Impact of Subjective Evaluations in Predicting Response to Ventriculoperitoneal Shunt for Idiopathic Normal Pressure Hydrocephalus

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■ BACKGROUND: **Cerebrospinal fluid tap test is a common procedure to predict the efficacy of ventriculoperitoneal shunt for idiopathic normal pressure hydrocephalus. Objective tests after cerebrospinal fluid tap test are used to establish the surgical indication, but subjective improvements may also be important in selection of surgical candidates. The aim of this study was to evaluate surgical outcomes of patients with ventriculoperitoneal shunt for idiopathic normal pressure hydrocephalus, comparing patients showing objective improvement with patients improving only on subjective assessments.**

■ METHODS: **In this retrospective analysis, patients were divided into 2 groups: group 1 included patients with improvement on objective evaluation after cerebrospinal fluid tap test; group 2 included patients who showed only subjective improvement. The surgical outcomes of the 2 groups were compared.**

■ RESULTS: **Of 28 included patients, 17 were objective responders (group 1), and 11 were subjective responders (group 2). Clinical and radiological characteristics were similar. The only significant difference was the baseline Berg Balance Scale, which was lower in objective responders ($P = 0.0015$). At 3 months after surgery and at last follow-up, there was no difference in surgical outcomes between the 2 groups. However, in the group of subjective responders, a continuous improvement for incontinence and gait was more frequently observed ($P = 0.04$ and $P < 0.001$, respectively).**

■ CONCLUSIONS: **Surgical outcomes after ventriculoperitoneal shunt were similar between the 2 groups, with a more favorable trend in terms of symptom improvement for subjective responders. Subjective assessment seems to be an important factor to consider in preoperative evaluation.**

INTRODUCTION

Idiopathic normal pressure hydrocephalus (iNPH) is a frequently encountered neurological disorder affecting approximately 6% of adults >80 years old.[1] It is characterized by a typical clinical combination of gait disorders, cognitive decline, and urinary incontinence, known as Hakim's triad, and is associated with ventriculomegaly and no evidence of cerebrospinal fluid (CSF) outflow obstruction on brain imaging.[2-4] The etiology of iNPH is not known[4,5]; it can occur secondary to different mechanisms, such as abnormal CSF dynamics, vascular disease, and hereditary factors.[4-6] Owing to the variable presentation of the disease and frequent comorbid conditions, such as Alzheimer disease or vascular encephalopathy, the diagnosis may be delayed and difficult to establish.

The CSF tap test, with drainage of 30–50 mL of CSF, is a common procedure to assess reversibility of symptoms.[7] Different tests may be used to evaluate the improvement of gait, balance, and cognition after a tap test, such as the Timed Up and Go

Key words
- Berg balance scale
- Normal pressure hydrocephalus
- Subjective assessment
- Surgery
- Ventriculoperitoneal shunt

Abbreviations and Acronyms
BBS: Berg Balance Scale
CSF: Cerebrospinal fluid
iNPH: Idiopathic normal pressure hydrocephalus
VP: Ventriculoperitoneal

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test, Tinetti Performance Oriented Mobility Assessment, Berg Balance Scale (BBS), and 10-m walk test.[8] These measures are considered objective assessments. Subjective improvements, namely, self-assessments from patients themselves and/or their families, may also have a role in the decision-making algorithm.[9,10]

Permanent CSF diversion by ventriculoperitoneal (VP) shunt is the mainstay of treatment, with a favorable postoperative outcome in >70% of cases.[11] Despite a large number of studies, reliable predictors of favorable outcomes after shunt surgery are still debated.[5,12-17] Furthermore, surgery is associated with an overall complication rate of approximately 20%, with 16% shunt revision rate, 3% infection, 6% subdural hematoma, and 1% mortality.[11] Literature addressing the role of subjective evaluation after the CSF tap test to predict the response to VP shunt is scarce. The aim of this study was to evaluate the surgical outcomes of a cohort of patients with VP shunt for iNPH, comparing patients showing improvement on objective testing and patients improving only on subjective assessments after CSF tap test.

