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Shunt options for normal pressure hydrocephalus: a comparison of complications, overdrainage rates and neurological outcomes between integra low flow regulated and Codman Hakim programmable shunts

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ABSTRACT

Aims: Shunt surgery is the most commonly performed treatment for idiopathic normal pressure hydrocephalus, and shunt systems with different operating principles are employed. This study aimed to retrospectively compare programmable ventriculoperitoneal shunts and flow-regulated shunts in terms of complications, overdrainage rates, and neurological outcomes.

Methods: Between January 2020 and May 2022, 44 patients who underwent shunt operation with a diagnosis of idiopathic normal pressure hydrocephalus at our clinic were retrospectively analyzed. Patients were categorized into two groups: the programmable ventriculoperitoneal shunt and the flow-regulated shunt group. Demographic characteristics, complications, rates of insufficient drainage/overdrainage, and surgical outcomes were compared.

Results: There were 26 patients in the programmable ventriculoperitoneal shunt group and 18 patients in the flow-regulated shunt group. In the programmable ventriculoperitoneal shunt group, 14 patients (53.8%) required 27 shunt setting adjustments owing to excessive or inadequate drainage. Subdural effusion was observed in five patients (19.2%), and shunt revision was performed in one patient (3.8%). Subdural effusion was observed in two (11.1%) patients in the flow-regulated shunt group. One of these patients (5.5%) underwent shunt revision. There was no significant difference between the groups in terms of the development of subdural effusion and need for shunt revision ($p>0.05$). The rate of improvement in at least one of the symptoms was 53.8% in the programmable ventriculoperitoneal shunt group at the 1st-month postoperative outpatient follow-up. In the flow-regulated shunt group, this rate was 72.2% and there was no statistically significant difference. Both groups showed similar clinical improvement at the 1-year follow-up.

Conclusion: There was no difference between the groups in terms of neurological outcomes and the need for shunt revision. However, the use of flow-regulated shunts has demonstrated earlier rates of clinical improvement without the need for reprogramming.

Keywords: Idiopathic normal pressure hydrocephalus, overdrainage, flow-regulated valve, programmable valve

INTRODUCTION

Idiopathic normal pressure hydrocephalus (iNPH) is a chronic hydrocephalus syndrome characterized by balance and gait disturbances, cognitive dysfunction, and urinary incontinence.[1] iNPH is a form of dementia that can be effectively treated with shunt surgery.[1–4] However, surgical failure and complications are not uncommon.

One of the most critical factors influencing the surgical success in patients with iNPH is the accurate selection of the shunt valve used. In recent years, programmable ventriculoperitoneal shunts (PVS) utilizing differential pressure valves have become the most commonly used shunt types for iNPH.[5,6] The major advantage of PVS is the capability to adjust the opening pressure noninvasively using an external magnetic field.[5–7] However, the valve pressure is affected by magnetic fields (e.g., during a MRI).[8–11] In addition close patient follow-up is needed.

These disadvantages of PVS can be overcome by using flow-regulated shunt valves (FRS). The FRS possesses a mechanism that can self-regulate constant drainage rates independent of patient position and differential pressure.[12–15] The FRS do not require repeated pressure adjustments during patient follow-up.[12,13,15,16] FRS are not associated with the risk of changing opening pressures after exposure to magnetic fields.[15,17]

This study aimed to retrospectively compare PVS and FRS used in the surgical treatment of iNPH in terms of neurological outcomes, complications, and overdrainage rates.

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METHODS

The study was carried out with the permission of Ethical Committe of Medicana Bursa Hospital (Date:06.07.2023, Decision No: 03/2023). All procedures were carried out in accordance with the ethical rules and the principles of the Declaration of Helsinki. In our study, we retrospectively reviewed 44 adult patients who underwent shunt placement surgery with a diagnosis of iNPH between January 2020 and May 2022 at our department. Age, sex, symptoms, neurological examination findings, intraoperative and postoperative complications, and early and late postoperative outpatient follow-up data of the patients were assessed.

During the inclusion period, patients who presented with at least two symptoms of Hakim's triad (gradual gait disturbance, cognitive impairment, and urinary incontinence) were diagnosed with iNPH in accordance with clinical guidelines and radiological examinations.

