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Case series

# Prognostic factors of shoulder manipulation under ultrasound-guided cervical nerve root block for frozen shoulder for patient with diabetes mellitus: A retrospective cohort study

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ARTICLE INFO	A B S T R A C T	
Keywords: Case series Prognostic factor Shoulder manipulation Ultrasound guided cervical nerve block Frozen shoulder	Introduction: Shoulder manipulation under ultrasound-guided cervical nerve root block (MUC) gives good clinical results in patients with frozen shoulder 1 week after the procedure. However, some patients are refractory to MUC. The present study was performed to investigate the prognostic factors of MUC for frozen shoulder. <i>Methods</i> : We evaluated 73 frozen shoulders (70 patients) to investigate the prognostic factors of MUC. The patients' mean age was 56.6 years, and 60% were female. The mean duration of symptoms before MUC was 8.6 months. We assessed pain using a numeric rating scale (NRS), range of motion (ROM), and the American Shoulder and Elbow Surgeons (ASES) score before and 1 year after MUC. We compared patients with an ASES score of <80 (defined as a poor clinical result) with those with an ASES score of $\geq$ 80 (good clinical result). To identify the risk factors for a poor clinical result, multiple logistic regression analysis was performed using the following variables: age, sex, duration of symptoms before MUC, diabetes mellitus (DM), initial NRS score, and initial ROM. <i>Results:</i> The initial NRS score and the prevalence of DM were significantly greater in the poor clinical results group. Multiple logistic regression analysis revealed that DM was the only independent risk factor for a poor clinical result after MUC (odds ratio, 51; 95% confidence interval, 10.9–237; <i>p</i> = .01). <i>Conclusions:</i> DM is a negative prognostic factor of MUC for frozen shoulder, and patients with DM should be informed of this before they undergo treatment for frozen shoulder.	

### 1. Introduction

Although frozen shoulder is one of the most common shoulder conditions, the management of frozen shoulder remains controversial. A current review of frozen shoulder reported that studies evaluating frozen shoulder treatment described outcomes at time points of more than 1 year after treatment [1], which is clinically too long for patients to wait for relief of symptoms; the goal of therapy is to reduce pain and thus enable the patient to sleep shortly after treatment. To shorten the treatment period, shoulder manipulation under ultrasound-guided cervical nerve root block (MUC) is performed in an outpatient setting without general anesthesia and hospitalization [2]. There was a significant improvement in shoulder pain and ROM at 1 week after MUC, and this improvement persisted at the 1-year follow-up.

Although MUC reportedly leads to good clinical results, some

patients are refractory to MUC. Among patients with frozen shoulder treated by shoulder manipulation under general anesthesia (MUG), those with DM had a higher incidence of treatment failure [4–6]. Furthermore, among patients with frozen shoulder treated by arthroscopic capsular release (ACR), those with DM also had inferior clinical outcomes [7,8]. However, comparative studies of the effects of DM on the outcomes of MUC are extremely rare. Furthermore, no studies have been performed to investigate the prognostic factors of MUC. The purpose of the present study was to investigate the prognostic factors of MUC for frozen shoulder.

## 2. Materials and methods

We retrospectively reviewed a consecutive series of 106 shoulders in 103 patients who underwent MUC for frozen shoulder at our institution

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from September 2013 to March 2017. This study received ethical approval (A14-02), and written informed consent was obtained from all patients. The inclusion criteria were pain and limitation of active and passive shoulder ROM in at least three directions [9] [forward elevation (FE) < 100°, external rotation at the side (ER) < 10°, and internal rotation (IR) < L5]; no response to nonoperative management, including physical therapy for at least 3 months, medication, and intra-articular corticosteroid injections; and follow-up for at least 1 year. The exclusion criteria were evidence of rotator cuff tear, osteoarthritis, or calcifying tendinitis, and a history of shoulder fracture.

Of the 106 shoulders in 103 patients who underwent MUC, 73 shoulders in 70 patients were followed up for at least 1 year. The mean patient age was 56.6 years (range, 37–73 years), and 60% were female. The mean interval from the occurrence of initial shoulder symptoms to MUC was 8.6 months (range, 3–36 months).

The MUC procedure was performed in an outpatient setting under a cervical nerve root (C5–6) block with ultrasound guidance. The detailed surgical procedure of the MUC and postoperative treatment has been described previously [2].

