3-way stopcock. The needle was inserted 1 cm lateral to the ultrasound transducer, penetrating the infraspinatus tendon and the posterior capsule. After placing the needle tip in the joint space, a fluid mixture (total 50 mL) of 1mL of 40mg triamcinolone; 10 mL of 1% lidocaine and 39 mL of normal saline was infused with a constant-speed pump at the rate of 7 mL / min. The infusion was terminated in

the following conditions: when the P-V curve reached the third phase; when the intra-articular pressure increased abruptly indicating impending rupture; when the patient asked for the termination of the procedure.

P-V data analysis

The P-V profiles were analyzed and reviewed in the following process by the 2 authors (W.K.C and S.G.C.). The P-V curve were derived from the Pressure-Time(P-T) curve obtained during the IHD. Then the P-V curve was divided into 3 phases: phase I the initial filling phase; phase II the elastic deformation phase; phase III the plastic deformation phase. The slope of the phase II was considered as the stiffness of the joint capsule (K_{cap}). The volume and pressure at the infusion termination point were defined as the maximal volume (V_{max}) and the maximal pressure (P_{max}), respectively. Figure 1 demonstrates a typical P-V curve with definitions of biomechanical properties (K_{cap}, V_{max} and P_{max}). A detailed processing methods of P-V profile analysis are described in the previous studies[23-26].

Statistical Analysis

We compared demographic variables (age, gender, symptom duration and dominant hand), clinical parameters (ROM of abduction, flexion, external rotation

and the sum of three ROMs) and biomechanical properties (K_{cap}, V_{max} and P_{max}) between the DM group and non-DM group using independent *t*-test for the numeric variables and chi-square test for categorical variables. A multiple linear regression model was used to evaluate the association between K_{cap} and DM after adjusting for other covariates. The correlation between K_{cap} and DM parameters (HbA1c, DM duration, time integrated HbA1c and insulin usage status) were analyzed with Spearman rho test and Mann-Whitney test because the sample size was not large enough to guarantee normal distribution. *p*-values of <0.05 were considered statistically significant. All analyses were performed using open-source R software.

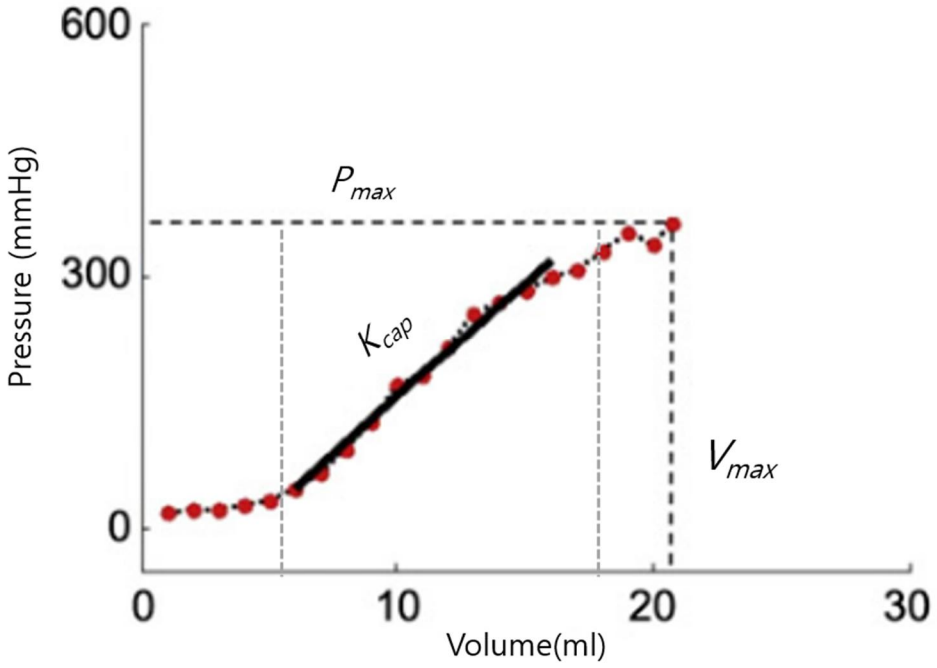

Figure 1. An example of P-V waveform acquired during IHD. The slope (black solid line) of the elastic deformation phase (between the gray dotted lines) was defined as K_{cap}, while the volume and pressure at the infusion termination point were defined as V_{max} and P_{max} respectively.

III. Results

Comparison of Demographic, Clinical and Biomechanical properties between the DM and non-DM group

There was significant difference of age between DM and non-DM group on analysis with 114 patients. (63.46 vs 57.16, $p=0.005$). Otherwise, there were no significant difference in the demographic, clinical and biomechanical variables ($P_{max,}$ V_{max} and K_{cap}) (Table 1).

