4th Annual Cedars-Sinai Intracranial Hypotension Symposium

Outcomes of EBP in patients who fail to meet ICHD-3 diagnostic criteria

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Cedars Sinai

Disclosures

Nothing to Disclose

Our research is supported by the Considine CSF leak Fund.

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ICHD-3 7.2- Headache attributed to low (CSF) pressure

Criteria A:

Any headache that has developed in temporal relation to low CSF pressure or CSF leakage, or led to its discovery

Criteria B: Either or Both of the following.

1. Low cerebrospinal fluid (CSF) pressure (<60 mm CSF)
2. Evidence of CSF leakage on imaging
   a. Brain imaging
   b. Spine imaging

ORIGINAL ARTICLE

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Floating Dural Sac Sign is a Sensitive Magnetic Resonance Imaging Finding of Spinal Cerebrospinal Fluid Leakage

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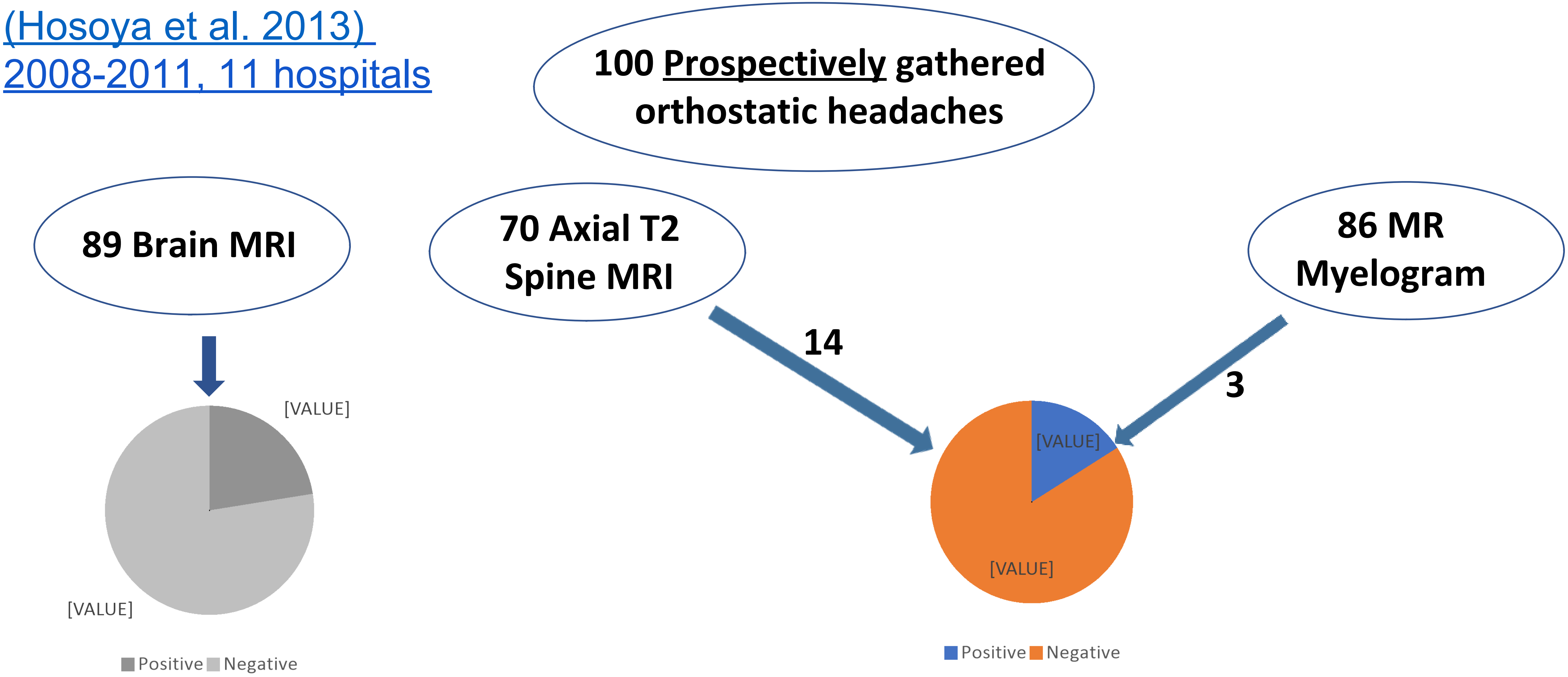
Abstract

