

Patient-reported outcomes for cervical disease in end-stage renal disease patients: Propensity matching analysis using volunteer data

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Patient-reported outcomes for cervical disease in end-stage renal disease patients: Propensity matching analysis using volunteer data

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Highlights	<ul style="list-style-type: none">·The cervical surgeries for end-stage renal disease (ESRD) patients is increasing.·The lower-extremity function and QOL in ESRD patients were lower than volunteers.· “Hemodialysis” was a significant negative factor of lower-extremity function and QOL.
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Highlights

The requirement of cervical surgeries for patients with end-stage renal disease (ESRD) has been increasing.

The differences in patient reported outcomes between a healthy population and patients with ESRD, adjusting for patients' daily physical activity such as sarcopenia, is still under investigation.

The cervical function, lower-extremity function, and quality of life in patients with ESRD were lower than those of healthy volunteers after adjusting for age and sex.

The treatment with hemodialysis was a significant negative factor of lower-extremity function and QOL independent of age, gender, and disability of physical activity.

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Abstract

As the number of patients with end-stage renal disease (ESRD) has been increasing, the number of cervical spine surgeries for the patients with ESRD has also been increasing. The purpose is to identify the differences in cervical disease-specific patient-reported outcomes (PROs) between a healthy population and patients with ESRD, adjusting for subjects' age and physical activity. [Methods] The ESRD group included patients with ESRD who were treated with hemodialysis in our outpatient clinic and healthy volunteers were individuals who attended public health lectures. Volunteers with a history of cervical disease were excluded. All participants answered the Japanese Orthopaedic Association Cervical Myelopathy Evaluation Questionnaire (JOACMEQ) and questionnaires that evaluate the disability in performing physical activities. [Results] A total of 111 participants were enrolled and divided into the ESRD group (n=40) and the control group (n=71). After adjusting for age and sex using propensity score, cervical function (p=0.008), lower-extremity function (p=0.007), and QOL (p<0.001) in patients in the adjusted ESRD group were significantly lower than those in the control group. In multivariate linear regression, the use of hemodialysis was a significant variable that was negatively related to lower-extremity function (p=0.004) and QOL (p=0.011) independent of age and disability in performing physical activity. [Conclusion] The ESRD was a significant negative factor of lower-extremity function and QOL, independent of age, sex, and disability in performing physical activity. These results can

help understand the cervical status of patients with ESRD and adjust the goal for such patients after cervical surgery.

Key words.

cervical; end-stage renal disease; hemodialysis; patient-reported outcome; spine; quality of life

Introduction

The number of patients with end-stage renal disease (ESRD) has been increasing with advances in medical management. In the United States, more than 700,000 patients per year are affected by ESRD and more than 2,000,000 people are treated with hemodialysis (HD) or kidney transplantation [1]. In Japan, up to 330,000 patients were treated with HD due to ESRD in 2016 and the number has doubled in the recent 20 years [2]. Patients with ESRD who are treated long term with HD are prone to several pathologic bone and joint disorders [3]. In addition, cervical and lumbar spine is also affected, which can eventually result in destructive spondyloarthropathy or spinal canal stenosis[4]. Hence, the requirement of spinal surgeries for patients with ESRD has also been increasing.

Evaluation of patient-reported outcomes (PROs) has become the standard and essential method in identifying the efficacy of treatment [5]. In general, PROs can be divided into two types based on its design: general PROs and disease-specific PROs. The general PROs such as the 36-item Short-Form Health Survey (SF-36) [6], EuroQol 5 Dimension (EQ-5D) [7], the Patient-Reported Outcomes Measurement Information System (PROMIS) [8], and visual analog scale (VAS) can be applied to all patients regardless of the disease. In contrast, disease-specific PROs can be applied only to patients with specific disease but can evaluate the outcome more precisely. In cervical spine surgery, the neck disability index (NDI) [9] and the JOA Cervical Myelopathy Evaluation Questionnaire (JOACMEQ) [10] can be standard options for disease-specific PROs.

