

Association of Delirium Incidence with Visitation Restrictions due to COVID-19 Pandemic in Patients with Acute Cerebrovascular Disease in a Stroke-Unit Setting: A Retrospective Cohort Study

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Keywords

Delirium · Visitation restrictions · Stroke · Cerebrovascular disease · Stroke unit · COVID-19 pandemic

Abstract

Introduction: Hospitals around the world introduced considerable visitation restrictions to reduce risk of infection during epidemic spread of SARS-CoV2. Understanding of negative impacts of visitation restrictions on subgroups of patients may help to balance and adjust policies accordingly or introduce further measures to mitigate their impact. We aimed to investigate the association of visitation restrictions with delirium incidence in stroke-unit patients. **Methods:** In a non-randomized observational design, data from 5,779 stroke-unit cases with transient ischemic attack or stroke (ischemic/hemorrhagic) admitted between January 2017 and November 2021 were compared between three groups depending on visitation policy implemented at time of admission: pandemic-associated absolute visitation restriction ($n = 1,087$), limited visitation policy ($n = 862$), and pre-pandemic visitation policy ($n = 3,830$). Univariate comparison and multiple logistic regression analyses were conducted to evaluate the association of delirium with visitation restrictions. **Results:** We observed delirium incidences of 6.3% dur-

ing pandemic-associated absolute visitation restriction, 5.8% with limited visitation policy, and 5.1% with pre-pandemic visitation policy ($p = 0.239$). In multiple logistic regression analyses adjusting for clinically relevant variables, we found the presence of any pandemic-associated visitation restriction (odds ratio [OR] 1.363, 95% confidence interval [CI]: 1.066–1.744, $p = 0.014$) and specifically absolute visitation restriction (OR 1.368, 95% CI: 1.016–1.843, $p = 0.039$) independently associated with delirium in patients with acute cerebrovascular disease. Other factors independently associated with delirium were older age, male sex, stroke versus transient ischemic attack, acute infection, history of dementia, and longer duration of hospital stay. **Conclusion:** Pandemic-associated visitation restrictions and specifically absolute visitation restrictions are associated with a higher incidence of delirium among stroke-unit patients with acute cerebrovascular disease. Benefit and harm of visitation restrictions should be carefully weighed and adjustments considered for patients otherwise at increased risk for delirium.

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Introduction

Hospitals around the world introduced considerable visitation restrictions during epidemic spread of SARS-CoV2 to protect health-care workers and patients and reduce risk of infection and disease spreading. Over the course of the pandemic, visitation restrictions varied greatly in scope, some limiting number of visitors or shortening visiting hours, some not allowing visitors at all with only specific exception categories such as in palliative care and birth [1, 2]. Various negative consequences of pandemic-associated restricted visitation policies have been described impacting patients, families, and health-care professionals; however, they are widely understudied [3, 4]. With regard to future pandemic policy adjustment, there is increasing awareness that benefits and harms need to be weighed in order to develop ethically reasonable policies [5]. Therefore, there is an emerging need to identify vulnerable subgroups at increased risk for negative impacts of visitation restrictions in particular.

Lack of family visitation due to pandemic-associated regulations has been discussed to be an independent risk factor for delirium in hospitalized COVID-19 patients [6] and emergency patients in general [7]. However, etiology of delirium is multifactorial with a number of factors contributing to increased risk. While interdisciplinary multi-component interventions have been demonstrated as an effective strategy for delirium prevention in the hospital setting [8], effects of flexible family visitation on delirium in intensive-care patients remain uncertain [9]. Patients with acute cerebrovascular disease comprise a subgroup at high risk for delirium and suffer higher mortality and poorer outcomes following this complication [10, 11]. Therefore, current national guidelines of acute stroke treatment strongly recommend standardized routine screening for delirium during stroke-unit treatment [12].