Gait disturbance was assessed using the 10-meter walk test, and dementia was assessed using the Mini-Mental State Examination (MMSE). Urinary continence was assessed via interviews with patients and/or their caregivers.

For radiological examination, all patients underwent brain MRI, CSF flow MRI, and CT imaging. The Evans index was calculated in each patient by dividing the maximum width between the frontal horns of the lateral ventricles by the distance between the two inner tabulae. Patients with an Evans index of <0.30 were excluded from the study.

All patients displayed ventriculomegaly in their MRIs. Patients with a history of head trauma, intracranial hemorrhage, stroke, meningitis, or primary malignancy were excluded. Additionally, seven patients with insufficient examination data owing to technical reasons were not included in the study.

A ventriculoperitoneal shunt was placed in all patients. Surgical decisions were supported by an assessment of gait after a lumbar tap test, which involved draining 40 ml of CSF via lumbar puncture. Recovery after lumbar puncture was defined as subjective improvement reported by patients themselves and/or family members.

Ventriculoperitoneal Shunting Protocol

The surgical procedure involved the insertion of a ventricular catheter via a burr hole in the right frontal Kocher's point and the placement of a peritoneal catheter via a midline or paraumbilical mini laparotomy. Since programmable valves were regularly utilized in our clinic before 2021, Codman programmable valves (Johnson and Johnson, MA, USA) were employed for patients with iNPH prior to that year (PVS group). The Integra® NPH Low Flow Valve (Integra Life Sciences Services, Lyon, France) was used in the patient group diagnosed after 2021 (FRS group).

Brain CT and/or MRI scans were conducted routinely on the first postoperative day to verify the proper positioning of the ventricular catheter and during each postoperative follow-up visit to rule out radiological indications of excessive drainage. The patients attended follow-up visits on day 15; at 1, 3, 6, and 12 months; and subsequently on an annual basis. Complications and readmissions associated with the ventriculoperitoneal shunting procedure were documented.

Assessment of Shunt Response

The shunt response was assessed during outpatient follow-up visits at the neurosurgery clinic following the shunt surgery. A 20% improvement in the 10-meter walk test was considered significant. An increase of ≥2 in the MMSE score was considered significant. Owing to the retrospective design of the study, postoperative objective measures of gait and cognition were only available in approximately 80% of the patients. For the remaining patients, scores were acquired via interviews with the patients and/or their caregivers. Improvement in at least one symptom of the hakim's triad was considered significant for clinical improvement.

Statistical Analysis

Continuous variables were expressed in terms of mean ± standard deviation. Moreover, two-way anova was used for comparisons between the two groups according to normality test results. Categorical variables were presented as frequency and percentage values [n (%)] and compared using the pearson chi-square test. Statistical analysis was performed using GraphPad Prism 10 (GraphPad Software, San Diego, CA, USA). A p value of <0.05 indicated statistical significance.

RESULTS

The PVS group included 26 patients (14 men and 12 women). There were 18 patients (11 men and 7 women) in the FRS group. Men and women were equally distributed between the groups. The mean age was 60.3±15.4 years in the PVS group and 67.05±11.73 years in the FRS group. There was no significant difference between the groups in terms of age (p>0.05)

The presenting symptoms, general demographic characteristics and clinical status of patients with iNPH are presented in Table 1. The rate of improvement in at least one of the symptoms was 53.8% in the PVS group at the 1st-month postoperative outpatient follow-up.

In the FRS group, this rate was 77.7% and there was no statistically significant difference compared to the PVS group. However, in the PVS group, the clinical improvement rates of the patients exhibited a significant difference between the 1st-month and 3rd month control visits (p <0.05). After 3 months, there was no difference in clinical improvement despite pressure adjustment.

In patients undergoing FRS placement, there was no significant difference in the rate of clinical improvement between the 1st-month and 1-year control visits (p>0.05). During a mean follow-up period of 37.8±27.1 months (42.4 ± 30.2–29±20.4 months), 21 (80.8%) patients in the PVS group exhibited improvement in at least one of the iNPH symptoms. This rate was 77.7% in the FRS group. Both groups showed similar clinical improvement at the 1-year follow-up (p>0.05)

(Table 2) (Figure 1). In 14 patients (53.8%) in the PVS group, shunt settings required adjustment for a total of 27 times. Nine (34.6%) patients underwent shunt adjustment at least once owing to insufficient drainage and five (19.2%) patients owing to subdural effusion/hematoma formation (Table 3). In three (11.5%) patients, shunt pressure changes were insufficient and required subdural drainage. In two (7.7%) patients, subdural effusion resolved completely after pressure elevation (Figure 2). Two patients (7.7%) underwent shunt revision because of inadequate clinical improvement. Subdural effusion was observed in two (11.1%) patients in the FRS group.