MATERIALS AND METHODS

Study Design

We performed a retrospective analysis of patients undergoing VP shunt surgery for iNPH at the University Hospital of Lausanne between January 2007 and December 2018. The local ethics committee approved the study protocol. We evaluated all patients clinically with gait and cognition assessment and radiologically with a computed tomography scan of the brain or, if possible, with a 1.5T or 3T magnetic resonance imaging scan. In cases in which iNPH was suspected, a CSF tap test was performed with drainage of 30–40 mL of CSF. Objective evaluation using the BBS, was performed before and 4 hours after CSF tap test (Figure 1). The same team of physical therapists performed all the tests. We then separated our cohort of patients into 2 groups. Group 1 included patients with an improvement on objective evaluation after CSF tap test, defined as an improvement of at least 4 points on the BBS between the pre–CSF tap test and the post–CSF tap test evaluations.[8] Group 2 included patients who showed only a subjective improvement, defined as an improvement of gait, cognitive dysfunction, or incontinence according to the patient or family members, measured through specific closed-ended questions (Figure 2). Furthermore, we collected impressions of patients and family members regarding independence in daily activities, gait, cognition, and continence. These subjective impressions were routinely recorded in patients' medical records by the members of the neurosurgical team performing the procedure. No improvement on objective tests was present in group 2, whereas a subjective improvement could be present in group 1.

When we detected an objective (group 1) or a subjective (group 2) improvement after the CSF tap test, we recommended a VP shunt to the patient. The following patients were excluded: patients who had a VP shunt for another pathology or another type of hydrocephalus, patients with no preoperative CSF tap test, and patients for whom the results of objective tests and subjective assessments after CSF tap test were not available. We also excluded patients with no objective or subjective improvements after the CSF tap test.

VP Shunting Protocol

Patients admitted for a VP shunt procedure were hospitalized for 1 night for clinical observation and radiological evaluation with a cerebral computed tomography scan to verify the absence of hematoma and other postoperative complications and the position of the ventricular catheter. Cervical and abdominal x-rays were obtained to verify the valve and the position of the distal catheter. Patients were discharged on day 1, with a first follow-up visit at 4 weeks after surgery. The timing for subsequent follow-up depended on symptomatic improvement, postoperative complications, and need for adjustments of the pressure of the valve. In general, follow-up visits were scheduled at 3, 6, and 12 months after surgery.

Clinical responses to VP shunt were assessed with basic cognitive evaluations and visual evaluation of gait and balance. Incontinence was assessed with specific closed-ended questions. Epidemiological data, clinical presentation, radiological features with preoperative and postoperative ventriculomegaly (Evans

Category	Component	Score
Sitting balance	Sitting unsupported	0-4
Standing Balance	Standing unsupported	0-4
	Standing with eyes closed	0-4
	Standing with feet together	0-4
	Standing on one feet	0-4
	Turning to look behind	0-4
	Retrieving objects from floor	0-4
	Tandem standing	0-4
	Reaching forward woth an outstretched arm	0-4
Dynamic balance	Sitting to standing	0-4
	Standing to sitting	0-4
	Transfer	0-4
	Turning 360 degrees	0-4
	Stool stepping	0-4
Total		0-56

Figure 1. Berg Balance Scale categories, components, and possible scores.

A Short FES-I Survey

We would like to ask you a few questions to determine if you are worried about the possibility of falling.
Respond by thinking about how you usually do this activity.
If you are not currently doing this activity, answer the question by imagining how worried you would be if you were actually doing this activity.
For each of the following activities, put a cross in the box that most closely matches your opinion and shows the level of concern you feel about being able to fall while carrying out this activity.

		Not worried at all 1	A little worried 2	Quite worried 3	Very worried 4
1	To dress and undress				
2	To take a shower or bath				
3	To get up from a chair or to sit down				
4	To go up or down stairs				
5	To reach for something above your head or on the ground				
6	To descend or ascend a slope				
7	To go out (family reunion, religious service, meeting with an association, etc.)				

Figure 2. Two surveys that were used as part of the subjective assessment to evaluate the patient's perception of the risk of falling (**A**) and the impact of urinary loss on daily activities (**B**). These surveys were used before and after cerebrospinal fluid tap test to assess if any improvement was present after surgery. FES-I, Falls Efficacy Scale—International; ICIQ, International Consultation on Incontinence Questionnaire.
(Continues)

index), surgical complications, and follow-up clinical outcomes at 3 months and at last follow-up after surgery were collected. Clinical outcomes were recorded as symptomatic improvement (compared with baseline for the evaluation at 3 months or the last follow-up performed), stability, or worsening.

