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Serial Assessment of Gait Changes After Interventions Using Smart Insole in a Patient With iNPH: A Proof-of-Concept Case Report

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Correspondence to
Na Young Kim
Department of Rehabilitation Medicine, Yonsei University Yongin Severance Hospital, 363 Dongbaekjukjeon-daero, Giheung-gu, Yongin 16995, Korea.
Email: kny8452@yuhs.ac

HIGHLIGHTS

- The smart insole detected changes in gait in a patient with hydrocephalus in real time.
- Gait analysis using smart insoles could assist clinical decision-making.

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Serial Assessment of Gait Changes After Interventions Using Smart Insole in a Patient With iNPH: A Proof-of-Concept Case Report

Wonhee Lee [1], **Seung-Ick Choi** [2], **Seok Jong Chung** [3], **Jun Kyu Hwang** [4], **Na Young Kim** [2,5]

[1]Department and Research Institute of Rehabilitation Medicine, Severance Hospital, Yonsei University College of Medicine, Seoul, Korea
[2]Department of Rehabilitation Medicine, Yongin Severance Hospital, Yonsei University College of Medicine, Yongin, Korea
[3]Department of Neurology, Yongin Severance Hospital, Yonsei University College of Medicine, Yongin, Korea
[4]Department of Neurosurgery, Yongin Severance Hospital, Yonsei University College of Medicine, Yongin, Korea
[5]Center for Digital Health, Yongin Severance Hospital, Yonsei University College of Medicine, Yongin, Korea

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Email: kny8452@yuhs.ac

ORCID iDs
Wonhee Lee
https://orcid.org/0009-0008-1132-893X
Seung-Ick Choi
https://orcid.org/0009-0009-0934-2596
Seok Jong Chung
https://orcid.org/0000-0001-6086-3199
Jun Kyu Hwang
https://orcid.org/0000-0002-1203-0800
Na Young Kim
https://orcid.org/0000-0001-9888-3953

ABSTRACT

Improvement in gait after a cerebrospinal fluid (CSF) tap test is a key indicator for shunt surgery in idiopathic normal pressure hydrocephalus (iNPH) patients. However, quantitative analysis of gait requires sophisticated equipment and specialists that limit practical use. Development of Bluetooth-connected sensors offers affordable way to assess gait. We present a case of iNPH patient in whom gait changes were serially assessed using a smart insole before and after intervention, which helped in clinical decision making. A 68-year-old female who showed the triad of iNPH symptoms (gait disturbance, cognitive decline, and urinary frequency) were evaluated. Before and after the CSF tap test, gait was analyzed and compared using the smart insole with four pressure sensors and accelerometer, along with conventional spatiotemporal parameters. While no significant changes were observed between pre- and post-tap test in conventional parameters of gait, several changes were found in the data collected from the smart insole, including improved heel strike, step regularity and symmetry. Advanced surgical intervention was performed based on subjective and objective improvement in gait. The improved gait was maintained at 3 and 6 months after surgery. Our case showed that easy-to-use smart insoles could assist clinical decisions by providing additional information.

Keywords: Gait Analysis; Wearable Electronic Devices; Digital Health; Normal Pressure Hydrocephalus; Ventriculostomy

INTRODUCTION

Idiopathic normal pressure hydrocephalus (iNPH) is characterized by the symptom triad of gait disturbance, cognition impairment, and urinary dysfunction [1]. Because these symptoms can be alleviated by cerebrospinal fluid (CSF) shunts, early diagnosis and intervention are beneficial for patients [2]. Gait disturbance is the earliest and most

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Conflict of Interest

The authors have no potential conflicts of interest to disclose.

Author Contributions

Conceptualization: Kim NY; Data curation: Choi SI, Chung SJ, Hwang JK; Formal analysis: Lee W, Kim NY; Funding acquisition: Kim NY; Investigation: Lee W, Choi SI; Methodology: Lee W, Kim NY; Project administration: Kim NY; Resources: Chung SJ, Hwang JK, Kim NY; Software: Lee W; Supervision: Kim NY; Validation: Lee W, Kim NY; Visualization: Lee W; Writing - original draft: Lee W, Kim NY; Writing - review & editing: Lee W, Kim NY.

prominent clinical feature in iNPH, and improvement in gait after temporary removal of CSF is generally used as an indicator for shunt surgery [2,3]. However, detailed gait analysis requires costly equipment in specialized space, limiting clinical application.