Table 1. General demographic characteristics and clinical status of patients with idiopathic normal pressure hydrocephalus (iNPH) treated with programmable and flow-regulated shunt.

Variables	PVS (n=26) (%)	FRS (n=18) (%)
Sex		
Female	14 (53.8)	11 (61.1)
Male	12 (46.2)	7 (38.9)
Mean Age ± SD, Years	60.3 ± 15.4	67.1 ± 11.7
Symptoms at Presentation		
Dementia	23 (88.5)	17 (94.4)
Gait disturbance	24 (92.3)	18 (100)
Urinary incontinence	21 (80.8)	15(83.3)
Headache	9 (34.6)	7 (38.8)
Dizziness	3 (11.5)	4 (22.2)
Nausea/vomiting	1 (3.8)	2 (11.1)
Mean Duration of Symptoms ± SD, Months		
Dementia	28.8 ± 45.5	22.3 ± 33.1
Gait disturbance	17.2 ± 24.9	21.3 ± 35.5
Urinary incontinence	15.7 ± 21.6	13.7 ± 30.6
Comorbidities		
Diabetes	11 (42.3)	11 (42.3)
HT	15 (57.7)	15 (57.7)
Coronary artery disease	5 (19.2)	5 (19.2)
Thyroid goiter	2 (7.7)	2 (7.7)
Parkinson	3 (11.5)	3 (11.5)
Alzheimer's disease	2 (7.7)	2 (7.7)
Cerebrovascular disease	1 (3.8)	1 (3.8)

FRS: Flow-regulated shunt, PVS: Programmable ventriculoperitoneal shunt, Standard deviation

Table 2. Clinical improvement rates during follow-up in patients with idiopathic normal pressure hydrocephalus (iNPH) treated with programmable and flow-regulated shuns. There was no statistically significant difference between the clinical improvement rates in both groups.

Follow-up period	PVS (n=26) (%)	FRS (n=18) (%)	p value
Postoperative 15th day	12 (46.1)	11 (61.1)	0.7319
Postoperative 1st month	14 (53.8)	14 (77.7)	0.5211
Postoperative 3rd month	20 (76.9)	14 (77.7)	0.6554
Postoperative 6th month	20 (76.9)	14 (77.7)	0.6554
Postoperative 1st year	21 (80.7)	14 (77.7)	0.5788

FRS: Flow-regulated shunt, PVS: Programmable ventriculoperitoneal shunt

One of these patients (5.5%) required subdural drainage, and this patient underwent shunt revision. In the FRS group, one patient (5.5%) underwent shunt revision owing to insufficient drainage. There was no statistically significant difference between the groups in terms of the development of subdural effusion and need for shunt revision (p >0.05).