We would like to propose floating dural sac sign, which is observed as a hyperintense band or rim around the spinal dural sac on axial T_2-weighted images, as a sensitive sign to identify cerebrospinal fluid (CSF) leakage. One hundred patients with orthostatic headache were prospectively registered in 11 hospitals. These patients were examined by brain magnetic resonance (MR) imaging (n = 89), radioisotope cisternography (n = 89), MR myelography (n = 86), axial T_2-weighted imaging of the spine (n = 70), and computed tomography myelography (n = 2). In this study, we separately evaluated the imaging findings of intracranial hypotension and spinal CSF leakage. Among 100 patients, 16 patients were diagnosed as having spinal CSF leaks. Of 70 patients examined with axial T_2-weighted imaging, 14 patients were diagnosed with spinal CSF leaks, and floating dural sac sign was observed in 17 patients, 13 patients with spinal CSF leaks and 4 without CSF leaks (sensitivity 92.9%, specificity 92.9%). Of 86 patients examined by MR myelography, extradural fluid was observed in only 3 patients (sensitivity 21.4%, specificity 100%). The floating dural sac sign was a sensitive sign that can be used to identify


(Hosoya et al. 2013)
2008-2011, 11 hospitals
100 Prospectively gathered orthostatic headaches
89 Brain MRI
70 Axial T2 Spine MRI
86 MR Myelogram
14
3
[VALUE]
[VALUE]
Positive
Negative
[VALUE]
[VALUE]
Positive
Negative