With this study, we aim to test the hypothesis that current pandemic-associated visitation restrictions affect delirium incidence in stroke-unit patients with acute cerebrovascular disease. Second, we aim to assess the association of delirium incidence in these patients with different scopes of visitation restrictions that were implemented over the course of the pandemic.

Methods

Study Design

We conducted a single-center, retrospective, observational cohort study in our university hospital in Mainz, Germany. Study protocols and procedures were conducted in compliance with the Declaration of Helsinki and in accordance with local ethical guidelines. In line with regional legislation of the responsible Ethics Committee of the Landesärztekammer Rheinland-Pfalz (Landeskrankengesetz §36 und §37), due to the retrospective nature of the current analysis, no additional ethical approval or informed consent to participate was deemed necessary. The article follows the STROBE guideline, as is outlined in the supplemental material (see www.karger.com/doi/10.1159/000526165).

Participants and Outcome Parameters

For the current study, we used data from 5,815 cases treated at the stroke unit of our university hospital, admitted between January 1, 2017 and November 4, 2021 (Fig. 1). Cases were selected by the diagnosis of transient ischemic attack (TIA) or ischemic/hemorrhagic stroke, as classified by the International Statistical Classification of Disease and related health problems – 10th revision (ICD-10) used for financial reimbursement from the health-care providers. Patients diagnosed with TIA and stroke during the same hospital stay ($n = 64$) were assigned to stroke category and patients diagnosed with ischemic and hemorrhagic stroke during the same hospital stay ($n = 313$) were assigned to ischemic stroke category. Additionally, ICD-10 diagnoses of delirium, acute infection (pneumonia, urinary tract infection, and/or sepsis), SARS-CoV-2 status (determined by SARS-CoV-2 polymerase chain reaction [PCR] from nasopharyngeal swab on day of admission or 1st working day following admission), and history of dementia were extracted. We

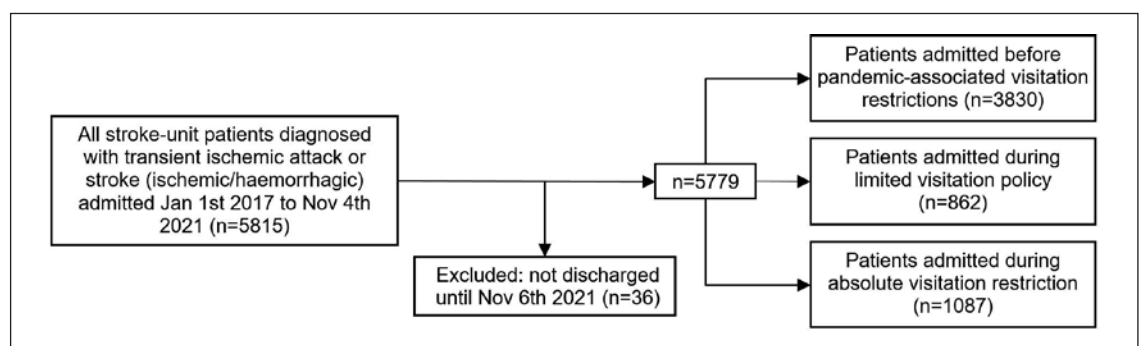


Fig. 1. Study cohort.

excluded patients not discharged by November 6, 2021 due to pending ICD-10 coding. We then divided the patient cohort into three groups depending on visitation policy implemented at the time of admission: pandemic-associated absolute visitation restriction (no visitors unless medical reasons or in palliative settings), limited visitation policy (one visitor per patient for 1 h a day between 3 and 6 p.m.) and pre-pandemic visitation policy (two visitors per patient any time between 2:30 and 6:30 p.m. + 10 and 12 a.m. on weekends). Figure 2a displays timeline of pandemic-associated visitation policy changes.