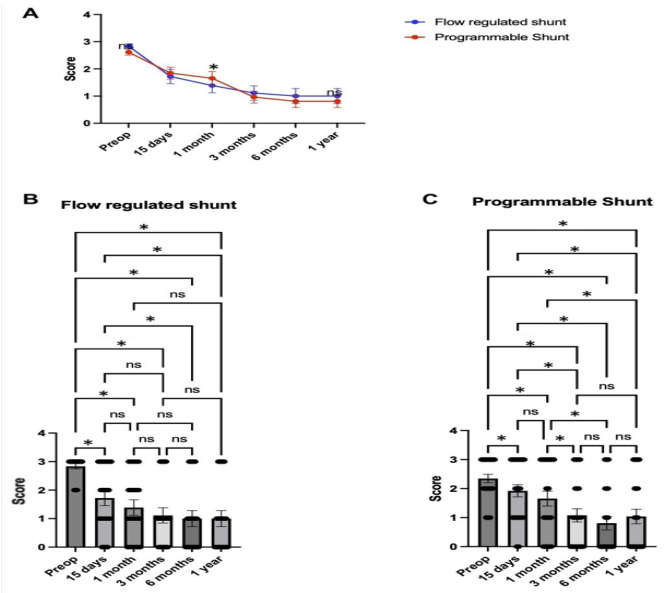

Figure 1. Comparison of clinical improvement rates of patients in PVS and FRS groups during 1-year follow-up.
FRS: Flow-regulated shunts, PVS: Programmable ventriculoperitoneal shunts , * Statistically significant (p<0.05) , ns: Not significant
Score: Each symptom of the Hakim's triad (gradual gait disturbance, cognitive impairment, and urinary incontinence) was scored 1 point and improvement in at least one symptom was considered significant for clinical improvement (maximum score: 3 (no improvement) and minimum score: 0 (complete improvement)).
A: Comparison of clinical improvement rates of patients in PVS and FRS groups during 1-year follow-up. Both groups showed similar clinical improvement at the 1-year follow-up.
B: Clinical improvement rates of FRS shunt patients during the follow-up period. FRS patients showed statistically significant improvement compared to the preoperative period in all follow-up periods. However, there was no significant difference between the clinical improvement rate at 1-month follow-up and the clinical improvement rate at the end of 1 year.
C: Clinical improvement rates of PVS shunt patients during the follow-up period. PVS patients showed statistically significant improvement compared to the preoperative period at all follow-up periods. However, there was no significant difference between the clinical improvement rate at the 3-month follow-up and the clinical improvement rate at the end of 1 year. During the follow-up period, recovery rates changed statistically significantly during the first 3 months, but no significant change was found after the 3rd month.

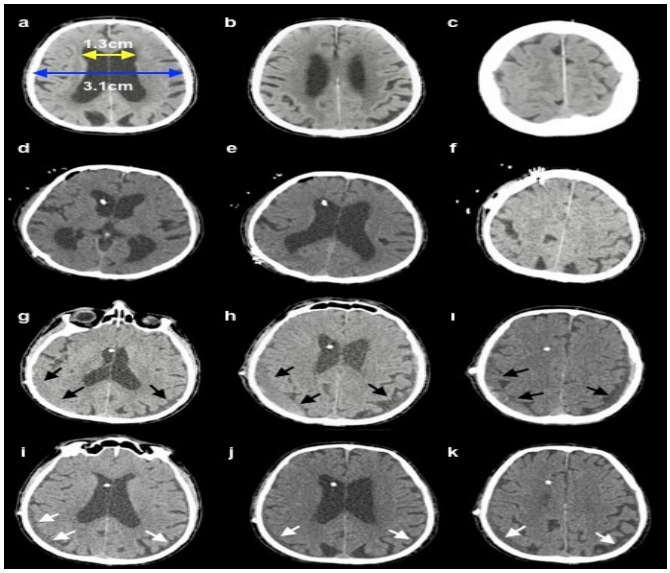

Figure 2. Serial axial computed tomography (CT) imaging scans of the brain of a patient with normal pressure hydrocephalus preoperatively and up to 3 months after programmable shunting (a-k). Preoperative axial images, Evans index >0.3. Evans index is defined as the ratio of the maximum width of the anterior horns (yellow arrow) to the maximum intracranial diameter (blue arrow) (a, b, c). Axial images in the first 24 hours postoperatively. The shunt catheter is in the anterior horn of the right lateral ventricle (d, e, f). Axial images at 1st month postoperatively show bilateral large subdural space. Subdural hematoma in the right parietooccipital region and subdural effusion in the left parietooccipital region (black arrow) are observed. After this imaging, the patient's shunt pressure setting was changed and increased (g, h, ı). Postoperative 3rd month axial images. Absorption of bilateral subdural hematoma and effusion (white arrow) and enlargement of bilateral hemispheres are seen (i, j, k)

Table 3. Number of shunt valve pressure settings changed due to over or inadequate drainage and clinical improvement in outpatient follow-up of idiopathic normal pressure hydrocephalus patients with ventriculoperitoneal programmable shunt.