Statistical Analysis

We performed statistical analysis of the data with Stata/IC 16.1 software (StataCorp, College Station, Texas, USA). We summarized all variables using the frequency and percentage of each category and mean and standard deviation for continuous variables. We used the t test to compare the 2 groups when a normal distribution was observed or Kruskal-Wallis test and Wilcoxon signed-rank test when the distribution of the data was not normal. For categorical variables, the χ^2 test was used. All analysis was performed on an intention-to-treat basis, and significance level was 2-sided $\alpha = 0.05$.

RESULTS

During the study period, we performed 204 CSF tap tests; 28 patients (13.7%) underwent VP shunt surgery and were included in

B

ICIQ Survey

Many people lose their urine from time to time.

We are trying to find out how many people have urine loss and how much it bothers them.

Please answer the following questions thinking about your case and how many times you had urine loss on average over the LAST FOUR WEEKS.

1. How often did you have urine loss? (Check one only):

Never	0
About once a week maximum	1
Two to three times a week	2
About once a day	3
Several times a day	4
All the time	5

2. We would like to know the amount of your urine loss, according to your estimate. What is your usual amount of urine loss (with or without protection)? (Check one only):

No urine loss	0
A small amount	2
A moderate amount	4
A large quantity	6

3. In general, how much does your urine loss bother you in your daily life?

Circle a number between 0 (not at all) and 10 (very much):

0 1 2 3 4 5 6 7 8 9 10

Not at all Really much

4. When do you have urine loss? (Check all that apply to you):

You never lose urine	0	
You leak urine before you can get to the toilet	1	
You leak urine when you cough or sneeze	2	
You leak urine when you sleep	3	
You leak urine when you are physically active or when you do exercises	4	
You leak urine when you have finished urinating and you have dressed again	5	
You leak urine with no apparent cause	6	

Figure 2. (*continued*).

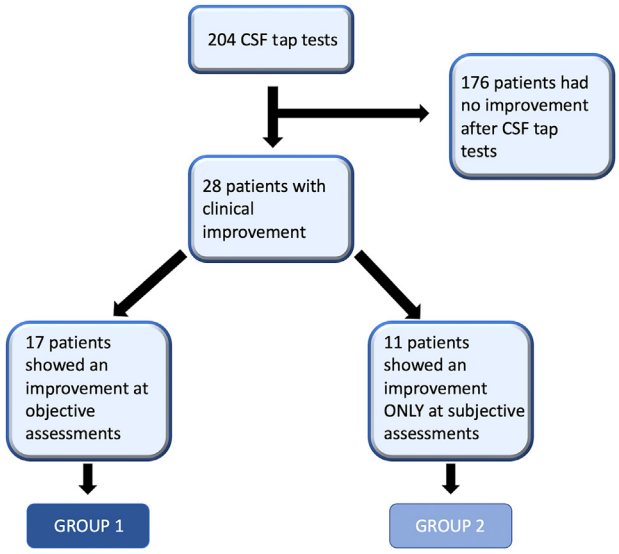

Figure 3. Flow chart showing the process of patient selection. Group 1 included patients showing an improvement on objective assessments (Berg Balance Scale) after cerebrospinal fluid tap test, with or without associated subjective improvements. Group 2 included only patients with a subjective assessment after cerebrospinal fluid tap test. CSF, cerebrospinal fluid.

this study. The objective responders group (group 1) contained 17 patients, and the subjective responders group (group 2) contained 11 patients (Figure 3). Clinical and radiological characteristics were similar between the 2 groups (Table 1). All patients included in the study described a subjective improvement in gait after the CSF tap test. Among the subjective responders, 6 of 10 patients (60%) also described an improvement in gait after the CSF tap test associated with an improvement of at least 1 other symptom of the classic triad versus 29.4% of objective responders (5 of 17). This difference was not statistically significant ($P = 0.12$). The only statistically significant difference between the 2 groups was the baseline BBS before the CSF tap test, which was lower (27 of 56) in the objective responders than the subjective responders (45 of 56) ($P = 0.0015$) (Table 1).