Statistical Analysis

Data are presented as median (interquartile range [IQR]) or proportions (absolute number), if not indicated otherwise. For univariate analyses, Kruskal-Wallis test, Mann-Whitney U test, and χ^2 test were used as appropriate. Differences in patient characteristics, delirium incidence, and comorbidities on univariate level were calculated between the three groups depending on visitation policy implemented at the time of admission. Other patient characteristics and comorbidities associated with delirium were investigated by comparing patients diagnosed with delirium to those without. For analysis of the primary outcome, multiple logistic regression analysis was conducted to estimate adjusted odds ratios evaluating association of delirium with visitation restrictions. The model adjusts for the following confounders: age, sex, stroke versus TIA, acute infection

(pneumonia, urinary tract infection, and/or sepsis), SARS-CoV-2 diagnosis based on routine PCR screening (regardless of symptoms), history of dementia, and duration of hospital stay. Linearity was assessed using the Box-Tidwell procedure. Due to nonlinear relationship, duration of hospital stay was dichotomized as $\geq/\leq 9$ days according to optimal criterion value by Youden Index calculation. Following this procedure, all continuous variables were found to follow a linear relationship. Significance of predictive capacity of the multiple logistic regression model was assessed by Nagelkerke's R^2 . Goodness of fit was assessed using the Hosmer-Lemeshow test, indicating a good model fit for $p > 0.05$. For multicollinearity diagnostics, we calculated variance inflation factors, assuming no relevant multicollinearity for values < 10 . A significant difference was considered for $p < 0.05$ in all analyses. Statistical analyses were performed using SPSS® (Version 27; IBM®, Armonk, NY, USA).

Results

Baseline Characteristics

5,779 cases were included in our analysis (median age 75 years, IQR: 64–83, 45.5% female), of which 1,087 were admitted during pandemic-associated absolute visitation