Recent development in Internet of Things (IoT) technology allows assessment of human movement with low-cost and easy-to-use devices. Bluetooth-connected sensors have yielded results as reliable as three-dimensional gait analysis and provide reports via smartphone or tablet PC [4]. Although several studies have analyzed gait in iNPH patients using IoT devices, most were laboratory prototypes [5,6]. Furthermore, those studies focused on spatiotemporal parameters, which have large variations in CSF shunt response depending on the patient without serial assessment [7,8]. Changes in heel-to-toe motion during the stance phase following intervention are also underexplored.

Herein, we tested whether data obtained from commercial smart insoles could assist clinical decision making in a patient with iNPH. Sensor-imbedded insoles were used to measure the gait following intervention, CSF tap and surgical treatment, and their additional value was reported.

CASE DESCRIPTION

A 68-year-old female patient visited the clinic complaining of gait disturbances over 10 years that presented as shuffling and stooped posture. She also reported increased urinary frequency and gradual cognitive decline. The patient had no notable medical history or specific signs such as tremor, bradykinesia, or rigidity on neurological examinations. Neuropsychological tests showed a deterioration in attention, visuospatial function, memory, and executive function (**Table 1**). Her urinary symptom was graded as moderate based on the Overactive Bladder Symptom Score (9/15) and the International Prostate Symptom Score (9/35). Brain MRI revealed ventriculomegaly with Evan's ratio of 0.41 without cortical atrophy and no obstruction at the level of the third or fourth ventricle (**Fig. 1A**). There was no focal defect in cerebral glucose metabolism on 18F-FDG PET scan (**Fig. 1B**), and normal DAT binding in the striatum was observed on 18F-FP-CIT PET scan (**Fig. 1C**). Under the diagnosis of iNPH, a CSF tap test was performed to decide on surgical treatment, measuring a tapping opening pressure of 15 cm H_2O and drainage of 30 mL of fluid.

The gait and balance of patient was assessed by two clinically experienced specialists (a neurosurgeon and a physiatrist) at pre- and post-12-hour CSF tap test. Presence and frequency

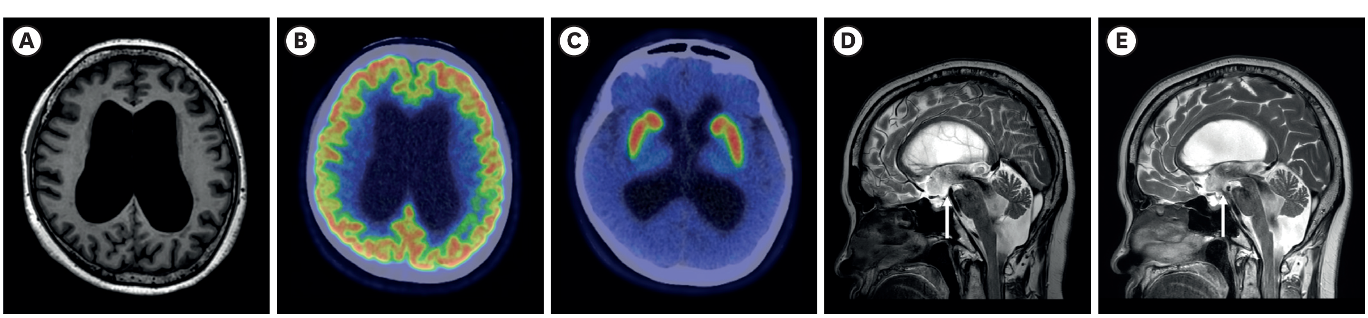

Fig. 1. Brain Imaging. (A) Pre-tap test brain magnetic resonance imaging demonstrated bilateral ventricular dilatation out of proportion to sulcal enlargement and no evidence of CSF flow obstruction. (B) No defect was found on 18F-FDG PET scan. (C) Striatal dopamine deficiency was not observed on 18F-FP-CIT PET scan. (D) Tuber cinereum was compressed by pressure (white arrow). (E) CSF flow toward the tuber cinereum was increased after endoscopic third ventriculostomy (white arrow).
CSF, cerebrospinal fluid.