PVS	Number of patients with adjusted valve pressure (n=26) (%)	Number of valve pressure adjustments (n=27)	Number of patients with clinical improvement (n=26) (%)
Inadequate drainage	9 (34.6)	16	7 (77.8)
Over drainage	5 (19.2)	11	2 (40)

PVS: Programmable ventriculoperitoneal shunt

In the PVS group, one patient (3.8%) experienced infection, which responded to medical treatment. During the early postoperative period, one patient (3.8%) in the PVS group developed an intraventricular hematoma. In addition, one patient (3.8%) in the PVS group who had coronary artery disease experienced a middle cerebral artery infarction on the first postoperative day. No catheter-related mechanical problems were observed in both groups (Table 4).

Table 4. Overall early (postoperative first 24 hours) and late postoperative (postoperative 6 months) complications following ventriculoperitoneal shunt surgery for idiopathic normal pressure hydrocephalus (iNPH) using programmable shunt and flow-regulated shunt. There was no statistically significant difference between early and late complications in both groups.

	PVS (n=26) (%)	FRS (n=18) (%)	p value
Early Complications			
Wound infection	1 (3.8)	0	0.49
Intraventricular hematoma	1 (3.8)	0	0.49
MCA infarct	1 (3.8)	0	0.49
Late Complications			
Subdural effusion/hematoma	5 (19.2)	2(11.1)	0.469
Subdural effusion/hematoma requiring drainage	3 (16.6)	1 (5.5)	0.497
Shunt revision	5(19.2)	2(11.1)	0.469

FRS: Flow-regulated shunt, MCA: Middle cerebral artery, PVS: Programmable ventriculoperitoneal shunt

DISCUSSION

In our study, there was no difference in clinical improvement rates between the FRS and PVS groups in the long-term. However, according to our findings, interestingly, in patients in the PVS group, the improvement rate at the 1st month follow-up (53.8%) was lower than that of at 1-year follow-up (80.8%) and the difference was statistically significant ($p<0.05$). In patients in the FRS group, the improvement rate was 72.2% at the 1st month control visit, which was not significantly different from that at 1-year control visit (77.7%) ($p >0.05$). This result can be viewed as a delayed clinical improvement in patients in the PVS group, possibly resulting from the insufficient drainage attributed to the initial high valve pressure.

Few publications in the literature have compared the efficacy of FRS and PVS so far.[13,14,17–20] Lund-Johansen et al.,[20] there was no statistically significant difference in the success rate of shunt surgery between patients undergoing FRS and PVS placement. Similarly, Weiner et al.[13] reported no statistically significant difference in shunt survival. In this regard, our study agrees with the existing literature. Therefore, complication rates owing to overdrainage and the incidence of mechanical problems related to the shunt should be prioritized when determining which shunt valve is to be employed.

In patients with PVS, over or under drainage can be prevented by changing the valve pressure.[21,22] Therefore, the use of PVS has been recommended in the guidelines for the treatment of iNPH published by the Japanese Normal Pressure Hydrocephalus Society in 2021.[23] Zemack et al.[6] reported that 42.4% of 583 patients with hydrocephalus treated using PVS placement required at least one valve pressure adjustment and that 64.6% of these patients displayed clinical improvement after the adjustment. Similarly, in a prospective European multicenter study by Klinge et al.[24], a total of 76 valve adjustments were performed in 36 patients during a 1-year follow-up of 115 patients who underwent PVS placement. While excessive or insufficient drainage was observed in 31% of the patients, only one patient required reoperation. Feletti et al.[21] reported that 37% of 102 patients with iNPH who underwent PVS placement required at least one valve pressure adjustment. In our study, 14 (53.8%) patients in the PVS group required a total of 27 adjustments to their shunt valve settings owing to either excessive drainage or inadequate clinical improvement.