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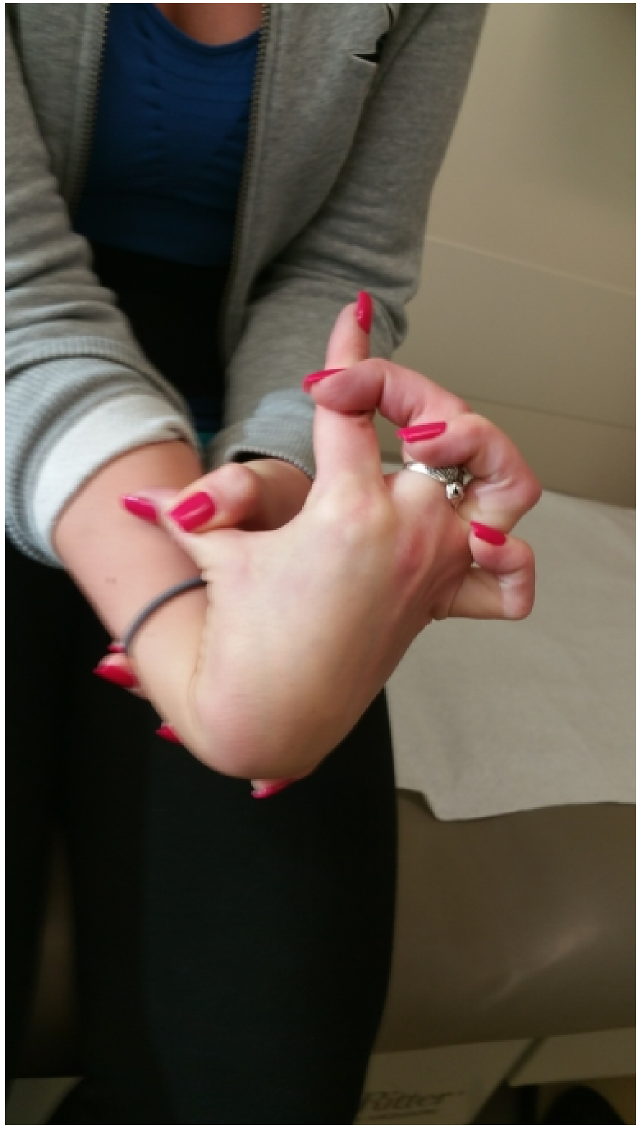
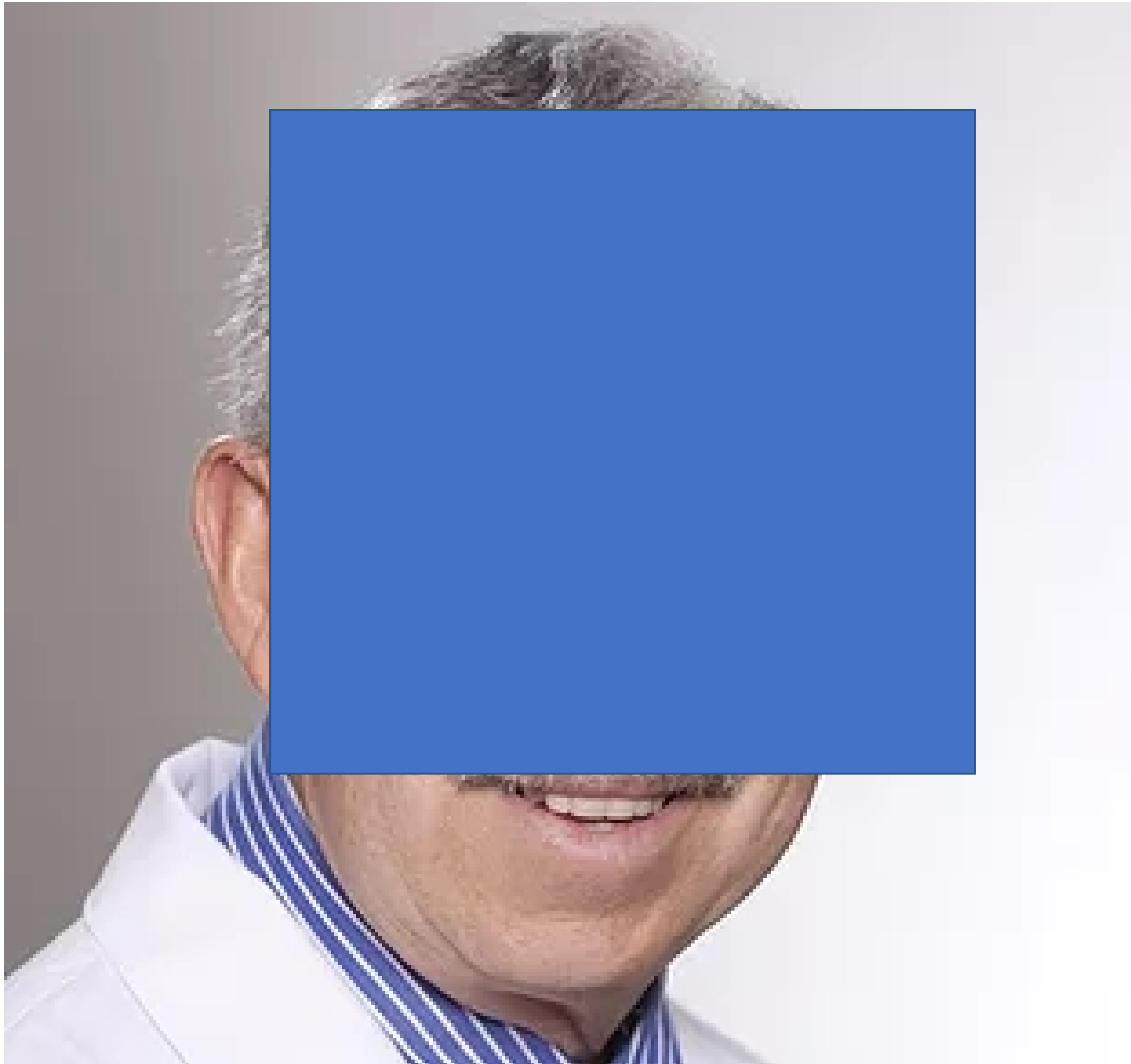
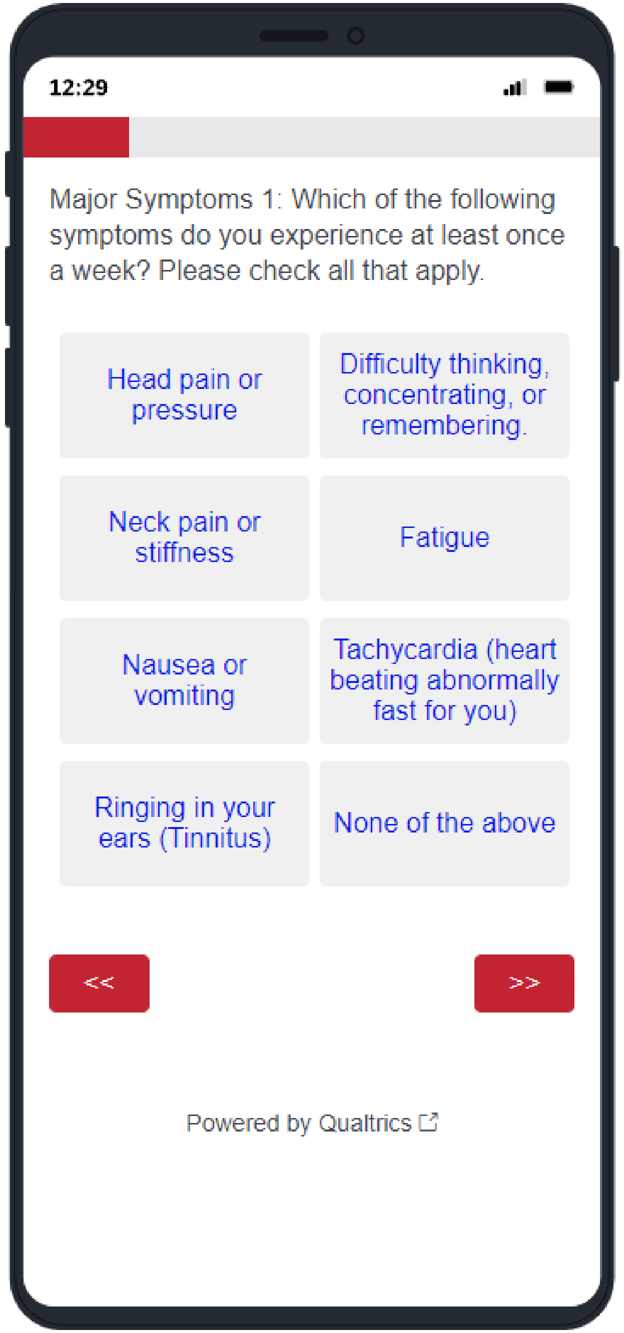
Should patients with suspected CSF leak who fail to meet ICHD-3 criteria be offered epidural patches- an inherently invasive therapy?