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Table 1. Changes in cognitive test and urinary symptom score

Variables	Pre-tap test	Post-Op 3 mon
Cognitive test		
MMSE	21	23
Digit span		
Forward	4 (13.97%ile)	4 (13.97%ile)
Backward	3 (29.95%ile)	3 (29.95%ile)
Forward-backward	1 (75.70%ile)	1 (75.70%ile)
Ray complex figure test		
Immediate recall	1 (3.34%ile)	2 (4.73%ile)
Delayed recall	0 (1.87%ile)	0 (1.87%ile)
Recognition	18 (22.61%ile)	17 (11.09%ile)
Seoul verbal learning test		
Immediate recall	12 (7.17%ile)	9 (1.67%ile)
Delayed recall	0 (0.57%ile)	1 (1.84%ile)
Recognition	14 (0.11%ile)	18 (13.27%ile)
Controlled oral word association test		
Animal	6 (1.38%ile)	12 (28.39%ile)
Supermarket	16 (54.73%ile)	13 (31.66%ile)
ㄱ	1 (4.57%ile)	3 (14.35%ile)
ㅇ	1 (5.26%ile)	1 (5.26%ile)
ㅅ	1 (4.42%ile)	2 (8.12%ile)
Phonemic total score	3 (2.46%ile)	6 (5.45%ile)
Korean-color word stroop test		
Word reading - number of correct response	110 (≥ 15%ile)	112 (≥ 15%ile)
Word reading - number of error	2 (5≤ * <10%ile)	0 (≥ 15%ile)
Word reading - response time	0.98 (5≤ * <10%ile)	1.00 (≥ 15%ile)
Color reading - number of correct response	36 (1.69%ile)	72 (41.99%ile)
Color reading - number of error	2 (≥ 15%ile)	0 (≥ 15%ile)
Color reading - response time	0.95 (≥ 15%ile)	1.00 (≥ 15%ile)
Urinary symptom score		
OABSS	9	10
IPSS	9	7

MMSE, Mini-Mental State Exam; OABSS, Overactive Bladder Symptom Score; IPSS, International Prostate Symptom Score.

of clinical features according to definitions provided by Jankovic et al. [9] such as slowness, abnormal postural adjustments, freezing, abnormal stance, disequilibrium, stiff trunk/legs, leg apraxia, improvement with cues, frontal signs, short stride, shuffling, narrow base, festination, start hesitation, turn en bloc and parkinsonian signs were observed and reached by consensus. Balance was evaluated using the Berg Balance Score. The result of the 10-meter walk test (10MWT) and the Timed Up and Go Test were recorded. The overall gait pattern was rated using the Tinetti Gait Assessment. During the 10MWT, the patient wore commercial smart insoles (GDCA-MD®, Gilon, Seongnam, Korea) equipped with four pressure sensors and a three-axis accelerometer on each insole. Four pressure sensors are located on the toe, medial midfoot, lateral midfoot, and heel, respectively. The data from each sensor, a total of 14 data streams, were collected at a sampling rate of 40 Hz (**Fig. 2**). The collected data were displayed on a tablet in real time, providing automatically estimated spatiotemporal gait parameters (**Fig. 3A**). Following parameters were computed: step count, velocity, cadence, stride length, stride time, swing ratio, regularity and symmetry. Regularity was computed based on the consistency of acceleration signals between neighboring strides, while symmetry was calculated based on the similarity of acceleration signals between left and right strides, both using the unbiased autocorrelation function [10]. Each phase time during stance, the heel-contact, mid-stance, and propulsive phases were determined using heel-on, toe-on, heel-off and toe-off time [11]. The reliability and validity of the data from GDCA-MD® were verified in a previous study [12,13]. In addition, the peak pressure and the relative load