It is well established that patients with ESRD have a much lower quality of life (QOL) than the general healthy population [11]. Surprisingly, the patients have poorer QOL than patients with other representative chronic diseases [12]. Although ESRD itself negatively influences QOL, factors associated with HD, such as time spent, costs, and complications, also have significant effects [13]. Therefore, an understanding of the characteristics of spine disease-specific PROs of the patients with ESRD is essential for spine surgeons to evaluate the improvement after surgery or to set the patient-specific goal before surgery. However, the impact of ESRD on the spine-specific PROs are unclear.

In addition, physical disabilities caused by loss of skeletal muscle mass and strength, such as sarcopenia, frailty, and/or locomotive syndrome, are essential issues that need to be considered [14, 15]. This is because 30-40% of patients with ESRD are diagnosed with sarcopenia [15], and it is well known that the physical disability itself can have a detrimental effect on health-related QOL [16]. Therefore, adjusting the severity of physical disability can help us understand the characteristics more precisely.

Therefore, our study aimed to identify the differences in JOACMEQ between a healthy population and patients with ESRD, adjusting for patients' daily physical activity. In this study, we analyzed the PROs relating to cervical spine disease because the possibility of using the cervical disease-specific PROs for patients with ESRD is much greater than that for patients with normal or mild renal disease.

Materials and Methods

COI and IRB statements

All study participants provided informed consent, and the study protocol was approved by the Institutional Review Board. No funds were received in support of this work.

Population

All patients treated with HD for more than 1 year in our outpatient clinic were enrolled in this survey as the ESRD group. The control group included volunteers who attended public health lectures and who agreed to participate in this survey. Participants with a history of cervical myelopathy or cervical disease were excluded from the current analysis.

Evaluation tools

JOACMEQ

JOACMEQ included five functional scores for the corresponding domains (cervical spine function, upper-extremity function, lower-extremity function, bladder function, and QOL, with a score of 0 being worst to 100 being best) according to the provided formulas using patient answers to 24 questions [10]. The aim of this scoring system is to evaluate the status of patients with cervical myelopathy based on five different aspects. Because the population treated with HD was not adequate to evaluate bladder function due to the nature of the scoring system, the outcomes of “bladder function” were eliminated from the analysis.

GLFS-25

The 25-question Geriatric Locomotive Function Scale (GLFS-25) was used to evaluate the difficulty and disability in performing daily physical activities [17] (Table 1). The GLFS-25 is a self-administered, relatively comprehensive measure that consists of 25 items, including 4 questions regarding pain during the last month, 16 questions regarding activities of daily living during the last month, 3 questions regarding social functions, and 2 questions regarding mental health status during the last month. These 25 items are graded on a 5-point scale from no impairment (0 points) to severe impairment (4 points) and then arithmetically added to produce a total score (with a score of 0 being worst to 100 being best). Therefore, a higher score is associated with worse locomotive function.

Study design and Statistical analysis

Firstly, average age and sex ratio of the ESRD and control groups were compared to evaluate the background differences of the two groups using Mann-Whitney U test or chi-squared test as appropriate.

Secondly, adjusted ESRD groups and adjusted control groups were created using propensity score matching analysis. The matching procedure classified patients into two groups according to the similarity of their propensity scores. To estimate the propensity score, we fitted a logistic regression model using patients' age and sex. A nearest-neighbor matching procedure was used, and the restriction that matched propensities had to be within 0.05 units of each other. Each score, except for bladder function of JOACMEQ, was compared between

two adjusted groups using the Mann-Whitney U test.

Finally, to eliminate the influence of confounding factors, multivariate linear regression analysis was performed using whole population data. In this analysis, each item of JOACMEQ, except for bladder function, was added as an objective variable. Age, sex, GLFS-25, and whether the individuals were treated with HD or not were included as explanatory variables in each calculation. All analyses were performed using the SPSS computer software (version 23; SPSS, Chicago, IL, USA). A *P* value <0.05 was considered statistically significant.