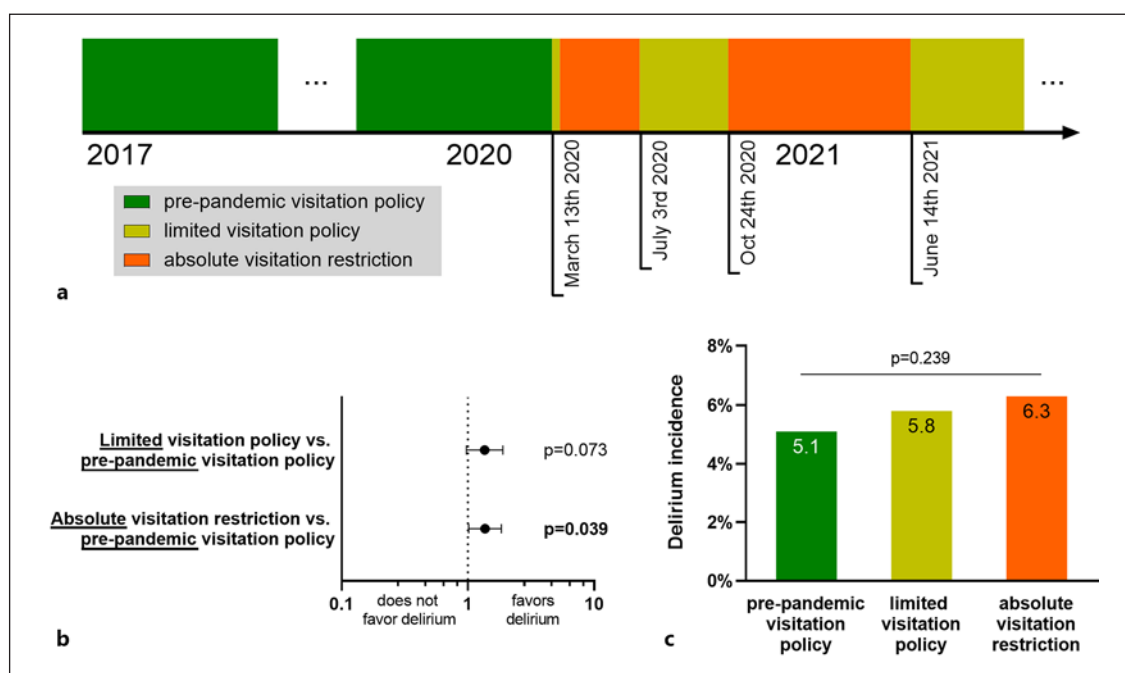


Fig. 2. **a** Timeline of pandemic-associated visitation restrictions. Pre-pandemic visitation policy: two visitors per patient between 2:30 and 6:30 p.m. + 10 and 12 a.m. on weekends, pandemic-associated limited visitation policy: one visitor per patient for 1 h a day between 3 and 6 p.m., pandemic-associated absolute visitation restriction: no visitors unless medical reasons or in palliative settings. **b** Adjusted odds ratio (OR) for delirium incidence by visitation restriction resulting from multiple logistic regression analysis

adjusted for age, sex, stroke versus TIA, acute infection (pneumonia, urinary tract infection, and/or sepsis), history of dementia, and duration of hospital stay: absolute visitation restriction independently predicts delirium incidence (aOR: 1.368, 95% CI: 1.016–1.843, $p = 0.039$). Limited visitation restriction (aOR: 1.357, 95% CI: 0.972–1.893, $p = 0.073$). **c** Delirium incidence in all patients depending on visitation policy at the time of admission.

Table 1. Baseline characteristics of the study cohort

Variable	Pre-pandemic visitation policy	Limited visitation policy	Absolute visitation restriction	<i>p</i> value
Patients	3,830	862	1,087	
Age	75 (64–82)	75 (63.75–83)	77 (65–83)	0.016
Female	44.3 (1,697)	46.3 (399)	48.9 (531)	0.026
TIA	20.8 (797)	21.5 (185)	23.6 (257)	0.133
Stroke	79.2 (3,033)	78.5 (677)	76.4 (830)	0.133
Ischemic stroke	74.4 (2,850)	74.7 (644)	72.2 (785)	0.308
Hemorrhagic stroke	4.8 (183)	3.8 (33)	4.1 (45)	0.384
Delirium	5.1 (195)	5.8 (50)	6.3 (69)	0.239
Acute infection of below (total)	20.2 (772)	18.2 (157)	20.2 (220)	0.412
Pneumonia	14.2 (544)	12.5 (108)	13.8 (150)	0.436
Urinary tract infection	7.4 (284)	6.7 (58)	8.8 (96)	0.176
Sepsis	1.7 (67)	0.9 (8)	0.8 (9)	0.031
SARS-CoV-2 status				<0.001
Negative	100.0 (3,830)	100.0 (862)	98.6 (1,072)	
Positive	0.0 (0)	0.0 (0)	1.4 (15)	
(a) Without pneumonic symptoms	0.0 (0)	0.0 (0)	1.0 (11)	
(b) With pneumonic symptoms	0.0 (0)	0.0 (0)	0.4 (4)	
History of dementia	6.0 (228)	4.9 (42)	5.7 (62)	0.467
Duration of hospital stay >9 days	32.9 (1,261)	26.7 (230)	27.8 (302)	<0.001

Data are presented as percentage (absolute number) except for age: median (IQR). TIA, transient ischemic attack.

restriction, 862 during limited visitation policy, and 3,830 during pre-pandemic visitation policy (Table 1). None of the cases meeting inclusion and exclusion criteria had missing data with regard to the obtained patient characteristics, outcomes, and covariates.