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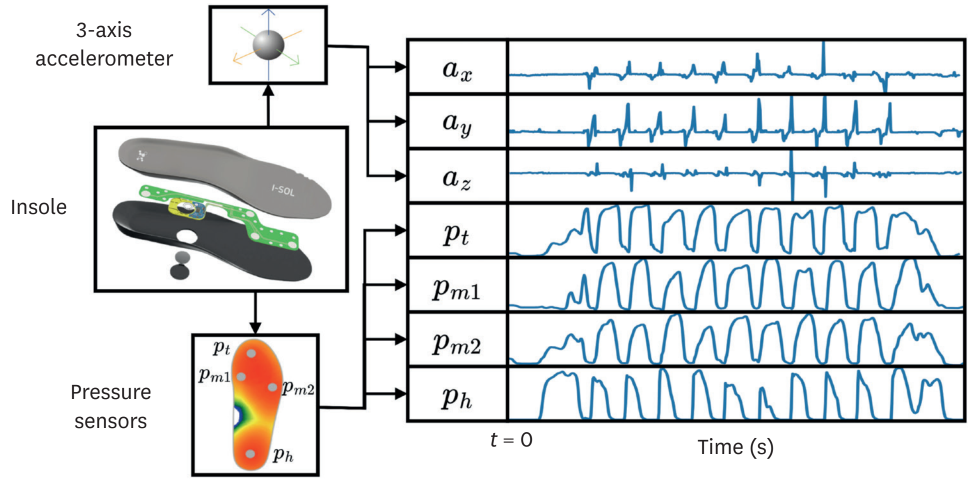

Fig. 2. Data from the Commercialized Instrumented Insole, GDCA-MD®. During the 10-meter walk test, seven data streams were collected, from a three-axis accelerometer and four pressure sensors at 40 Hz on each insole. p_t, p_{m1}, p_{m2}, and p_h represent pressure measured from sensors located at the toe, medial midfoot, lateral midfoot, and heel, respectively.

of each sensor per step was extracted and averaged over whole 10MWT test. The relative load of each sensor was calculated by dividing the force-time integral of each area of the foot by the total force-time integral and multiplying by 100.

Although there was no significant change in the results of conventional tests including the Berg Balance Score, the Timed Up and Go Test and the Tinetti Gait Assessment after CSF tap test, several changes were detected in the data obtained from the smart insoles (**Table 2**). In spite of decreased walking speed, the regularity and symmetry of the steps were enhanced (0.79 to 0.83 and 0.60 to 0.70, respectively). Heel contact time was increased by 45.87% on the left and 24.84% on the right foot. Data obtained from the heel pressure sensor showed increased mean peak pressure in both feet (571.3 ± 44.5 to 613.0 ± 19.9, +7.3% in the left foot and 660.2 ± 27.9 to 688.5 ± 24.6, +4.3% in the right foot, **Fig. 3B**). The mean relative load of each step increased for the heel compared to the toe and midfoot (16.4% ± 4.2% to 22.0% ± 2.5% for the heel of left foot and 23.4% ± 4.4% to 29.4% ± 5.7% for the heel of right foot, **Fig. 3C**). Subjective improvement in gait and balance was also reported by the patient and her family members.

Based on clinical observations and additional information obtained from the insoles before and after the tap test, the neurosurgeon decided to proceed with the surgery. The patient underwent endoscopic third ventriculostomy (ETV) that created an opening in the floor of the third ventricles via an endoscope introduced through a right precoronal burr hole and corticotomy [14]. The peak flow velocity of the CSF toward the tuber cinereum improved from 6.11 cm/s (**Fig. 1D**) to 8.47 cm/s after ETV (**Fig. 1E**). At 3 and 6 months post-ETV, a consistent increment of heel strike as well as an increase in walking speed and cadence were observed. Otherwise, no significant changes in neuropsychological tests and urinary symptoms were noted at 3 months (**Table 1**).