Results

Univariate analysis before adjustment

A total of 111 participants were enrolled in this survey: 40 patients comprised the ESRD group and 71 healthy volunteers comprised the control group. There were significant differences between the ESRD group and the control group in terms of average age (65.2 vs 76.1, $p < 0.001$) and sex ratio (21 males in the ESRD group and 15 males in the control group, $p = 0.001$, Table 2). The average period of HD in the ESRD group was 9.8 ± 8.9 years (a minimum of 1 year and a maximum of 32 years).

Univariate analysis between adjusted groups

After propensity score matching using age and sex data, 44 subjects were selected as the adjusted ESRD group ($n = 22$) and the adjusted control group ($n = 22$). There were no significant differences between the two adjusted groups in terms of age (69.3 vs 70.2, $p = 0.760$) and sex ratio (13 males in the adjusted ESRD group and 12 males in the control group, $p = 1.000$). In the univariate comparison between two adjusted groups, the average scores of the adjusted ESRD group were significantly lower in terms of cervical function ($p = 0.008$), lower-extremity function ($p = 0.007$), and QOL ($p < 0.001$) of JOACMEQ than those of the adjusted control group (Table 3). In terms of the scoring of daily physical activities, the adjusted ESRD group showed a significantly worse score of GLFS-25 than the adjusted control group (19.3 vs 10.1, $p = 0.029$).

Multivariate linear regression analysis

The use of HD was a significant negative factor for lower-extremity function ($B=-12.7$, $p=0.004$) and QOL ($B=-8.3$, $p=0.011$) independent of age, sex, and disability in performing physical activity. Regarding cervical and upper-extremity functions, the use of HD was not a significant factor ($p=0.067$ and $p=0.617$).

Discussion

The current survey demonstrated that cervical function, lower-extremity function, and QOL in patients treated with HD due to ESRD were lower than those of healthy volunteers after adjusting for age and sex. Furthermore, we found that treatment with HD was a significant negative factor of lower-extremity function and QOL independent of age, sex, and disability of physical activity.

Chronic kidney disease is classified into stages 1 to 5 based on the patient's glomerular filtration rate (GFR). Stage 5 is ESRD and is identified by a GFR less than 15 ml/min or the need for dialysis including HD [18]. ESRD is characterized by diminished metabolic and endocrine functions of the kidney with subsequent retention and accumulation of toxic metabolites. Thus, dialysis is a life-saving treatment and the current standard of treatment for patients with ESRD. Therefore, in this study, we selected patients undergoing long-term HD as the ESRD group.

So far, the standard questionnaire for cervical disease-specific PROs is NDI rather than JOACMEQ [19]. The NDI is a 10-item scaled questionnaire and it represents the status of patient's health-related QOL with only one value. Meanwhile, the JOACMEQ can assess patients based on five aspects such as cervical function, upper-extremity function, lower-extremity function, bladder function, and QOL separately. Because the current study aimed to identify the characteristic of cervical disease PROs of patients with ESRD multi-directionally, we analyzed JOACMEQ in this survey.

In terms of the relationship between QOL and ESRD, many previous studies have shown a negative relationship [11-13, 20]. This negative relationship may be not due to only the ESRD itself but also due to the factors associated with HD such as time spent, costs, and complications [13]. Our results were similar to those of previous studies; QOL in patients treated with HD due to ESRD were lower than those of healthy volunteers.

Meanwhile, to our knowledge, this is the first report to demonstrate that the use of HD for ESRD was a significant negative predictor of lower-extremity function independent of age and disability in performing physical activity. We postulate two possible reasons for this. First, chronic lower-extremity ischemia in patients with ESRD may influence outcomes. It is well known that chronic renal disease can modulate the response to pharmacotherapy and revascularization and thus influence prognosis of ischemia [21]. The second postulated reason is joint destruction due to dialysis-related amyloidosis, which is commonly seen in patients with ESRD undergoing long-term HD therapy [22]. The pain or/and disability of the hip, knee, and ankle joint may contribute to the poor scores of lower-extremity functions in patients with ESRD. Because we adjusted our findings with the disability in performing physical activity using GLFS-25 to detect the disability due to muscle weakness, the disability caused by lower-extremity ischemia and joint destruction cannot be dismissed by the scoring system.

