BY 4.0

https://doi.org/10.23934/2223-9022-2019-8-4-391-395

The Effect of Telemedicine Consultation on Outcomes in Patients with Intracerebral Hemorrhage

A.M. Alasheyev*, A.A. Smolkin, E.V. Prazdnichkova, A.A. Belkin

Neurology Department
Sverdlovsk Regional Clinical Hospital No. 1
185 Volgogradskaya Street, Yekaterinburg 620102, Russian Federation

*** Contacts:** Andrey M. Alasheyev, Cand. Med. Sci., Head of the Neurology Department of Sverdlovsk Regional Clinical Hospital No. 1. E-mail: alasheev@live.ru

RELEVANCE Telemedicine solves the problem of the availability of highly qualified personnel at the decision-making stage in the management of patients with intracerebral hemorrhage.

AIM OF STUDY We set out to evaluate the effect of teleconsultation on outcomes in patients with intracerebral hemorrhage 30 days after the event.

MATERIAL AND METHODS A prospective, open, nonrandomized clinical trial in two parallel groups. The first group included adult patients up to 80 years of age with a hemorrhagic stroke from 4 to 36 points according to NIHSS due to unilateral supratentorial intracerebral hematoma of non-aneurysmal genesis, who were examined by a neurosurgeon and resuscitator of the Regional Vascular Center in a ward. The second group included similar patients, but they received telemedicine consultation of the above specialists. The primary endpoint of the study was mortality 30 days after the onset of the stroke. The hypothesis of non-superiority was tested where the 95% confidence interval (CI) for the difference in mortality between the groups should not go over 15 percentage points.

RESULTS A total of 140 patients (70 in each group) with intracerebral hematomas were studied. Mortality in the bedside group was 14.3% (CI 7.1%; 24.7%), and in the remote group it was 25.7% (16.0%; 37.6%), p=0.091. However, there was no evidence of superiority, since the difference between the groups in mortality was 11.4 with CI from –0.07 to 24.5 percentage points, which was beyond the predefined limit.

CONCLUSIONS At the current level of development of medicine and information technology, telemedicine cannot fully replace the traditional (bedside) consultation of an expert level of neurosurgeon and neuroresuscitator in patients with intracerebral hematomas.

Keywords: telemedicine, intracerebral hemorrhage, outcome

For citation Alasheyev AM, Smolkin AA, Prazdnichkova EV, Belkin AA. The Effect of Telemedicine Consultation on Outcomes in Patients with Intracerebral Hemorrhage. *Russian Sklifosovsky Journal of Emergency Medical Care.* 2019;8(4):391–395. https://doi.org/10.23934/2223-9022-2019-8-4-391-395 (in Russ.)

Conflict of interest Authors declare lack of the conflicts of interests

Acknowledgments The study had no sponsorship

Affiliations

Andrey M. Alasheyev	Cand. Med. Sci., Head of the Neurology Department, Sverdlovsk Regional Clinical Hospital No. 1, https://orcid.org/0000-0003-1610-2127
Andrey D. Smolkin	neurologist of the Sverdlovsk Regional Clinical Hospital No. 1, https://orcid.org/0000-0001-9819-2351
Elena V. Prazdnichkova	Head of the Organization and Instruction Department, Sverdlovsk Regional Clinical Hospital No. 1, https://orcid.org/0000-0002-6537-1940
Andrey A. Belkin	Dr. Med. Sci., Professor, Head of the Regional Vascular Center, Sverdlovsk Regional Clinical Hospital No. 1, https://orcid.org/0000-0002-0544-1492

CI – confidence interval
ICHm – intracerebral hematoma
ICHg – intracerebral hemorrhage
LEC – Local Ethics Committee
PEP – primary endpoint
PVD – primary vascular department
RVD – regional vascular department

Telemedicine is recognized as one of the priority areas of healthcare development in the Russian Federation. The greatest benefit from the use of telemedicine technologies is expected for patients with a high risk of adverse outcome [1], which includes patients with intracerebral hemorrhage (ICHg). The successful management of these patients requires staged assistance and timely routing to medical institutions of a higher level with a department of neurosurgery and resuscitation. However, not all patients, due to a number of circumstances, should be re-hospitalized in medical organizations of the higher level. In such cases, telemedicine becomes a solution to the dilemma of routing and the availability of highly qualified personnel. With the help of telemedicine, medical organizations gain access to the knowledge and experience of rare specialists: neurosurgeons and neuroresuscitators, regardless of the remoteness of the patient. A narrow specialist helps the consulted party to determine the tactics of patient management: he solves the question of transferring the patient to the next stage of medical care (tele-routing) or gives recommendations for treatment on the spot with subsequent dynamic monitoring for timely review of tactics (telemonitoring).