There were no significant differences in the demographic and clinical characteristics between the AC patients with and without DM after propensity score matching was done (Table 2). All the biomechanical variables were also not significantly different between the two patient groups (434.15 vs 436.10 $p=0.947$, 22.57 vs 21.04 $p=0.478$ and 33.03 vs 25.99 $p=0.141$ respectively).

Factors associated with Capsular Stiffness

Table 3 shows the multiple linear regression model between K_{cap} and age, gender(female), symptom duration and presence of DM. Presence of DM as well as younger age and female gender were associated higher K_{cap} (adjusted r^2=0.112).

Table 1 Demographic, clinical and biomechanical properties of the patients (N = 114)

	DM (N = 24)	Non-DM (N = 90)	*P*
Demographic / Clinical properties			
Sex ratio, M:F	11:13	28:62	0.268
Age (yr)	63.46(9.49)	57.16(9.62)	**0.005***
Involved side, R:L	9:15	51:39	0.778
Symptom duration (mo)	11.83(9.33)	7.85(6.74)	0.060
Abduction ROM (')	61.17(16.68)	53.73(13.79)	0.211
Forward flexion ROM (')	98.13(13.69)	100.10(19.80)	0.574
External rotation ROM (')	32.21(13.55)	34.21(11.37)	0.463
Sum of 3 ROMs (')	191.50(33.51)	188.04(31.64)	0.640
Biomechanical properties			
P_{max} (mmHg)	434.15(125.93)	439.08(105.77)	0.862
V_{max} (ml)	22.57(10.40)	20.03(7.66)	0.273
K_{cap} (mmHg/ml)	33.03(20.63)	27.65(14.87)	0.241

*P<0.05, ROM = range of motion; P_{max} = pressure at the maximal volume; V_{max} = maximum volume, K_{cap} = capsular stiffness.

Table 2 Demographic, clinical and biomechanical properties of the patients after age, gender matching (N = 72)

	DM (N = 24)	Non-DM (N = 48)	*P*
Demographic / Clinical properties			
Sex ratio, M:F	11:13	19:29	.800
Age (yr)	63.46(9.49)	62.42(8.49)	.639
Involved side, R:L	9:15	22:26	.674
Symptom duration (mo)	11.83(9.33)	8.42(7.32)	.093
Abduction ROM (')	61.17(16.68)	54.94(12.22)	.076
Forward flexion ROM (')	98.13(13.69)	100.54(19.67)	.592
External rotation ROM (')	32.21(13.55)	33.56(9.80)	.629
Sum of 3 ROMs (')	191.50(33.51)	189.04(29.27)	.750
Biomechanical properties			
P_{max} (mmHg)	434.15(125.93)	436.10(112.56)	.947
V_{max} (ml)	22.57(10.40)	21.04(7.52)	.478
K_{cap} (mmHg/ml)	33.03(20.63)	25.99(14.08)	.141

*P<0.05, ROM = range of motion; P_{max} = pressure at the maximal volume; V_{max} = maximum volume, K_{cap} = capsular stiffness.

Table 3 Factors associated with K_{cap} in the patients with adhesive capsulitis.

	β±SE
Age	-0.43±0.15†
Gender (Female)	8.55±3.10†
Symptom duration	-0.01±0.20
Presence of DM	9.37±3.76*

*P<0.05, †P<0.01 by multiple linear regression analysis after adjusting for other covariates.

Correlation between the Capsular Stiffness and DM parameters

DM duration had positive correlation with K_{cap} (r = 0.436, *p=0.048*) while HbA1c and time integrated HbA1c showed no significant correlation with K_{cap} (*p=0.989*, *p=0.238* respectively). There was no significant difference of K_{cap} between the insulin usage group and oral hypoglycemic agent(OHA) only group (38.60 vs 21.45, *p=0.216*). (Figure 2A-2D)