Assessed items included pain during motion (motion pain) evaluated with the numeric rating scale (NRS), active ROM (FE, ER, and IR) evaluated with a goniometer, and shoulder function evaluated using the ASES shoulder scoring system [3] before MUC and at 1 year after MUC. We defined a poor clinical result as an ASES score of <80 and used this criterion to divide the patients into two groups: those with a poor clinical result and those with good clinical result. Multiple logistic regression analysis was performed to identify the risk factors for a poor clinical result of MUC using the following variables: age, sex, prevalence of DM, initial NRS score, initial ROM (FE, ER, and IR), and duration of symptoms before MUC. DM was diagnosed by each patient's current primary care physician based on the patient's medical record. Hemoglobin A1c and glucose levels were not used because all of the patients with a diagnosis of DM were currently being treated with medications and were thus likely to have had artificially low levels.

All statistical analyses were performed using SPSS for Windows, version 20.0 (IBM Corp., Armonk, NY, USA). We used the Wilcoxon signed-rank test to assess the differences in the NRS score, ROM, and ASES score between pre- and post-MUC. After the patients were divided into the two groups (good or poor clinical result), the Mann-Whitney test was used to compare the two groups regarding age, duration of symptoms before MUC, initial NRS, and initial ROM (FE, ER, and IR), while Pearson's chi-squared test was used to compare sex and the prevalence of DM. For the multivariate analysis, a multiple logistic regression analysis was performed. All data were entered into the multivariate analysis. A p value of <0.05 was regarded as significant. An a priori sample size calculation for the primary outcome was performed. The minimum sample size for an  $\alpha$  error of  $\leq 0.05$ ,  $\beta$  error of  $\leq 0.20$ , and effect size of 0.5 was calculated using G\*Power 3.1 (Franz Paul, Kiel, Germany). The minimum required number of patients was 48. There were 49 patients in the good clinical results group and 24 patients in the poor clinical results group. The power analysis calculated an  $\alpha$  error of 0.05 and  $\beta$  error of 0.05 (i.e., power of 0.95). Reporting on the clinical parameters of the case was done in line with the SCARE 2018 criteria [10].

#### 3. Results

Motion pain (mean NRS score) improved significantly from  $6.0 \pm 2.5$  preoperatively to  $1.9 \pm 2.3$  at 1 year after MUC (p < .01). The mean preoperative FE, ER, and IR were  $84.9^{\circ} \pm 15.0^{\circ}$ ,  $3.4^{\circ} \pm 10.8^{\circ}$ , and to the sacrum, respectively; these variables had improved significantly at 1 year after MUC to  $142.2^{\circ} \pm 21.5^{\circ}$ ,  $45.8^{\circ} \pm 20.8^{\circ}$ , and Th11, respectively. The mean ASES score significantly improved from  $35.0 \pm 17.1$  before MUC to  $82.7 \pm 20.8$  at 1 year after MUC (p < .01).

Patients with a poor result had a significantly higher initial NRS score and prevalence of DM (Table 1). Multiple logistic regression analysis showed that DM was the only independent risk factor for a poor

Table	1
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Patients	characteristics.

	Good results $(n = 49)$	Poor results $(n = 24)$	P value
Age, years	$\textbf{55.0} \pm \textbf{9.3}$	$59.7 \pm 10.1$	.07
Sex, male:female	17:32	11:13	.36
Duration of symptoms, months	$\textbf{8.2} \pm \textbf{5.0}$	$9.3\pm7.5$	.79
Diabetes mellitus	3	18	.01
NRS <sup>a</sup> , degrees	$5.5\pm2.6$	$\textbf{7.2} \pm \textbf{2.0}$	.01
FE <sup>a</sup>	$85.6 \pm 14.1$	$83.5 \pm 17.2$	.97
ER <sup>a</sup>	$\textbf{2.2} \pm \textbf{7.5}$	$5.9\pm1~5.9$	.81
IR <sup>a</sup>	Sacrum	Sacrum	.15

Good results: patients with an American Shoulder and Elbow Surgeons score of >80 after shoulder manipulation under ultrasound-guided cervical nerve root block for frozen shoulder; poor results: patients with an American Shoulder and Elbow Surgeons score of <80 after shoulder manipulation under ultrasound-guided cervical nerve root block for frozen shoulder; DM: diabetes mellitus; NRS: numeric rating scale for pain during motion; FE: forward elevation; ER: external rotation; IR: internal rotation.