At 3 months after surgery, there was no difference between the 2 groups in terms of rate of improvement for gait and balance, cognitive performance, and incontinence. When we evaluate the outcomes at last follow-up (median of 30.5 months for group 1 and of 40 months for group 2), the rate of symptomatic improvement of the classic triad was similar. However, in the group of subjective responders, a continuous improvement for incontinence and gait was observed more frequently than in the group of objective responders ($P = 0.04$ and $P < 0.001$, respectively) (Table 2). This means that subjective responders continued to experience improvement in their symptoms during the whole follow-up period, while many objective responders did not experience continued improvement after an initial postoperative improvement (Figure 4).

Combining the 2 groups, a positive response to the CSF tap test at objective and/or subjective assessments predicted a favorable response to shunting of at least 1 symptom of the classic triad in 89% of patients in the postoperative period. The rates of postoperative complications and surgical revision were also similar between the 2 groups of patients (Table 1). The average preoperative and postoperative Evans index at 3 months after surgery was similar between the 2 subgroups (Table 1), and a significant ventricular size reduction was observed in only 4 of 19 patients (21%) among shunt responders with a reduction of Evans index to <0.3 postoperatively. Therefore, we found no correlation between clinical improvement and ventricular size.

DISCUSSION

Our study shows how preoperative evaluation is crucial for the management of patients with iNPH to optimize the selection of surgical candidates. An interesting point is that even patients with no improvement on objective tests such as the BBS, but with improvement on subjective assessment, could benefit from a VP shunt.[10] Indeed, our results showed that an improvement on subjective assessment was associated with a favorable response to VP shunt in >90% of cases in terms of symptomatic improvement. These results are in accordance with other studies that claim the value of subjective assessments.[10,18] Moreover, even if subjective responders showed results similar to objective responders at 3 months and at last follow-up after surgery (mean 34.4 months), they continued to show improvement between these 2 timelines in terms of incontinence and gait, while the objective responders did not show continued improvement in symptoms. This difference was statistically significant, and it could probably be attributed to the fact that the group of subjective responders had a better BBS before the CSF tap test than the cohort of objective responders. This could indicate that the former group had a better clinical status at diagnosis, while the latter presented with more advanced disease. This factor could reflect the fact that patients with more advanced disease may show an inferior rate of symptomatic improvement even after surgery and that early diagnosis is key to optimizing the surgical outcome. Indeed, treatment delay increases the mortality associated with untreated iNPH.[3,11]

According to different studies, the sensitivity of the CSF tap test is 72%–100%, and the specificity is 33%–100%, but it remains a valid initial test to help in predicting the response to shunt for patients with iNPH.[7,13,19,20] On the other hand, objective assessments commonly used to evaluate the response to LP, such as the BBS, may lack sensitivity to detect slight changes and dynamic measurements, and this might be accentuated with a higher value at first evaluation, corresponding to a better clinical status.[10,21,22] Recently, some authors are suggesting the use of inertial sensors to evaluate gait ataxia and improve the tap test prediction capacity[23,24] as a complement to gait tests.

Table 1. Epidemiological and Clinical Data of Patients

Characteristics	Subjective Responders	Objective Responders	*P* Value
Number of patients	11	17	
Sex, male	6 (54.54%)	8 (47.06%)	0.69
Age at diagnosis, years	73.63 (6.60)	70.94 (10.2)	0.44
Age at surgery, years	73.81 (6.86)	71.58 (10.39)	0.54
Clinical presentation			
Classic triad presentation	5 (45%)	11 (65%)	0.31
Gait disorder	11 (100%)	17 (100%)	1
Cognitive disorder	9 (81.80%)	14 (82.36%)	0.97
Incontinence	5 (45.45%)	13 (76%)	0.09
Medical comorbidity			
Hypertension	3 (27.27%)	7 (41.18%)	0.45
Periventricular leukoencephalopathy	1 (9.10%)	4 (23.53%)	0.33
Alzheimer disease	1 (9.10%)	1 (5.88%)	0.75
Polyneuropathy	2 (18.18%)	2 (11.76%)	0.64
Type 2 diabetes mellitus	1 (9.10%)	4 (23.53%)	0.33
Dementia	2 (18.18%)	4 (23.53%)	0.74
Objective assessment and CSF tap test			
BBS before CSF tap test	45.14 (8.67)†	27 (11.57)‡	0.0015*
BBS after CSF tap test	47.15 (7.87)§	38.8 (10.16)‖	0.07
Subjective assessment after CSF tap test			
Improvement in gait	10/10 (100%)¶	17 (100%)	1
Improvement in gait and at least 1 other symptom of classic triad	6/10 (60%)¶	5 (29.41%)	0.12
Surgical complications			
Infection rate	1/11 (9.1%)	0 (0%)	0.20
Revision rate	3/11 (27%)	1/17 (5.9%)	0.11
Follow-up, months	40 (31.1)	30.3 (29.2)	
Radiological characteristics			
Mean Evans index, preop	0.38 (0.05)	0.37 (0.06)	0.61
Mean Evans index, 3 months postop	0.36 (0.07)	0.34 (0.08)	0.54
Significant ventricular size reduction, 3 months postop	1/8 (12.50%)	3/14 (21.43%)	0.52