The results of this survey can help understand and improve the surgical outcome of patients with ESRD. Firstly,

these results can aid surgeons in explaining improvement after surgery, which can be one of the main issues for patient satisfaction after surgery [23]. Second, we may need to adjust the lower-extremity function and QOL scores when we evaluate patients with ESRD. Several previous studies have shown that the presence of the severe chronic renal disease itself can be the factor relating to the low improvement after spine surgery. Silverstein et al. reported that no patient with chronic renal disease achieved the minimum clinical important differences in EQ-5D among 212 patients who underwent lumbar decompression surgery [24]. However, on the basis of our results, spine physicians can set similar goals for ESRD patients and control patients regarding cervical function and upper-extremity function, but not regarding lower-extremity function and QOL. Finally, patients should be treated not only for neurological complications but also for muscle weakness due to sarcopenia after cervical surgery to achieve better surgical outcomes. This is because worse GLFS-25 is negatively correlated to each JOACMEQ score independently. Our hypothesis is that physical exercise therapy and adequate dietary supplementation before and after cervical surgery can improve muscle mass and muscle function, resulting in the improvement of lower-extremity function and QOL even in patients with ESRD [25].

The current survey has some limitations. First, radiological and physical examinations of the participants were not performed. Although we confirmed that all participants had no history of cervical disease or myelopathy, patients with subclinical symptoms may be included. Second, there may be a sampling bias, which means that the intended population is less likely to be included than others. In this study, we recruited participants who attended the public lecture of medicine as healthy volunteers. This method may have included a health-

conscious population which is more than the nationwide average ratio. Third, the lack of patients' medical records made it difficult to verify the factor that caused a decrease in lower-extremity function, and QOL in patients with ESRD. Finally, our findings may not apply to patients undergoing renal transplantation for ESRD. To overcome these limitations, further studies analyzing the data of the nationwide population with precise medical information in detail are needed to validate our findings.

Conclusion

The cervical function, lower-extremity function, and QOL were lower in patients with ESRD than in healthy volunteers after adjusting for age and sex. In addition, the use of HD was a significant negative factor for lower-extremity function and QOL independent of age, sex, and disability in performing physical activity. We believe that our findings can provide guidance in understanding the characteristics of patients with ESRD.

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Table 1 GLFS-25 questionnaire items

Questionnaire item
1. Did you have any pain (including numbness) in your neck or upper limbs?
2. Did you have any pain in your back, lower back or buttocks?
3. Did you have any pain (including numbness) in your lower limbs?
4. To what extent has it been painful to move your body in daily life?
5. To what extent has it been difficult to get up from a bed or lie down?
6. To what extent has it been difficult to stand up from a chair?
7. To what extent has it been difficult to walk inside the house?
8. To what extent has it been difficult to put on and take off shirts?
9. To what extent has it been difficult to put on and take off trousers and pants?
10. To what extent has it been difficult to use the toilet?
11. To what extent has it been difficult to wash your body in the bath?
12. To what extent has it been difficult to go up and down stairs?
13. To what extent has it been difficult to walk briskly?
14. To what extent has it been difficult to keep yourself neat?
15. How far can you keep walking without rest?
16. To what extent has it been difficult to go out to visit neighbors?
17. To what extent has it been difficult to carry objects weighing 2 kg?
18. To what extent has it been difficult to go out using public transportation?
19. To what extent have simple tasks and housework been difficult?
20. To what extent have load-bearing tasks and housework been difficult?
21. To what extent has it been difficult to perform sports activities?
22. Have you been restricted from meeting your friends?
23. Have you been restricted from joining social activities?
24. Have you ever felt anxious about falls in your house?
25. Have you ever felt anxious about being unable to walk in the future?