<sup>a</sup> All data are the initial (pretreatment) data.

clinical outcome after MUC (odds ratio, 51.0; 95% confidence interval, 10.9–237; p = .01) (Table 2).

#### 4. Discussion

The present study showed that the mean NRS score for shoulder motion pain, active ROM, and ASES score were significantly improved 1 year after MUC, and that the negative prognostic factor of MUC was DM.

DM was a negative prognostic factor in patients undergoing MUC for frozen shoulder. Similarly, DM has been associated with poorer outcomes of MUG and ACR for frozen shoulder in previous studies. A study in which MUG was performed in 730 patients with frozen shoulder revealed that additional MUG was required in 17.8% of patients, and that patients with type 1 DM had a 38% increased risk of requiring additional MUG [6]. Another study of patients with frozen shoulder showed that repeat MUG was required in 36% of patients with DM versus 15% of patients without DM [5]. One recent study of patients who underwent ACR for frozen shoulder showed poorer postoperative improvement of shoulder ROM, FE, and IR in patients with than without DM [8]. Furthermore, Kanbe investigated 255 patients with frozen shoulder treated with ACR and reported inferior clinical outcomes in patients with than without DM [7]. Although poorer outcomes of MUG and ACR in patients with than without DM have already been reported, few studies have investigated the outcomes of MUC. Only one previous study revealed an inferior outcome of MUC for frozen shoulder in patients with versus without DM [11]. The study compared the clinical results of MUC between patients with and without DM; however, the authors did not report the prognostic factors of MUC. Our study is the first to report the prognostic factors of MUC for frozen shoulder, which is a major strength of this study.

Inferior clinical outcomes in patients with DM have also been reported in other types of orthopedic surgery. Sun et al. reported that patients with post-traumatic elbow stiffness and abnormal glucose metabolism were at increased risk of poorer outcomes after open arthrolysis, and that patients with DM had the poorest performance [12]. They emphasized the importance of glycemic control in patients with abnormal glucose metabolism before open arthrolysis. Moreover, one study showed inferior IR recovery after total shoulder arthroplasty for osteoarthritis in patients with than without DM [13]. Although the

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Multiple logistic regression analysis results.

	Odds ratio	95% CI	P value
Diabetes mellitus	51.0	10.9–237	.01

DM: diabetes mellitus; CI: confidence interval.

precise mechanism of the poorer prognosis in patients with than without DM is difficult to determine, the outcomes may be affected by advanced glycation end-products. One study revealed that older adult patients with DM showed limited joint motion for shoulder abduction and flexion, ankle dorsiflexion and plantar flexion, hip flexion, and adduction compared with their age-matched counterparts [14]. The authors inferred that non-enzymatic glycosylation of collagen with advanced glycation end-product formation and the subsequent increase in intermolecular collagen cross-links was the main pathogenetic mechanism. The outcomes of orthopedic treatments may be improved by physiotherapy and proper control of hyperglycemia, but also pharmacological interventions, which may influence advanced glycation end-product formation or removal and prevent or reverse joint stiffness. Research on advanced glycation end-product formation may help to develop new treatments for DM-related orthopedic conditions.

The limitations of the present study include its retrospective design and small sample size. Additionally, we did not evaluate the duration of DM, glucose level, or HbA1c level, all of which may have influenced the outcomes.

#### 5. Conclusions

DM was found to be a negative prognostic factor of MUC. Therefore, clinicians should inform patients with DM of the inferior outcome of MUC for diabetic stiff shoulder compared with idiopathic frozen shoulder.

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#### **Ethical approval**

The institutional review board of the ethics committee at our institution approved the study, waiving the requirement for formal written informed consent because of the retrospective nature of the study (protocol A14-02).

#### Consent

Written informed consent was obtained from the patient for publication of this case report and accompanying images. A copy of the written consent is available for review by the Editor-in-Chief of this journal on request.

#### CRediT authorship contribution statement

T.S.: Literature review, writing - original draft.

- H.S.: Literature review, discussion.
- Y.I.: Literature review, discussion.
- K.T.: Literature review, discussion.
- All authors read and approved the final manuscript.

#### **Registration of research studies**

Not applicable.

#### Guarantor

Tomohiro Saito was the guarantor of the study.

#### Provenance and peer review

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#### Declaration of competing interest

All authors report no declarations of interest.

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