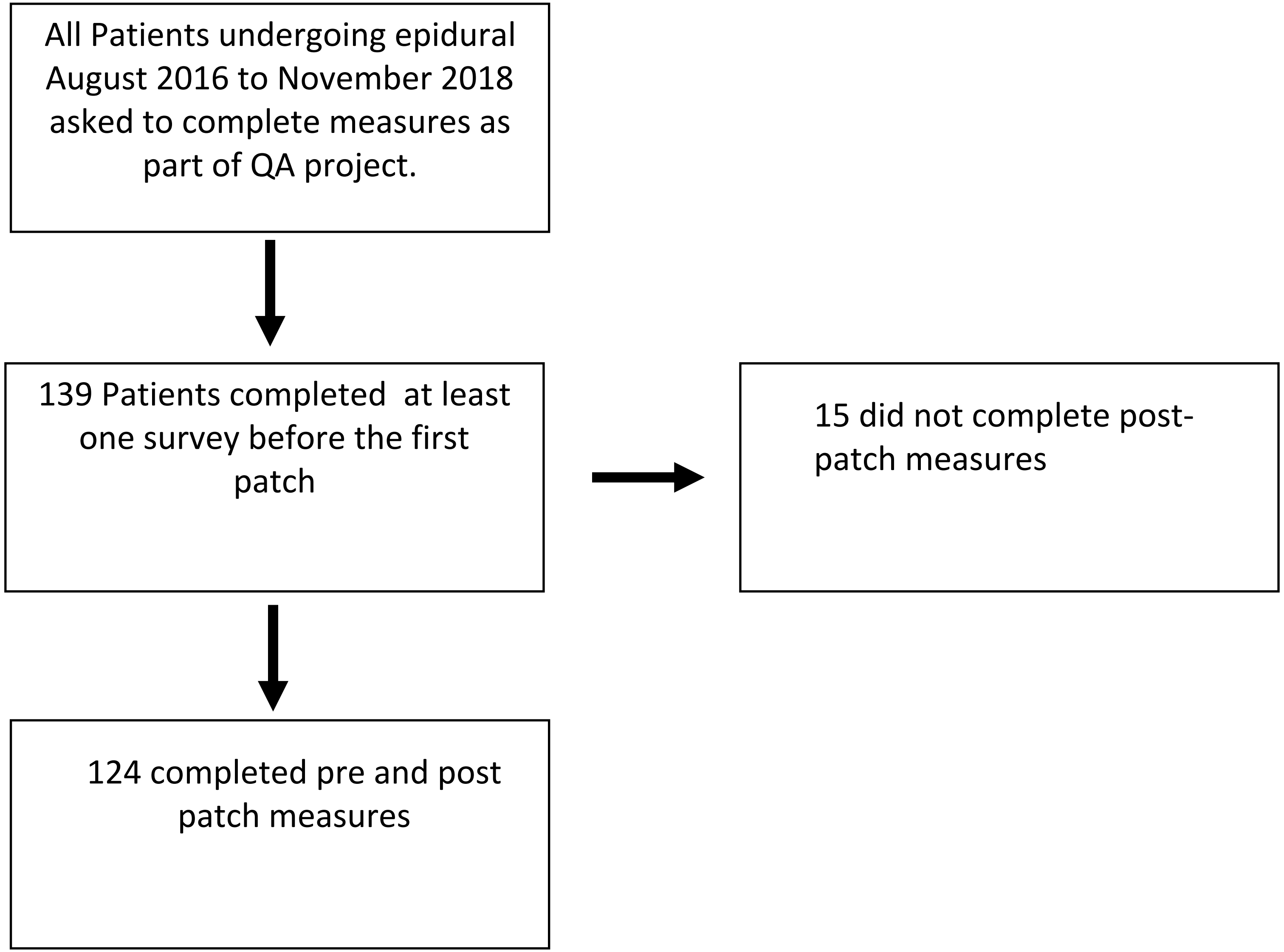






1. PROMIS Quality of Life
2. HIT-6
3. Neck Disability Index
4. Rhodes Index and Nausea Vomiting and Retching (INVR)
5. Tinnitus Handicap Inventory
6. PROMIS Applied Cognitive Questionnaire
7. Dizziness Handicap Inventory
8. PROMIS Fatigue