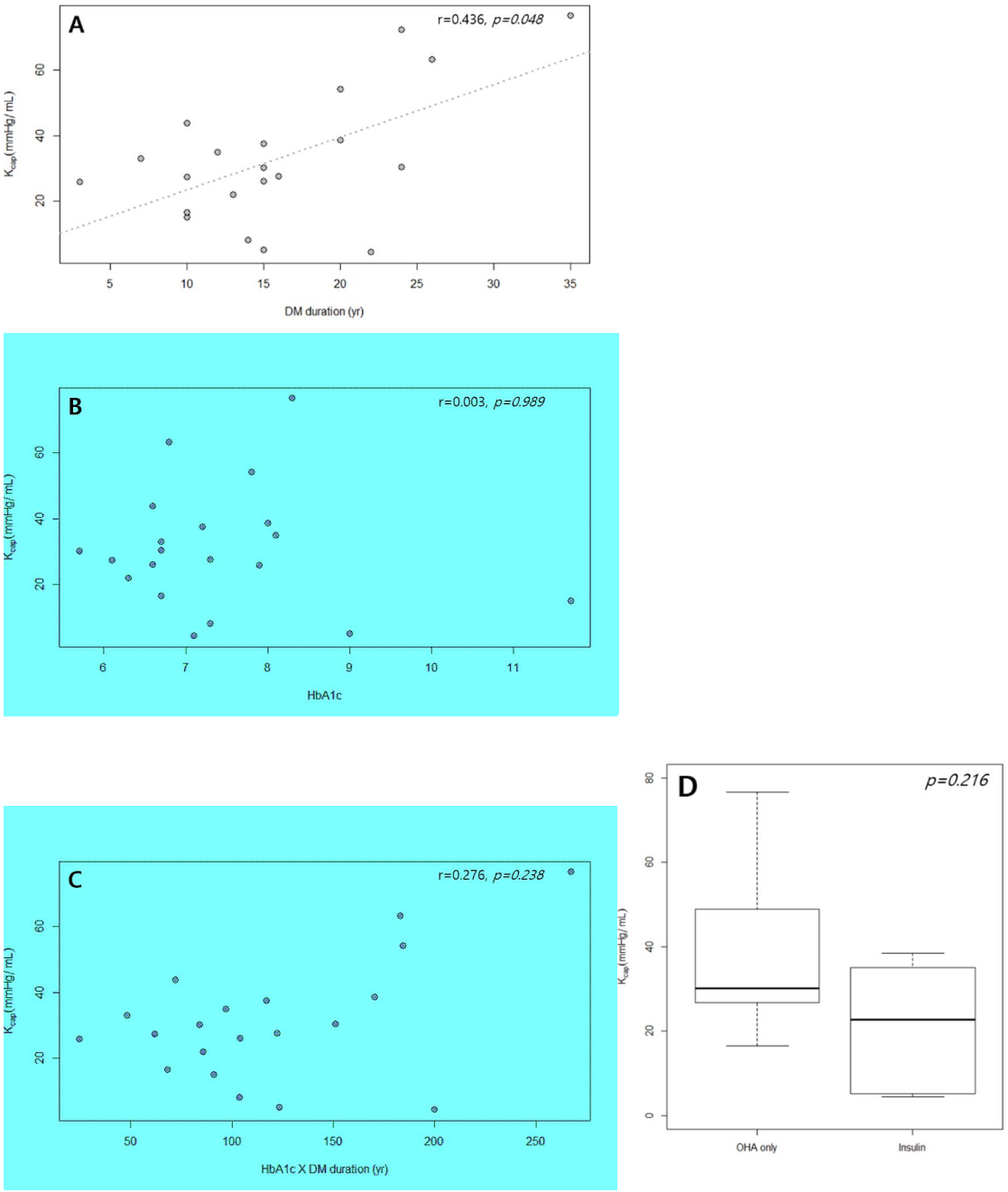

Figure 2. Scatterplots showing relationship between capsular stiffness (K_{cap}) and DM duration (A), HbA1c (B) time integrated HbA1c (C) and the Boxplot of capsular stiffness according to Insulin usage status (D).

IV. Discussion

This study aimed to unveil the relationship between DM and the severity of AC by comparing the capsular stiffness of patients with and without DM, and examining the DM parameters that were related to the capsular stiffness. K_{cap}, which is considered as a biomechanical and quantitative indicator of the severity of AC, was calculated from the P-V curve obtained during IHD. We have hypothesized that the glenohumeral joint capsule would be stiffer in the patients with DM and both duration of DM and glycemic status would be correlated to the capsular stiffness. There was no significant difference of K_{cap} between the AC patients with and without DM, although linear multiple regression analysis has revealed presence of DM is associated with higher K_{cap} after adjusting covariates. Among DM parameters, only duration of DM had positive correlation with K_{cap}.

Duration of DM had positive correlation with K_{cap} while HbA1c and insulin usage status were not related to the K_{cap}. Considering AC is a condition with insidious onset and gradual progression[2, 3], HbA1c and insulin status which represents the glycemic status at the time of examination, might not fully appreciate the long-term glycemic burden related to the severity of AC in the patient with DM. These findings are concurrent with the previous studies on the relationship between DM

parameters and prevalence of AC[12, 13, 28], which implies DM duration is an important factor in both development and aggravation of AC in the patients with DM.