DISCUSSION

In this case, smart insoles detected changes in gait following intervention in real time, whereas the result of conventional tests were not changed. The patient showed a general

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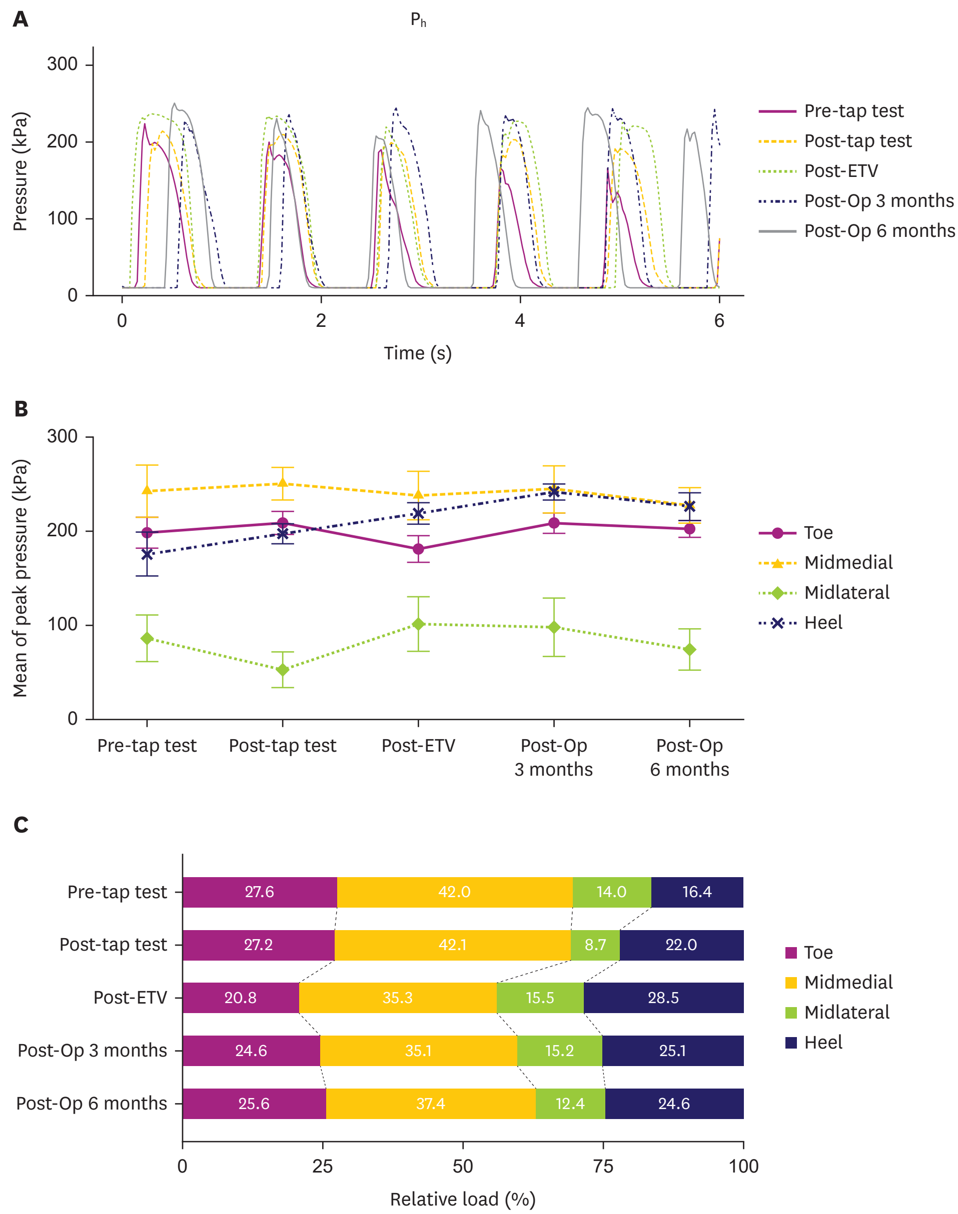

Fig. 3. Analysis of data obtained from the pressure sensor in the smart insole. (A) The values obtained from the pressure sensor located on the left heel were displayed over time in the first five steps during the 10MWT. (B) The graph shows changes in the mean peak pressure of each sensor on the left foot in each gait cycle during the 10MWT before and after the intervention. The whiskers represent the standard deviation. (C) The bar chart shows changes in mean relative load of each step during 10MWT for each area of left foot before and after the intervention.
10MWT, 10-meter walk test; ETV, endoscopic third ventriculostomy.

load shift from the mid- and forefoot regions towards the heel regions during stance phase and increased regularity and symmetry of gait compared to the initial status, which was maintained for 6 months after surgical treatment.