Stanford Epidural Patch Cohort



Characteristic		Patients With Suspected CSF Leak (N = 124) Mean± SD /n (%)
Age, y		41.30 ± 13.95
Sex		
	Male	23 (18.55)
	Female	101 (81.45)
Race		
	White	101 (81.45)
	Non-White/Other	10 (14.52)
Ethnicity	Hispanic	9 (7.25)
	Non-Hispanic	112 (90.32)

Characteristic		Patients With Suspected CSF Leak (N = 124) Mean± SD /n (%)
Age, y		41.30 ± 13.95
Sex		
	Male	23 (18.55)
	Female	101 (81.45)
Race		
	White	101 (81.45)
	Non-White/Other	10 (14.52)
Ethnicity	Hispanic	9 (7.25)
	Non-Hispanic	112 (90.32)

Characteristic		Patients With Suspected CSF Leak (N = 124) n (%)
CSF Protein (mg/dl)	≤ 45 [Normal]	97 (78.23)
	> 45 [Abnormal]	27 (21.77)
Symptoms Precipitated by a Discrete Trauma		30 (24.19)

Variable	Total N with results	Positive/ Abnormal n (%)	Negative/Normal n (%)
Meets ICHD-3 Criteria	120	23 (19.2)	97 (80.8)
MRI Brain Scan	106	9 (8.5)	97 (91.5)
MRI Spine	94	5 (5.3)	89 (94.7)
CT Myelogram	95	7 (7.4)	88 (92.6)
Opening pressure <60 mm CSF	93	8 (8.6)	85 (91.4)

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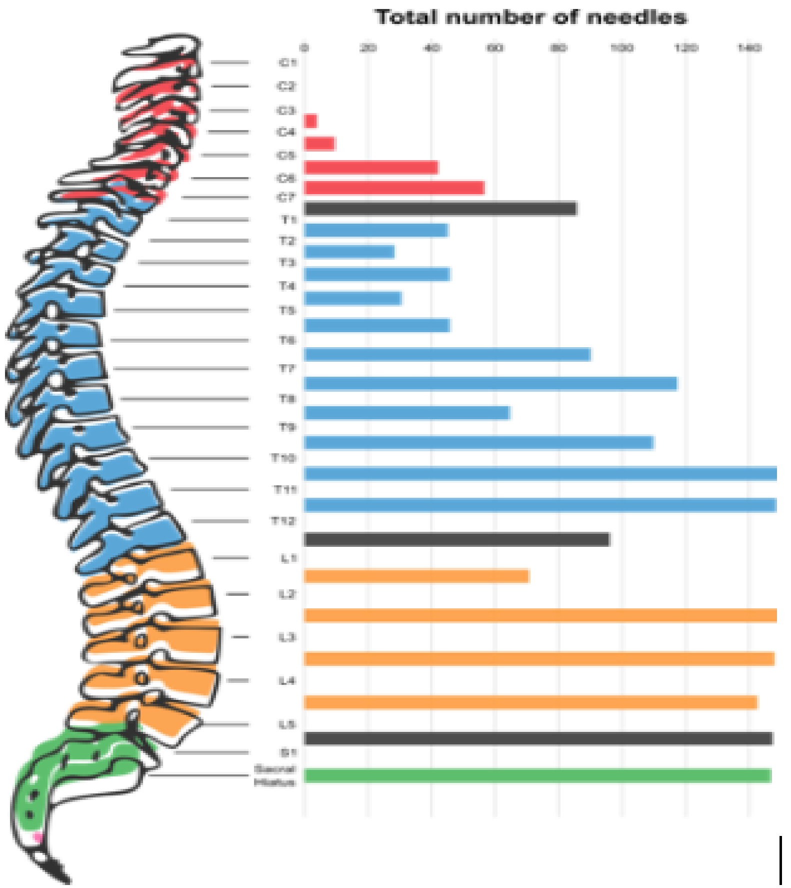
Epidural Patch Characteristics (N=124)	
Variable	Mean± SD
Number of Epidural Patches	5.55 ± 4.30
Days Between Patches	85.35 ± 144.15
Spinal Levels Patched Per patch	2.13 ± 0.93

Figure 2: Illustration of number of needles



5 Potential Reasons for Improvement

- Placebo effect
- Regression to the mean
- Hawthorne effect
- Natural history may be trajectory of improvement
- Actual treatment effects