In a previous study, we did not prove the effect of telemedicine consultation on the outcome of the disease in patients with ICHg [2]. The study was retrospective, and we were not able to gather full information about the type of intracerebral hematoma (ICHm), the severity of multiple organ failure, video conferencing quality and other circumstance to eliminate their influence on the study endpoints. The need for a study with a prospective set of patients determined the relevance of this work.

MATERIAL AND METHODS

From June 2015 to August 2017, the Sverdlovsk Regional Clinical Hospital No. 1 (Yekaterinburg) and 6 resuscitation and intensive care units of medical organizations of the Sverdlovsk Region, which include Primary Vascular Department (PSD), in two parallel groups, a prospective, open, non-randomized clinical study of the effects of teleconsultation on outcome after 30 days was conducted in patients with intracerebral hemorrhage. The study was approved by the Local Ethics Committee (LEC) of the hospital.

By decision of the LEC, additional informed consent was not required from patients to participate in the study, since the methods used did not contradict established local practice, and the study protocol did not contain additional risks for patients.

The Group 1 included patients hospitalized from the attached territory via ambulance and who received advice from a neurosurgeon and a neuroresuscitator at the patient's bedside. The Group 2 included patients admitted to the PSD who participated in the study, but had one or more telemedicine consultations of the above specialists.

The study included patients who met the following criteria: age from 18 to 80 years; the first day of a hemorrhagic stroke with the formation of a hematoma in the parenchyma of the cerebral hemispheres; *NIHSS* score from 4 to 36. Additional inclusion criteria for patients of the Group 2 were teleconsultation on the 1st day of the disease and excellent quality of videoconferencing, which was evaluated on the original 5-point scale [3].

The study did not include patients: with clinical signs of brain death; from beneath the eye on the aneurysmal nature of hemorrhage; with bilateral brain damage; with the presence of subtentorial ICHm; with a combination of hemorrhagic and ischemic stroke; pregnant.

The primary endpoint (PEP) of the study is the difference between the groups in the frequency of deaths on the 30th day from the onset of the disease.

Secondary endpoints of the study: the difference between the groups in the frequency of neurosurgical operations and the percentage of unfulfilled recommendations.

Technical support and regulations for teleconsultation were published by us earlier [4] and were similar in this study. The telecommunication system consisted of 3 components: the post of the consulting party, telematic channels for transmitting information and the terminal of the consulted party. A telecommunication session was preceded by an e-mail request in which the consultant could familiarize himself with the questionnaire containing the patient's demographic data and a preliminary diagnosis. In order to carry out this study, we used the *Cisco TelePresence SX* 20 mobile installations (*Cisco Systems*, USA) and the *Edge* 75 *MXP* fixed installation (*Tandberg*, Norway) with the ability to remotely control a camera. During the video conferencing, the consultant physician controlled the remote camera, which made it possible to conduct a more detailed search and assessment of symptoms during a neurological examination. Communication was provided through a virtual private network on the channels of Rostelecom JSC. The communication channel of an automatic telephone station of Sverdlovsk RVC consulted prior to resuscitation departments and intensive care was organized using digital subscriber line technology. Upon completion of the teleconsultation, the written opinion of the medical consultant was sent by e-mail.

Diagnostic and treatment advice was given according to the clinical guidelines for the management of patients with acute ICHg [5]. According to the indications, some patients received repeated teleconsultations on day 3, 7, 14 and 30 of the disease.

Upon completion of the recruitment of patients, an analysis of case histories was carried out to verify information by endpoints, as well as to count the number of recommendations made that were given as a result of teleconsultations. If the patient was discharged from the hospital earlier than 30 days from the onset of the disease, then information on the end points of the study was collected using a telephone interview with the patient or his relatives.

For all patients, data on demographic indicators, hemorrhage characteristics, stroke severity on the *NIHSS* and *ICH* scales [6], the degree of disability on the Rankin scale, and the severity of multiple organ failure on the *SOFA* scale were collected. The hematoma volume was calculated by the *ABC*/2 method according to computed tomography of the brain [7].

All statistical procedures were performed using the *Stata* 15 program (*Stata Corp*, USA).

The sample size was calculated according to the generally accepted method [8], based on the following assumptions: the hypothesis of non-excellence is tested; one-sided Chi-square test is used, mortality in the RVC is 14.9%; the frontier of excellence is 15%; the error of the first kind is taken equal to 5%; an error of the second kind is taken equal to 20%, which corresponds to a power of 80%; distribution of patients between groups 1: 1; retirement of patients was not planned due to their short-term participation in the study. The estimated sample size was 140 patients (70 in each group). All 140 study participants were monitored 30 days before the outcome. Patients did not drop out of the study.

The chosen boundary of excellence reflects a clinically acceptable difference between the groups, taking into account the different levels of medical care in the RVC compared with the PVD in the studied nosology.