Incubation time and glucose concentration are two key factors in the accumulation of AGE in the soft tissues[15]. Time integrated HbA1c, which incorporates both factors, seemed to be a good proxy for reflecting the degree of AGE accumulation in the glenohumeral joint capsule. Time integrated HbA1c showed good correlation with prevalence of adhesive capsulitis in the type 1 DM patients with over 45 years of follow-up[29], thus we supposed it would also present a good correlation with the K_{cap}, which did not in result. Since our study was performed at tertiary hospital OPD clinic for AC, we were not able to trace the glycemic status for the whole period of DM duration in the most of our patients, resulting in less accurate approximations of glycemic burden. A more controlled study including patients' medical data on whole duration of DM might give us more information on the relationship between DM and capsular stiffness.

Although DM duration was associated with capsular stiffness, there was no difference of K_{cap} between DM and non-DM patient with AC which might seem to be somewhat conflicting. We believe the patient pool selection of our study is largely responsible for this result. K_{cap} was calculated with P-V profiles obtained

during IHD procedures which were performed to the AC patients with moderate to severe degree of pain on limitation of ROMs. For mild AC patients, physiotherapy including shoulder stretching on the directions of LOM and NSAIDs were treatment of choice in our clinic, thus K_{cap} of these mild AC patients were unobtainable. The influence of confounding factors such as age and gender on K_{cap} might also account for this result. As reported in the previous study[25], female gender was associated with higher K_{cap} and after adjusting covariates (age, female gender, duration of symptom), presence of DM was associated with higher K_{cap}. From these results, we can speculate AC patients with DM would have stiffer glenohumeral joint capsule than those without DM.

The real-time pressure monitoring and P-V analysis technique we implemented in this study has an advantage to be acknowledged. It allowed us to measure the tightness by the degree of stretching of the soft tissues in the glenohumeral joint capsule during IHD. The tightness of the soft tissues including coracohumeral ligament and rotator interval are considered as the key features of AC[30, 31], thus this technique has advantage of appreciating the severity of the AC in a biomechanical and physiological manner. Since previous studies on the relationship between DM and the severity of AC adopted pain scale[9] or questionnaires(The Shoulder Pain and

Disability Index; SPADI)[8, 10, 11] as main outcomes to evaluate the severity of AC. Our study's strength lies in the evaluation method of the severity of AC and to our knowledge, this is the first study on the impact of DM on the severity of AC using a biomechanical, quantitative outcome measure.

On analyzing the pressure-volume profiles acquired during IHD, we found a few notable waveforms which were observed among patients with very high K_{cap} (Figure 3A,3B). Patients with these "Serrated" P-T curves had very high K_{cap} (mean: 66.727), which could implicate a certain subgroup of patients might have stiffer capsule than the others. Although this study has failed to identify the characteristics of such subgroup with high K_{cap}, further research is required to uncover such subgroups of AC patients with high K_{cap}.

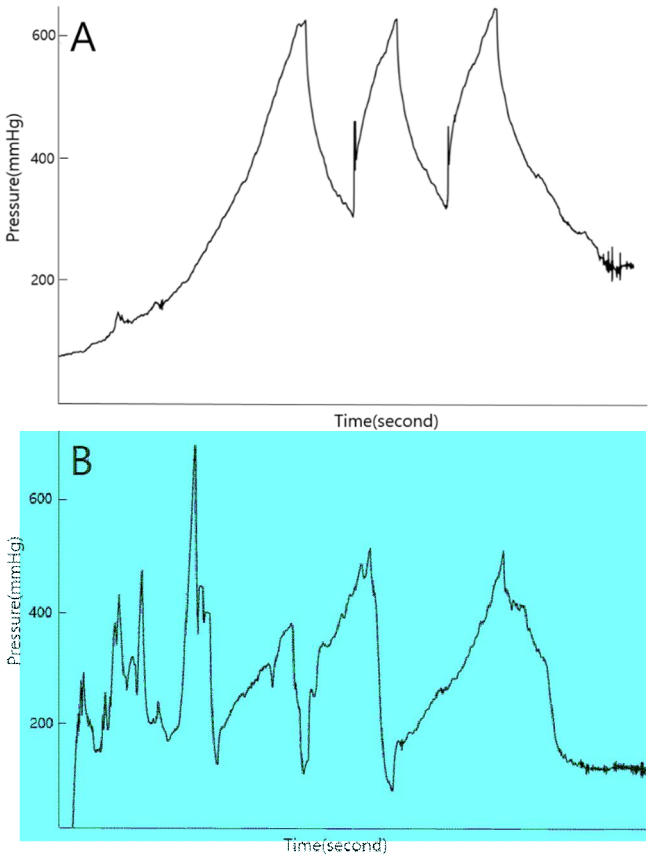

Figure 3. Examples of "Serrated" Pressure-Time curve shown in the patients with high K_{cap}