Table 3. CSF Leak Patient Qualtrics Survey Scores

Survey Scores	N	PRE-PATCH Mean ± SD	POST-PATCH Mean ± SD	P-value	% (Median)
Pre Epidural Patches Compared to 1 Month After First patch					
PROMIS Physical Health	118	32.4 ± 6.8	35.4 ± 7.9	<0.001	7.16 ▲
PROMIS Mental Health	118	39.5 ± 7.7	40.4 ± 8.0	.164	0
PROMIS Fatigue	108	46.1 ± 11.1	49.5 ± 12.1	.001	1.18 ▲
Headache Impact Test-6 (HIT-6)	114	65.7 ± 6.8	62.1 ± 8.5	<0.001	3.39 ▼
Neck Disability Index	113	22.4 ± 10.8	19.6 ± 11.3	.001	8.11 ▼
Dizziness Handicap Inventory	99	43.8 ± 26.5	37.9 ± 24.7	.004	14.40 ▼
Tinnitus Handicap Inventory	112	20.3 ± 22.4	19.0 ± 21.5	.444	
Rhodes Index of Nausea, Vomiting and Retching (RINVR)	38	6.8 ± 5.9	5.6 ± 4.8	.111	
Pre Epidural Patches Compared to Final Assessment After Last Patch					
PROMIS Physical Health	117	32.5 ± 6.8	36.6 ± 8.5	<0.001	9.46 ▲
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Dizziness Handicap Inventory	99	43.8 ± 26.5	37.9 ± 24.7	.004	14.40 ▼
Tinnitus Handicap Inventory	112	20.3 ± 22.4	19.0 ± 21.5	.444	
Rhodes Index of Nausea, Vomiting and Retching (RINVR)	38	6.8 ± 5.9	5.6 ± 4.8	.111	
Pre Epidural Patches Compared to Final Assessment After Last Patch					
PROMIS Physical Health	117	32.5 ± 6.8	36.6 ± 8.5	<0.001	9.46 ▲
PROMIS Mental Health	118	39.5 ± 7.7	41.1 ± 8.8	.024	5.32 ▲
PROMIS Fatigue	105	46.4±11.0	50.8±13.5	<0.001	8.05 ▲
Headache Impact Test-6 (HIT-6)	111	65.6 ± 6.9	61.1 ± 8.8	<0.001	5.41 ▼
Neck Disability Index	111	22.1 ± 10.7	18.2 ± 11.0	<0.001	12.90 ▼
Dizziness Handicap Inventory	93	44.3 ± 26.3	36.3 ± 24.4	<0.001	19.51 ▼
Tinnitus Handicap Inventory	112	19.6 ± 22.0	18.1 ± 20.3	.406	▼
Rhodes Index of Nausea, Vomiting and Retching (RINVR)	36	7.1 ± 6.6	5.4 ± 4.6	.025	

Table 3. CSF Leak Patient Qualtrics Survey Scores					
Pre Epidural Patches Compared to 1 Month After First patch					
Survey Scores	**N**	**PRE-PATCH Mean ± SD**	**POST-PATCH Mean ± SD**	**P-value**	**% (Median)**
PROMIS Physical Health	118	32.4 ± 6.8	35.4 ± 7.9	<0.001	7.16 ▲
PROMIS Mental Health	118	39.5 ± 7.7	40.4 ± 8.0	.164	0
PROMIS Fatigue	108	46.1 ± 11.1	49.5 ± 12.1	.001	1.18 ▲
Headache Impact Test-6 (HIT-6)	114	65.7 ± 6.8	62.1 ± 8.5	<0.001	3.39 ▼
Neck Disability Index	113	22.4 ± 10.8	19.6 ± 11.3	.001	8.11 ▼
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What is a clinically relevant change on the HIT-6 questionnaire? An estimation in a primary-care population of migraine patients

Antonia FH Smelt[1], Willem JJ Assendelft[1,2], Caroline B Terwee[3], Michel D Ferrari[1] and Jeanet W Blom[1]

Abstract

Objective: To interpret questionnaire scores, clinicians and researchers need to know what change in score reflects a meaningful change in the condition of an individual patient, and what difference reflects a meaningful difference between groups. These values differ between different populations. We determined the within-person minimally important change (MIC) and the between-group minimally important difference (MID) of the Headache Impact Test-6 (HIT-6) questionnaire in a primary-care population of migraine patients.

Methods: We included 490 patients who participated in a clinical trial on the treatment of migraine in primary care. We compared their change scores on the HIT-6 questionnaire between baseline and at three-months follow-up with the answers to two anchor questions according to the 'mean change approach' and the 'ROC curve approach'.