The general approach in the use of PVS is to avoid overdrainage by initially adjusting to high pressures as overdrainage is more challenging to manage than insufficient drainage and may require repeat surgical procedures. In the literature, it has been shown that gradually decreasing the initial pressure from high to low values to achieve an optimal pressure setting can minimize the complication rate.[25,26] Farahmand et al.[26] suggested that the initial pressure be set at 120 mm H2O and adjusted based on clinical follow-up. However, starting from a high pressure setting requires multiple changes to reach the optimum pressure setting, and it is time consuming. Consequently, there may be a delay in the improvement of symptoms. In our study, the initial pressure was set at 110–120 mm H2O in patients undergoing PVS placement. During the follow-up of these patients, in five patients (19.2%), adjustment was made because of subdural effusion. Three patients (11.5%) required surgical intervention as their subdural effusion did not improve despite all adjustments. We believe that there could be several reasons for the development of subdural effusion in these patients despite the high initial pressure setting. First, although the initial opening pressure was adjusted to values specified in the literature, it is possible that the patient might have required a higher valve pressure. Of the patients in our study, there were two (7.6%) patients whose shunt pressure was increased in the first controls. The findings supported this theory. Second, excessive reduction of pressure in the valve settings might have been done to achieve clinical improvement. In our study, subdural effusion was detected in three (11.9%) patients 1 month after the first operation by decreasing the shunt valve pressure. Third, we observed that in some patients the pressure differences were very sensitive. Specifically, PVS allow adjustment in intervals of 10 mm H2O. However, owing to the absence of an anti-siphon mechanism, changes in the patient's position might have resulted in increased drainage, potentially leading to subdural effusion.

FRS are shunt systems with different characteristics that can be used in the treatment of iNPH. FRS self-regulate a constant amount of drainage independent of the patient's position and alterations in intracranial pressure. No external adjustment is required.[14,15,17] FRS aim to provide a consistent flow irrespective of changes in intracranial pressure.[19] The disadvantage of FRS is that it requires repeat surgical intervention in patients with excessive drainage.[5] However, this excessive drainage is not very common. Wetzel et al.[15] reported that flow-regulated valves are associated with low overdrainage rates and do not require reprogramming. Their study showed that approximately 80% of patients with iNPH treated with the Integra® NPH Low Flow Valve placement exhibited significant improvement on the iNPH rating scale and that the rate of improvement was stable at mid-term follow-up.[15]

In our study in the FRS group, subdural effusion was detected in two (11.1%) patients and surgical intervention was required in one patient (5.5%). Feletti et al.[21] demonstrated that in comparison with fixed-pressure shunts, the use of programmable pressure shunts led to a significantly lower rate of revision surgeries. Another aim of our study was to compare PVS and FRS in terms of overdrainage and repeat surgery rates. In our study, contrary to findings in the literature, no statistically significant difference was found between the two groups in terms of the development of subdural effusion and the rates of shunt revision surgery.

In addition, programmable valves are sensitive to magnetic fields and therefore require routine reprogramming when an MRI is performed. In their prospective study, Capitanio et al.[9] published a change of 40% in valve settings with 1.5-telsa MRI. Patients should visit a neurosurgery department after each MRI scan to either verify their valve settings via X-ray or have them readjusted. The type of FRS that does not require pressure adjustment may offer an alternative solution for patients who undergo frequent MRI examinations for other medical reasons or reside at a considerable distance from a hospital.[15]

In our study, patients with PVS placement underwent valve readjustment and/or X-ray control after each MRI, complicating follow-up for both the patient and the physician.

Early and late complications following shunt surgery in the treatment of iNPH have been documented in the literatüre.[22,27–29] Schenker et al.[28] observed in their series that 58% of patients with iNPH experienced some types of surgical complications; however, only approximately half of these complications required reoperation. In our study, there was no significant difference between the groups in terms of surgical complications ($p>0.05$) (Table 2).

CONCLUSION

Our findings support that the use of both FRS and PVS is effective and safe in the treatment of iNPH. The time to adequate clinical improvement is shorter in patients undergoing FRS placement than in those undergoing PVS placement owing to the lack of need for valve adjustment. Although iNPH guidelines advocate for the use of PVS, we believe that FRS may be a suitable option for eligible patients as well. Future prospective studies may further elucidate the difference in complications and neurological improvement rates between PVS and FRS.

ETHICAL DECLARATIONS

Ethics Committee Approval

The study was carried out with the permission of Ethical Committe of Medicana Bursa Hospital (Date:06.07.2023, Decision No: 03/2023).

Informed Consent

Because the study was designed retrospectively, no written informed consent form was obtained from patients.

Referee Evaluation Process

Externally peer-reviewed.

Conflict of Interest Statement

The authors have no conflicts of interest to declare.

Financial Disclosure

The authors declared that this study has received no financial support.

Author Contributions

All of the authors declare that they have all participated in the design, execution, and analysis of the paper, and that they have approved the final version.

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