Data are expressed as mean (SD) for continuous variables and as number of patients (%) for categorical variables. Data were missing for some categories. For continuous variables, details are reported in footnotes. For categorical variables, correct denominator is presented in table.
CSF, cerebrospinal fluid; BBS, Berg Balance Scale; preop, preoperative; postop, postoperative.
*Statistically significant difference between the 2 groups ($P < 0.01$).
†BBS before tap test not reported in 4 patients.
‡BBS before tap test not reported in 2 patients.
§BBS after tap test not reported in 4 patients.
‖BBS after tap test not reported in 2 patients.
¶Subjective assessment after tap test not reported in 1 patient.

Similar to objective assessments, subjective evaluations have limitations. They depend mainly on the perception of the patients and their relatives as well on their degree of awareness and are therefore individually biased. In addition, subjective data collection may be reported and perceived differently among caregivers, which further increases the bias. There may be over- or under-

Table 2. Surgical Outcomes After Ventriculoperitoneal Shunt

VP Shunt Responsiveness	Subjective Responders	Objective Responders	*P* Value
Shunt Responsiveness at 3 Months	11 Patients	16 Patients	
Cognitive improvement	3/11 (27.27%)	5/16 (31%)†	0.82
Incontinence improvement	5/11 (45.45%)	7/16 (43.75%)‡	0.93
Gait improvement	10/11 (90.91%)	14/16 (87.50%)‡	0.78
Improvement in ≥2 symptoms	7/11 (63.64%)	9/16 (56.25%)‡	0.70
Improvement in any symptoms	10/11 (90.91%)	14/16 (87.50%)‡	0.78
Shunt Responsiveness at Last Follow-Up	10 Patients	14 Patients	
Cognitive improvement	5/10 (50%)	7/14 (50%)	1
Incontinence improvement	9/10 (90%)	10/13 (77%)	0.6
Gait improvement	9/10 (90%)	11/14 (78.6%)	0.61
Further cognitive improvement during time line	4/10 (40%)	3/14 (21.4%)	0.4
Further incontinence improvement during time line	6/10 (60%)	2/13 (15.4%)	0.04*
Further gait improvement during time line	7/10 (70%)	0/14 (0%)	0.0003*
Shunt nonresponders	1/11 (9.09%)	2/16 (12.50%)‡	0.78

Data are expressed as number of patients (%) for categorical variables.
VP, ventriculoperitoneal.
*Statistically significant difference was found between the 2 groups when considering patients showing a continuous improvement between the first follow-up at 3 months after surgery and the last follow-up ($P < 0.05$), in favor of the subjective responders. This means that subjective responders continued to experience improvement in symptoms during the whole follow-up period, while many objective responders did not experience continued improvement after initial postoperative improvement.
†Shunt responsiveness not reported in 1 patient.
‡The shunt responsiveness not reported in 1 patients.

reporting leading to false-positive and false-negative results, respectively.[10] It is therefore relevant to assess improvement of patients' symptoms with a dedicated questionnaire frequently after a CSF tap test to limit false-negative results.[9] This assessment should focus on the improvement of gait, as this symptom is the most responsive to surgery (80%–88%), while cognitive symptoms and incontinence are responsive in only 30%–65% and 30%–56% of cases, respectively.[2,4,5] In our study, gait instability was the symptom most responsive to surgery, while cognitive symptoms and incontinence improved in a more limited percentage of cases. Our results are consistent with those found in the literature.[5,25,26] Despite tetraventricular