Univariate Comparison of Visitation Policy Groups

We observed an absolute delirium incidence in our cohort of 6.3% (69 per 1,087 cases) during pandemic-associated absolute visitation restriction, 5.8% (50 per 862 cases) during limited visitation policy, and 5.1% (195 per 3,830 cases) during pre-pandemic visitation policy ($p = 0.239$, Fig. 2b). The study groups divided by visitation policies were unbalanced with regard to age (median [IQR] pre-pandemic: 75 [64–82] years, limited visitation: 75 [63.75–83], absolute restriction: 77 [65–83], $p = 0.016$), sex (females pre-pandemic: 44.3%, limited visitation: 46.3%, absolute restriction: 48.9%, $p = 0.026$), duration of hospital stay >9 days (pre-pandemic: 32.9%, limited visitation: 26.7%, absolute restriction: 27.8%, $p < 0.001$), and diagnosis of sepsis (pre-pandemic: 1.7%, limited visitation: 0.9%, absolute restriction: 0.8%, $p = 0.031$). We observed a total of 15 SARS-CoV-2 infections (corresponding to 0.8% of all patients admitted during the pandemic period of visitation restrictions) within our cohort. Few

of them (26.7%, 4/15) were diagnosed with pneumonic symptoms.

Patient Characteristics and Comorbidities Associated with Delirium

Patients diagnosed with delirium were older (median [IQR] age 81 [75–86] vs. 75 years [64–82], $p < 0.001$) and more often male (63.7 vs. 54.0%, $p = 0.001$). They were more often diagnosed with ischemic stroke or hemorrhagic stroke and less often with TIA. Acute infections as of pneumonia, urinary tract infection, and/or sepsis were more common in patients with delirium (47.5 vs. 18.3%, $p < 0.001$) and so was diagnosis of dementia (12.7 vs. 5.3%, $p < 0.001$). SARS-CoV-2 diagnosis based on routine PCR screening (regardless of symptoms) was not significantly associated with development of delirium (6.7 vs. 5.4%, $p = 0.833$). Median duration of hospital stay was found to be more than twice as high in patients with delirium (median [IQR] 13 [7–21] vs. 6 days [3–11], $p < 0.001$); further details are depicted in Table 2.

Multiple Logistic Regression Analysis of Association of Delirium with Visitation Restrictions

When adjusting for baseline characteristics and comorbidities in multiple logistic regression analysis, pan-

Table 2. Factors associated with delirium

Variable	No delirium	Delirium	<i>p</i> value	Factor-specific delirium incidence
Patients	5,465	314		
Age	75 (64–82)	81 (75–86)	<0.001	
Female	46.0 (2,513)	36.3 (114)	0.001	4.3 (114/2,627)
Male	54.0 (2,952)	63.7 (200)	0.001	6.3 (200/3,152)
TIA	22.2 (1,215)	7.6 (24)	<0.001	1.9 (24/1,239)
Stroke	77.8 (4,250)	92.4 (290)	<0.001	6.4 (290/4,540)
Ischemic stroke	73.6 (4,021)	82.2 (258)	0.001	6.0 (258/4,279)
Hemorrhagic stroke	4.2 (229)	10.2 (32)	<0.001	12.3 (32/261)
Acute infection of below (total)	18.3 (1,000)	47.5 (149)	<0.001	13.0 (149/1,149)
Pneumonia	12.6 (689)	36.0 (113)	<0.001	14.1 (113/802)
Urinary tract infection	7.1 (389)	15.6 (49)	<0.001	11.2 (49/438)
Sepsis	1.3 (73)	3.5 (11)	<0.001	13.1 (11/84)
History of dementia	5.3 (292)	12.7 (40)	<0.001	12.0 (40/332)
Duration of hospital stay >9 days	29.2 (1,594)	63.4 (199)	<0.001	11.0 (199/1,793)
SARS-CoV-2 status			0.833	
Negative	99.74 (5,451)	99.68 (313)		5.4 (313/5,764)
Positive	0.26 (14)	0.32 (1)		6.7 (1/15)
(a) Without pneumonic symptoms	0.18 (10)	0.32 (1)		
(b) With pneumonic symptoms	0.07 (4)	0.00 (0)		

Data are presented as percentage (absolute number) except for age: median (IQR). TIA, transient ischemic attack.