Although unclear heel strike and shuffling gait are well known major features of gait disturbance in iNPH [15,16], it is difficult to objectify these features in clinical practice. The Gait Assessment and Intervention Tool [17] has been suggested as the most suitable

Table 2. Changes in balance and gait parameters

Variables	Pre-tap test	Post-tap test	Post-ETV	Post-Op 3 mon	Post-Op 6 mon
Berg Balance Score	55	55	55	55	55
Timed Up and Go Test (sec)	14.14	14.25	15.34	14.58	13.31
Tinetti Gait Assessment	8	8	9	10	10
Gait parameters					
Step count (n)	13	12	11	10	10
Velocity (km/h)	3.43	3.19	3.34	3.81	4.25
Cadence (spm)	111.63	106.98	105.98	114.80	119.04
Stride length (m)	1.02	1.00	1.05	1.11	1.18
Stride time (s)	1.08	1.13	1.14	1.06	1.02
Regularity	0.79	0.83	0.85	0.86	0.87
Symmetry	0.60	0.70	0.64	0.87	0.92
Right foot					
Swing ratio (%)	39.08	37.76	38.01	37.82	37.01
Heel contact time (%)	22.62	28.24	27.49	25.02	25.82
Mid-stance time (%)	37.79	33.41	35.82	38.08	37.40
Propulsive time (%)	39.59	38.35	36.70	36.90	36.78
Left foot					
Swing ratio (%)	36.15	37.00	37.05	36.96	37.68
Heel contact time (%)	15.48	22.58	25.56	22.86	21.97
Mid-stance time (%)	36.08	29.86	35.32	33.87	33.05
Propulsive time (%)	48.44	47.56	39.12	43.27	44.98

for both clinical practice and research [18], but it is comprised of 31 items that should be rated by trained experts. The Tinetti Gait Assessment is based on binary assessment and has poor sensitivity to assess the effects of intervention [19]. Indeed, the score of the Tinetti Gait Assessment of our patient was not changed after CSF tap, and there was only a 2-point increase even though other parameters including walking speed had improved further at 6 months follow up. Furthermore, the patient had a good balance function and scored high on the Berg Balance Scale, changes in the score was not expected due to the ceiling effect.

Quantitative gait analysis has been suggested to evaluate characteristic gait features that respond to intervention. Previous studies have found that the gait velocity and stride length are the gait parameter that shows the greatest improvement after tapping in NPH patients [7,8]. However, in this case, walking speed decreased immediately after the CSF tap test and the surgical treatment and then gradually increased during follow-up as well as the stride length. This may have been influenced by the patient's anxiety and caution immediately following the intervention. It should also be noted that the patients had milder symptoms and faster walking speeds than the patient population in previous studies (0.95 m/s vs. 0.46 ± 0.19 m/s and 0.55 ± 0.48 m/s). Although walking speed slowed after the intervention, both the neurosurgeon and the physiatrist concluded improvement in clinical features by visual observation, which was in accordance with changes in other parameters. We observed increases in both peak pressure and relative load at the heel during the stance phase after intervention, which might imply a reverse of the reduced impact at heel strike. Changes in the heel to toe motion of the foot are well known in patients with Parkinson's disease [20], but the evidence for this in NPH patients is still lacking. Future prospective studies with larger sample size are warranted further to validate changes in heel-to-toe motion in NPH patients.

Improvement of gait disturbance was observed [and maintained after ETV; however, significant changes in cognitive function and urinary dysfunction did not occur. Three months may have been insufficient to observe improvement in these symptoms. In previous studies, more than 60% of iNPH patients showed long-term cognitive improvement within

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6–12 months after shunt surgery [21]. Improvement of symptoms may also vary depending on the patient, with urinary urgency and urge incontinence more common than urinary frequency [22], which was the main symptom in this case. Further study is needed with a larger number of patients to investigate the progress of individual symptoms of iNPH.

Our case showed that smart insoles can assist clinical decision-making by providing additional information easily, quickly, and inexpensively. This can also improve understanding and participation in the treatment process by enhancing information sharing with patients and caregivers. In addition, the results can be utilized to discover new indicators for patient selection for shunting.

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