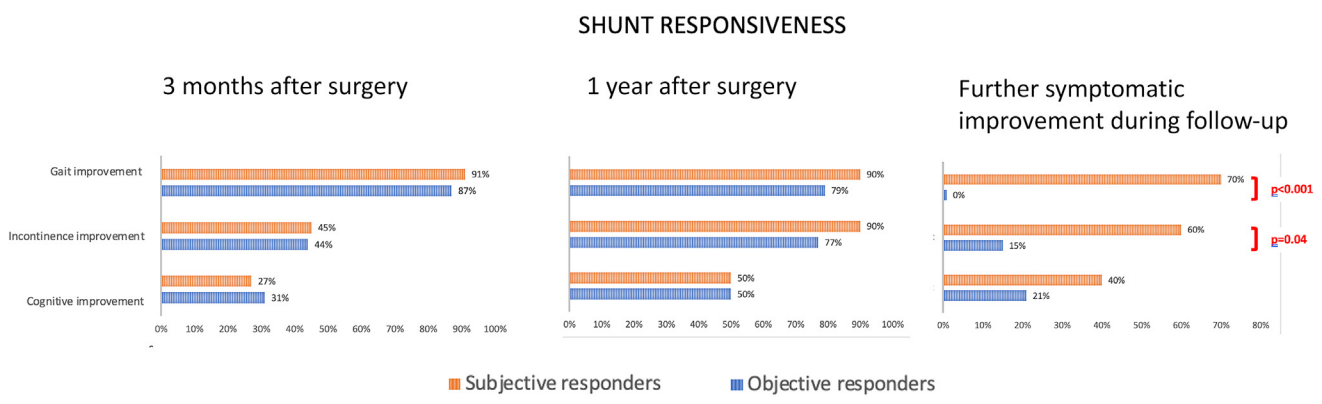

Figure 4. Surgical outcomes after surgery. The only significant difference between the 2 groups was reported when considering the portion of patients showing a continuous improvement during the follow-up period for gait and incontinence.

dilatation in all our patients, only 21% of shunt responders had a significant reduction in ventriculomegaly, and this suggests that reduction in ventriculomegaly is not predictive of clinical improvement postoperatively, as previously reported in other studies.[9]

The main limitation of this study is the small number of patients included, which is due to the retrospective design of the study. This could prevent the identification of possible factors such as specific patient characteristics or comorbidities to predict a clinical response in patients experiencing an improvement in classic triad symptoms (objective and/or subjective) after a CSF tap test and could limit our analysis of comorbidities and disease duration before treatment. Moreover, the BBS after the CSF tap test was performed only 4 hours after CSF withdrawal and not repeated at 24–48 hours as suggested by some authors,[27] and this might also limit the power of our analysis. Further prospective multicentric studies investigating patients with iNPH will be necessary to support the findings of this study.

CONCLUSIONS

The surgical outcomes after VP shunt in objective and subjective responders were similar, with a more favorable trend in terms of improvement of postoperative symptoms for subjective responders. This implies that subjective assessment is important in the preoperative evaluation of patients with iNPH, and it would be appropriate to consider a subjective assessment through a dedicated questionnaire to improve the identification of shunt responders and the medical care of this disease.

CRediT AUTHORSHIP CONTRIBUTION STATEMENT

Mahmoud Messerer: Formal analysis, Writing — original draft. **Marius Blanchard:** Formal analysis, Writing — original draft. **Kyriakos Papadimitriou:** Formal analysis, Writing — original draft. **Alberto Vandenbulcke:** Investigation, Formal analysis. **Dionys Rutz:** Formal analysis. **Valerie Beaud:** Formal analysis. **Ehab Shiban:** Writing — review & editing. **Julien Bally:** Writing — review & editing. **Gilles Allali:** Writing — review & editing. **Roy T. Daniel:** Writing — review & editing. **Giulia Cossu:** Conceptualization, Writing — original draft, Writing — review & editing, Supervision.

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Marius Blanchard and Kyriakos Papadimitriou equally contributed to the redaction of this paper and are considered as co–second authors.

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