demic-associated visitation restriction (limited visitation or absolute restriction) was noted to be independently associated with delirium (adjusted odds ratio [OR] [95% confidence interval (CI)] 1.363 [1.066–1.744], $p = 0.014$). When further investigating effects of the distinct visitation policies, we observed a significant independent association of absolute visitation restriction versus pre-pandemic visitation policy (adjusted OR [95% CI] 1.368 [1.016–1.843], $p = 0.039$), while limited visitation policy versus pre-pandemic visitation policy showed solely a tendency toward significant association (adjusted OR [95% CI] 1.357 [0.972–1.893], $p = 0.073$), see also Figure 2c. Other factors independently associated with delirium in multiple regression analysis (see also Fig. 3) were older age, male sex, stroke versus TIA, acute infection, history of dementia, and duration of hospital stay of >9 days. SARS-CoV-2 diagnosis based on routine PCR screening (regardless of symptoms) was not independently associated with delirium (adjusted OR [95% CI] 0.511 [0.061–4.299], $p = 0.537$). For detailed model characteristics and estimators, see Table 3.

Discussion

In this study, we investigated the association of delirium incidence with visitation restrictions due to the ongoing COVID-19 pandemic in patients with acute cerebrovascular disease in a large, overregional university hospital stroke unit. We report an incidence of delirium of 6.3% during pandemic-associated absolute visitation restriction, 5.8% during limited visitation policy, and 5.1% during pre-pandemic visitation policy. After adjustment for patient characteristics and clinically relevant comorbidities, visitation restrictions appeared to be independently associated with delirium.

This finding is in line with a recent study by Kandori et al. [7], reporting increased delirium incidence during a short interval of absolute pandemic-associated visitation restrictions in patients admitted to a Japanese emergency ward. Also before the pandemic, absence of family visitation had been identified as a potential risk factor for delirium in intensive-care patients and been used in the discussion about optimal visitor policy in severely diseased patients [13]. However, evidence regarding effects of absolute visitation restriction is scarce, due to ethical reasons with regard to study design. In contrast, a recently

Fig. 3. Independent predictors of delirium in stroke-unit patients diagnosed with transient ischemic attack or stroke admitted between January 1, 2017 and November 4, 2021. Displayed are adjusted odds ratios with 95% confidence intervals resulting from multiple logistic regression. All predictors with $p < 0.05$, except PCR-based SARS-CoV-2 diagnosis ($p = 0.537$).

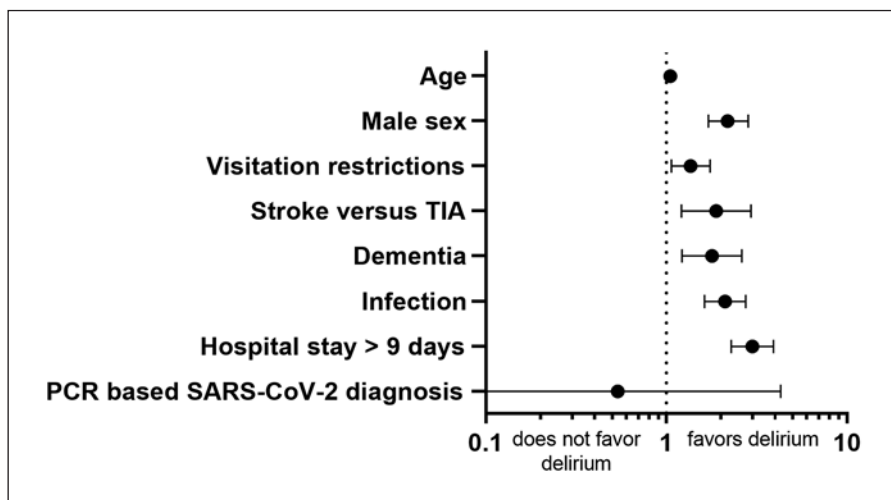


Table 3. Independent predictors of delirium resulting from multiple logistic regression analysis