Limitations

There are several limitations to be mentioned in this study. First, there was a fair difference of baseline age between DM and non-DM patients (63.46 vs 57.16, p=0.005) and similar age differences were shown in the previous studies carried out in the tertiary hospital settings[10][32]. To minimize the effect of the age and gender, which are well-known factors affecting the capsular stiffness[25], this study adopted propensity-score matching technique.

Secondly, since the medical history was obtained retrospectively, several known risk factors of AC such as hyperlipidemia[33], familial history of AC and Dupuytren's disease[6] were not assessed.

Finally, due to the small number of DM patients, the statistical analysis between DM parameters and K_{cap} were nonparametric, which resulted in reduced statistical power. Further prospective research on larger sample size will provide a clearer relationship between DM parameters and capsular stiffness.

V. Conclusion

In this study, duration of DM was positively correlated with the K_{cap}, suggesting longer duration of DM was associated with more severe AC in the patients with DM. There was no significant difference of K_{cap} between AC patients with and without DM, although presence of DM was associated with higher K_{cap} after adjustment of confounding factors. Further prospective research with larger subjects is require to conclude the relationship between DM and the severity of AC.

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국문 초록

당뇨병이 있는 유착성 견관절낭염 환자에서 견관절낭의 생역학적 특성

서론: 유착성 견관절낭염(adhesive capsulitis)은 통증을 동반하며 서서히 진행하는 견관절의 가동범위의 감소를 특징으로 하는 질환으로 흔히 '오십견'이라 불린다. 이전 연구들을 통해 당뇨병이 유착성 견관절낭염의 위험인자임이 잘 알려졌으나 당뇨병이 유착성 견관절낭염의 심각도에 미치는 영향에 대해서는 보고된 바 많지 않다. 이에 본 연구에서는 당뇨병이 있는 유착성 견관절낭염 환자와 그렇지 않은 환자의 관절낭의 강직도(stiffness)의 차이가 있는지를 비교하고 당뇨병이 있는 유착성 견관절낭염 환자에서 관절낭의 강직도에 영향을 미치는 당뇨병 관련 지표가 무엇이 있는지를 알아보았다.

방법: 유착성 견관절낭염 환자 총 114명 (당뇨 환자 24명, 비당뇨 환자 90명)에 대하여 수압팽창술을 시행하는 도중 압력 센서를 이용하여 실시간으로 관절낭 내부의 압력-용량 데이터를 얻었고 이를 분석하여 관절낭의 최대 부피, 최대 부피에서의 압력, 관절낭의 강직도를 확인하였다. 후향적 리뷰를 통해 환자들의 역학적, 임상적 변수들을 확인하였다.

결과: 당뇨병이 있는 유착성 견관절낭염 환자와 당뇨병이 없는 환자의 관절낭의 강직도는 유의미한 차이가 없었다(33.03 ± 20.63 대 25.99 ± 14.08, p=0.141). 그러나 다중선형회귀모형을 통하여 공변인들을 보정하자 당뇨병은 견관절낭의 강직도와 연관성을 보였다. (β=9.37, p=0.014)당뇨병이 있는 환자에서 당뇨병 유병 기간, 혈당화색소(HbA1c), 시간으로 적분한 혈당화색소, 인슐린 사용 여부와 관절낭의 강직도와의 관계에서는 당뇨병 유병 기간만이 의미 있는 상관관계를 나타내었다(r=0.436, p=0.048).

결론: 당뇨병의 유병기간과 관절낭의 강직도는 양의 상관관계를 지니며 이는 당뇨병의 유병기간이 길수록 유착성 견관절낭염의 심각도가 커짐을 시사한다. 당뇨병이 있는 유착성 견관절낭염 환자와 그렇지 않은 환자간의 관절낭의 강직도의 유의미한 차이는 없었으나 공변인들을 보정한 후 당뇨병은 견관절의 강직도와 연관성을 보였다. 당뇨병과 유착성 견관절낭염의 심각도간의 관계에 대한 결론을 내기 위해서는 향후 더 많은 환자를 대상으로 전향적인 연구가 필요하다.

주요어: 유착성 견관절낭염, 당뇨병, 수압팽창술, 관절낭의 강직도, 당뇨병 유병기간

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