GLFS-25: 25-question Geriatric Locomotive Function Scale.

Table 2 Comparison between non-adjusted groups

	ESRD group	Control group	p-value
Number	40	71	
Age (years old)	65.2 ± 9.6	76.1 ± 8.1	0.001 [#]
Sex (Female/Male)	19 /21	56 / 15	0.001 [†]
Period of HD (yrs)	9.8 ± 8.9		
JOACMEQ			
Cervical function	81.5 ± 21.5	82.5 ± 23.1	0.823 [#]
Upper limb function	94.0 ± 12.2	90.8 ± 15.9	0.247 [#]
Lower limb function	75.1 ± 21.1	77.3 ± 21.8	0.610 [#]
Quality of life	52.8 ± 13.6	59.3 ± 16.6	0.031 [#]
GLFS-25	16.1 ± 14.7	15.1 ± 16.5	0.741 [#]

[#]: Mann-Whitney U test, [†] : Chi-square test

ESRD: end-stage renal disease, JOACMEQ: Japanese Orthopaedic Association Cervical Myelopathy Evaluation

Questionnaire, GLFS-25: GLFS-25: 25-question Geriatric Locomotive Function Scale

Table 3 Comparison between adjusted groups

	Adjusted ESRD group	Adjusted control group	p-value
Number	22	22	
Age (years old)	69.3 ± 9.1	70.2 ± 9.7	0.760 [#]
Sex (Female/Male)	13 / 9	12 / 10	1.000 [†]
Period of HD (yrs)	10.8 ± 9.0		
JOACMEQ			
Cervical function	78.9 ± 19.2	92.4 ± 11.8	0.008 [#]
Upper limb function	91.8 ± 14.8	96.6 ± 6.30	0.177 [#]
Lower limb function	70.6 ± 20.9	86.4 ± 15.5	0.007 [#]
Quality of life	52.0 ± 13.6	65.9 ± 9.70	<0.001 [#]
GLFS-25	19.3 ± 15.6	10.1 ± 10.6	0.029 [#]

[#]: Mann-Whitney U test, [†] : Chi-square test

ESRD: end-stage renal disease, JOACMEQ: Japanese Orthopaedic Association Cervical Myelopathy Evaluation

Questionnaire, GLFS-25: GLFS-25: 25-question Geriatric Locomotive Function Scale, yrs: years

Table 4 Linear regression of the segments of JOACMEQ (n=111)

Objective variable	explanatory variable	B	95%CI	p-value
Cervical function	Age	-0.69	-9.03, 7.65	0.870
	Sex	-0.46	-0.89, -0.04	0.031
	GLFS-25	-0.60	-0.84, -0.36	<0.001
	Hemodialysis	-8.20	-17.0, 0.59	0.067
Upper limb function	Age	-1.99	-6.66, 2.68	0.399
	Sex	-0.20	-0.43, 0.04	0.098
	GLFS-25	-0.40	-0.54, -0.27	<0.001
	Hemodialysis	1.24	-3.68, 6.17	0.617
Lower limb function	Age	5.20	-2.95, 13.35	0.208
	Sex	-0.68	-1.09, -0.27	0.001
	GLFS-25	-0.48	-0.72, -0.25	<0.001
	Hemodialysis	-12.70	-21.3, -4.11	0.004
Quality of life	Age	-2.13	-8.21, 3.95	0.488
	Sex	-0.30	-0.60, 0.10	0.058
	GLFS-25	-0.52	-0.69, -0.34	<0.001
	Hemodialysis	-8.34	-14.7, -1.93	0.011

JOACMEQ: Japanese Orthopaedic Association Cervical Myelopathy Evaluation Questionnaire, GLFS-25: GLFS-

25: 25-question Geriatric Locomotive Function Scale, CI: confidence interval