Variable	Adjusted odds ratio	95% CI	<i>p</i> value
Age	1.051	1.039–1.064	<0.001
Male sex	2.197	1.705–2.831	<0.001
Stroke versus TIA	1.886	1.209–2.943	0.005
Acute infection	2.111	1.624–2.743	<0.001
History of dementia	1.787	1.221–2.615	0.003
Duration of hospital stay >9 days	2.988	2.281–3.914	<0.001
Any pandemic-associated visitation restriction versus pre-pandemic visitation policy	1.363	1.066–1.744	0.014
Limited visitation policy versus pre-pandemic visitation policy	1.357	0.972–1.893	0.073
Absolute visitation restriction versus pre-pandemic visitation policy	1.368	1.016–1.843	0.039
PCR-based (symptomatic or asymptomatic) SARS-CoV-2 diagnosis	0.537	0.061–4.299	0.537

Model characteristics: Nagelkerke's R^2 : 0.160, $p < 0.001$. Acute infection by means of pneumonia, urinary tract infection and/or sepsis. 95% CI, 95% confidence interval; TIA, transient ischemic attack; PCR, polymerase chain reaction.

conducted randomized controlled trial comparing flexible with limited visitation policy in an intensive-care setting did not show reduction of delirium incidence under a flexible visitation scheme, stressing the importance of multicomponent prevention strategies and further investigation of optimal patient-benefiting visitation policies [9]. Our study adds new evidence of possible negative consequences of visitation restrictions affecting patients with acute cerebrovascular disease, a well-defined patient cohort undergoing standardized stroke care that is otherwise already prone to complications and development of delirium [11]. Our findings are of high clinical relevance with regard to future concepts and adjustment of visitation policies. The pandemic events are still challenging health-care systems worldwide and management strate-

gies involve limitation of family visitation in various designs. Those are especially affecting older and multimorbid patients with need for assistance not only during the in-patient setting but also in their nursing home's private lives, where increased neuropsychiatric symptoms such as agitation and aggression have been observed during the visiting-restriction period [14, 15]. Recommendations to mitigate negative consequences of physical visitation restriction have included technological solutions to enable alternative communication strategies via phone and video conversations [5, 16, 17]. However, in patients with acute cerebrovascular disease, this strategy may not solve the issue as they often suffer new neurological deficits such as paresis and aphasia as well as premorbid cognitive impairment. Such deficits often limit an indepen-

dent use of technological gadgets; hence, these patients may not benefit from technological communication options or need additional nursing assistance to use them [18, 19]. Patients with acute cerebrovascular disease therefore depict a disadvantaged subgroup with regard to visitor restrictions and research of feasible strategies to compensate by technical solutions in this cohort is urgently needed.

Yet, not all visitation policies can be addressed in an equivalent manner, since they differ significantly in their scope and design [1, 2, 5]. Interestingly, we show an association of delirium incidence specifically with absolute visitation restrictions in our cohort, whereas limited visitation policy as compared to pre-pandemic policy did only show a tendency of association without reaching significance. This stresses the importance to further evaluate different scopes of visitation policies and their differential impacts, especially addressing patient cohort-specific impairments and needs. Accordingly, general recommendations for design and adjustments of pandemic-associated visitation restriction policies already advise to implement stepwise approaches encompassing different extents of restriction with respect to number of visitors and length of visitation times depending on current infection incidence [17]. Further recommendations even suggest to regularly include presence of a caregiver for hospitalized patients with disabilities and not consider them as visitors bound to visitation policy at all [20].