Results: The within-person MIC was estimated to be between −2.5 points (mean change approach) and −6 points (ROC curve approach). The choice for the within-person MIC value depends on the consequences of false positives and false negatives in a particular setting. The between-group MID was estimated at −1.5 points.

Conclusions: We determined the within-person MIC and between-group MID for the HIT-6 in a primary-care population of migraine patients. We recommend the use of these values for clinical care and for research.

Keywords

Migraine, Headache Impact Test (HIT-6), minimally important change, minimally important difference, outcome research

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The minimal clinically important difference of the PROMIS and qDASH instruments in a non-shoulder hand and upper extremity patient population

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[3]University of Utah, Department of Economics, 260 Central Campus Dr #4100, Salt Lake City, UT, United States

Abstract

Purpose—The minimal clinically important difference (MCID) is used in research and clinical settings as a benchmark to gauge response to treatment. The purpose of this study was to provide anchor-based MCID estimates for PROMIS and legacy instruments in a non-shoulder hand and upper extremity population.

Methods—Adult patients (≥ 18 years) seeking care at a tertiary academic outpatient hand surgery clinic completed patient-reported outcome measures on tablet computers between January 2015 and August 2017. Data were collected at baseline and at six ± two weeks of follow-up. The PROMIS Upper Extremity (UE), Physical Function (PF), and Pain Interference (PI) Computer Adaptive Test (CAT) instruments were administered, along with the qDASH. A mean-change anchor-based method was used to estimate MCIDs by comparing scores between anchor groups reporting ‘no change’ versus ‘slightly improved’ in terms of function and pain.

Results—Scores for each instrument significantly improved over the study period. With significant differences in scores between groups reporting ‘no change’ and ‘slightly improved’ function, anchor-based MCID estimates were calculated as follows: 2.1 for the PROMIS UE CAT, 1.7 for the PROMIS PF CAT, and 6.8 for the qDASH. There was no significant difference in PROMIS PI CAT scores between anchor groups when queried for level of pain improvement, precluding estimation of the MCID.

Clinically Meaningful Improvement			
Measure	N	Improved n(%)	Not Improved
HIT-6 (≥-2.5)	113	62 (55)	51 (45)
PROMIS Physical Function(≥2.5)	119	78 (66)	41 (34)

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Research

JAMA Neurology | Original Investigation

Assessing Spinal Cerebrospinal Fluid Leaks in Spontaneous Intracranial Hypotension With a Scoring System Based on Brain Magnetic Resonance Imaging Findings

Tomas Dobrocky, MD; Lorenz Grunder, MD; Philipe S. Breiding, MD; Mattia Branca, MSc; Andreas Limacher, PhD; Pascal J. Mosimann, MD; Pasquale Mordasini, MSc; Felix Zibold, MD; Levin Haeni, MD; Christopher M. Jesse, MD; Christian Fung, MD; Andreas Raabe, MD; Christian T. Ulrich, MD; Jan Gralla, MSc; Jürgen Beck, MD; Eike I. Piechowiak, MD

Cedars Sinai

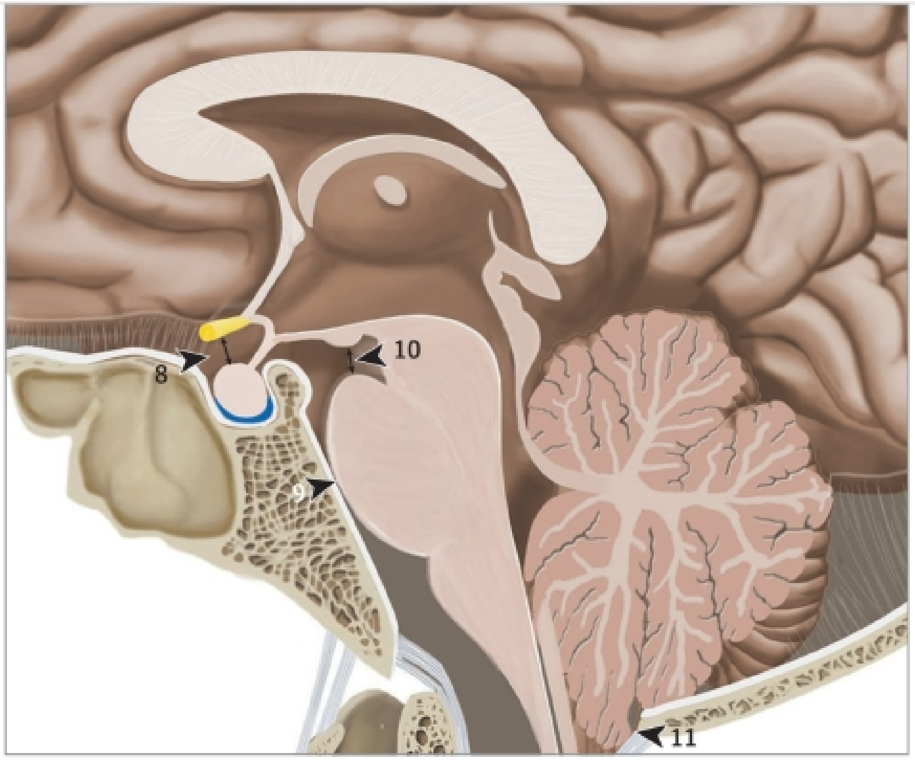

Table 2. Six Imaging Signs With Good Discriminative Power and Interrater Agreement That Were Included in the Final Diagnostic Score and Assigned Score Points

Characteristic	Coefficient (95% CI)	Odds Ratio (95% CI)	*P* Value	Score Points
Engorgement venous sinus	2.95 (1.18-4.72)	19.12 (3.26-112.30)	.001	2
Pachymeningeal enhancement	4.04 (2.50-5.59)	57.01 (12.18-266.78)	<.001	2
Subdural fluid collection	1.54 (−0.10 to 3.17)	4.65 (0.90-23.92)	.07	1
Suprasellar cistern[a]	3.48 (2.36-4.60)	32.32 (10.55-99.02)	<.001	2
Prepontine cistern[b]	1.47 (0.41-2.52)	4.34 (1.51-12.47)	.007	1
Mamillopontine distance[c]	1.13 (0.07-2.19)	3.08 (1.07-8.90)	.04	1

Bern Probability Score	n(%)
Low (≤ 2)	56 (53)
Moderate (3-4)	40 (38)
High (≥ 5)	10 (9)

Bern Criteria (n=106)		
Variable	Positive/Abnormal n (%)	Negative/Normal n (%)
BERN Criteria Measures		
Venous Sinus Engorgement	12 (11.3)	94 (88.7)
Pachymeningeal Enhancement	7 (6.6)	99 (93.4)
Suprasellar Distance ≤ 4 mm	52 (49.1)	54 (50.9)
Subdural Fluid Collection	3 (2.8)	103 (97.2)
Prepontine Distance ≤ 5 mm	75 (70.8)	31 (29.2)
Mamillopontine Distance ≤ 6.5 mm	60 (56.6)	46 (43.4)

MRI Brain: Neuroradiology Assessment vs Bern Score				
		Low (≤2)	Moderate (3-4)	High (≥5)
MRI Brain (Official Read)	Negative	56	39	2
	Positive	0	1	8

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Predictors of PROMIS physical Meaningful Improvement (n=124)				
		Improved	Not Improved	P value
ICHD-3	Positive	17	6	0.32
	Negative	61	36	
Orthostatic Headache	Positive	69	32	0.009
	Negative	9	14	
CSF Protein ≥45	Positive	26	10	0.25
	Negative	37	24	
Opening Pressure ≤ 6	Positive	6	2	1.0 (fishers)
	Negative	57	28	
Bern Criteria	Low (≤2)	33	23	0.048
	Medium (3-4)	33	7	
	High (≥5)	7	3	

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	Medium (3-4)	33	7	
	High (≥5)	7	3	

Predictors of HIT-6 Meaningful Improvement				
		Improved	Not Improved	P value
ICHD-3	Positive	14	9	.284
	Negative	47	50	
Orthostatic Headache	Positive	54	47	.106
	Negative	8	15	
CSF Protein ≥45	Positive	18	18	.938
	Negative	30	31	
Opening Pressure ≤ 6	Positive	5	3	0.72 (fishers)
	Negative	44	41	
Bern Criteria	Low (≤2)	25	31	0.287
	Medium (3-4)	24	16	
	High (≥5)	6	4	

Predictors of HIT-6 Meaningful Improvement				
		Improved	Not Improved	P value
ICHD-3	Positive	14	9	.284
	Negative	47	50	
Orthostatic Headache	Positive	54	47	.106
	Negative	8	15	
CSF Protein ≥45	Positive	18	18	.938
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	High (≥5)	6	4	

Conclusions and Caveats?

“ First Do No Harm”

"Harm"

A reduction in patient quality of life that can be objectively measured.

First Type of Harm

1: Harm through my positive action that causes a new or worsened problem reducing quality of life.

- e.g., I do a blood patch on someone who I incorrectly identify as having a CSF leak- resulting in back pain.

This happens.

Second Type of Harm

2. Harm through my positive action aborting a patient’s pursuit of (what would otherwise have been) beneficial therapy.

e.g., a patient with a real and fixable leak sees me and I incorrectly tell them they do not have a CSF leak- closing their access to that treatment.

This happens too.

I believe the data shown here suggests (but does not prove) we are overweighting the first kind of harm at the expense of unnecessarily increasing the second kind of harm.