Our study has several limitations. First, by nature of the single-center observational study design, our findings are limited with regard to generalizability. Delirium diagnosis is based on routine-care evaluation as opposed to standardized measures of delirium by means of validated tools such as the CAM-ICU, which have only recently been recommended to be routinely used during stroke-unit care in Germany [12]. Due to use of clinical routine data, we also lack information about severity and duration of delirium in our patients, which have already been described to be influenced by family presence [21]. Also, exceptions to visitation restrictions, that might have been made due to case-specific medical reasons by the treating physician, could not be captured. Furthermore, inference of causality is limited due to the nature of our observational, non-randomized study. We lack information about possible confounding pandemic-associated effects on in- and out-patient care, that are independent of visitation restrictions and might influence delirium incidence in our stroke unit during these periods. Possibly, these might include understaffing or increased workload of stroke-unit personnel with resulting quantitative and

qualitative changes in caregiving routines and multicomponent nonpharmacologic delirium prevention [22]. Also, increased hygiene measures and implementation of protective face mask routine among health workers might contribute to development of delirium, especially in patients with premorbid or stroke-associated sensory deficits, due to limited interpersonal interaction through facial expression. Patients that were living in institutionalized care, might have already experienced increased levels of emotional distress by policy changes within their long-term care institutions before admission due to acute cerebrovascular disease, as for example increased rates of agitation and aggression were reported in nursing homes during pandemic periods of limited visitation possibilities [4]. Furthermore, although we did not observe a significant change in the proportion of TIA and stroke diagnoses during visitation restriction periods, changes in treated stroke severity, acting as an independent risk factor of delirium [11], could not be ruled out.

Our study is based on a large cohort of patients with acute cerebrovascular disease in which we were able to capture pandemic-associated visitation restrictions over a long period of time. Thereby, we were able to reduce impact of random or confounded temporary effects at smaller intervals. Furthermore, variation in visitation policy implemented at our university hospital over time allowed us to differentiate several scopes of visitation restrictions and their association with delirium incidence. This allows interpretation of our findings on a broader level of various existing visitation policies that are subject to adjustment over time as the pandemic is evolving. Also, by adjusting for important confounding risk factors known to predispose to delirium, such as premorbid dementia and infective complications, we were able to further increase validity of our results. Thereby, we were able to identify an independent association of delirium in stroke-unit patients with pandemic-associated visitation restrictions and specifically with absolute visitation restriction.

To conclude, we suggest that patients diagnosed with acute cerebrovascular disease treated on a stroke unit might be a subgroup particularly vulnerable to delirium in the context of pandemic-associated (absolute) visitation restrictions. Benefit and harm of visitation restrictions should be carefully weighed and adjusted for patients otherwise at increased risk for delirium. Further investigation of impacts of different scopes of visitation restrictions is necessary to guide an adequate design of policies mitigating negative consequences in patients with acute cerebrovascular disease.

Acknowledgments

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Statement of Ethics

Study protocols and procedures were conducted in compliance with the Declaration of Helsinki and in accordance with local ethical guidelines. In line with regional legislation of the responsible Ethics Committee of the Landesärztekammer Rheinland-Pfalz (Landeskrankenhausgesetz §36 und §37), due to the anonymized, retrospective nature of the current analysis, no ethical approval or informed consent to participate was deemed necessary.

Conflict of Interest Statement

Marianne Hahn reports personal fees from Bristol-Myers Squibb. Timo Uphaus reports personal fees from Merck Serono, Pfizer, and BMS and grants from Else Kröner-Fresenius Stiftung and DFG (SFB-TR 128). Klaus Gröschel reports personal fees and/or nonfinancial support from Abbott Medical, Alexion Pharma, Bayer Healthcare, Boehringer Ingelheim, Bristol-Myers Squibb, and Daiichi Sankyo. Sonja Gröschel reports no disclosures.

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Author Contributions

Marianne Hahn designed and conceptualized the study, performed data acquisition and statistical analyses, interpreted the data, and drafted the manuscript for intellectual content. Timo Uphaus performed statistical analysis, interpreted the data, and critically revised the manuscript. Klaus Gröschel interpreted the data and critically revised the manuscript. Sonja Gröschel critically revised the manuscript. All authors approved the final version of the manuscript for submission.

Data Availability Statement

The data supporting the findings of this study are not publicly available on the grounds of regional legislation. The data are available from the corresponding author Klaus Gröschel upon reasonable request from any qualified investigator.

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