To assess the normality of the distribution of quantitative characteristics, a visual assessment of the frequency distribution (according to the histogram and the normality graph) was used, followed by the use of the Shapiro-Wilk and D 'Agostino criteria. The normal distribution of signs was not observed, therefore, non-parametric statistics methods were used. Quantitative characteristics are given in the form of the median and the boundaries of the interquartile range (in brackets). Binary quality data is presented as a percentage share and the boundaries of the 95% confidence interval (CI) for the share (in brackets). Quantitative traits were compared using the Mann-Whitney test or the exact Fisher-Pitman test. Qualitative traits were compared with the Chi-square test or Fisher's exact test. Multivariate analysis was performed using binary logistic regression. An error of the first kind was set equal to 0.05. The null hypothesis (absence of differences) was rejected if the probability (p) did not exceed an error of the first kind.

RESULTS

The main characteristics of patients are presented in Table 1. In the Group 1, patients were younger, among them there were fewer women and patients with subcortical localization of the hematoma. The groups did not statistically significantly differ in the severity of hemorrhage and the volume of hematoma.

Table 1

The main characteristics of the patients and the results

Parameter	Bedside	Remotely	p
Age, years	58 (50; 65)	61.5 (54; 70)	0.033
Male, %	67.1 (54.9; 77.9)	48.6 (36.4; 60.8)	0.026
Subcortical location,%	31.4 (20.9; 43.6)	52.9 (40.6; 64.9)	0.010
Ventricular component,%	41.4 (29.8; 53.8)	31.4 (20.9; 43.6)	0.219
Volume of hematoma, ml	10.3 (3.6; 25.0)	7.2 (3.0; 15.2)	0.329
NIHSS score	12.5 (8; 16)	13 (8; 19)	0.647
ICH score	2 (1; 3)	2 (1; 2)	0.550
SOFA score	2 (1; 3)	2 (2; 2)	0.399
Surgical treatment,%	21.4 (12.5; 32.9)	2.9 (0.3; 9.9)	0.001
Duration of hospitalization, days	14 (11; 18)	14 (9; 19)	0.938
Rankin 30 days later, score	4 (3; 4)	4 (3; 6)	0.153
Mortality 30 days later, %	14.3 (7.1; 24.7)	25.7 (16.0; 37.6)	0.091

Quantitative characteristics are given in the form of the median and the boundaries of the interquartile range (in brackets). Binary quality data is presented as the fraction and boundaries of 95% CI for the fraction (in brackets).

Based on the results of telemedicine consultations, 89 recommendations were given, of which 7 (7.9% CI 3.2%; 15.5%) were not implemented for objective reasons due to changes in the clinical situation shortly after the consultation.

The mortality rate in the Group 1 was 14.3% (CI 7.1%; 24.7%), and in the Group 2 it was 25.7% (16.0%; 37.6%), $p = 0.091$. However, no superiority was proved, since the difference between the mortality groups was 11.4 with CI from –0.07 to 24.5 percentage points, and, therefore, the CI crosses a predetermined border.

An imbalance of groups by gender, age, and hematoma localization was revealed (Table 1). In order to control biasing factors, a multivariate analysis of the effect of group imbalance on the primary endpoint was carried out. Significant effect of the imbalance of the groups according to the initial signs on mortality between the groups was not detected (table. 2).

Table 2

Multifactor analysis

Parameter	OR	95% CI for OR	p
Group	0.46	0.18; 1.14	0.095
Male	0.94	0.38; 2.26	0.886
Age	1.01	0.97; 1.04	0.611
Subcortical location	0.97	0.40; 2.34	0.951

Note: OR – odds ratio

A total of 17 patients were operated on (12.1%). The operational activity in the Group 1 was significantly higher than in the Group 2: 21.4% (12.5%; 32.9%) versus 2.9% (0.3%; 9.9%), $p = 0.001$ (statistically significant). The mortality rate among operated patients in the Group 1 was lower than in the Group 2 46.7% (CI 21.3%; 73.4) versus 100% (CI 15.8%; 100%), but statistically not significant, $p = 0.471$.

DISCUSSION

At the time of submitting the article to the publishing house (March 2019), we are not aware of the results of any other published prospective studies in the field of clinical telemedicine in patients with ICHg.

According to the results of the study, 30-day mortality in patients with ICHm in groups did not reach clinically significant comparability. Given that the recommendations of the consultants were implemented, the lack of comparability can be explained by the different level of medical care in the RVC compared to the PVD in general. At the RVC interdisciplinary team of specialists with a neurosurgeon and neuroresuscitator assist the patient with hemorrhagic stroke. According to the data obtained, the difference in mortality between groups can be more than 15 percentage points, which can no longer be explained only by the level of medical care. Therefore, the management of the patient by specialists of expert level is better than their only remote participation.

The low operational activity in the Group 2 is explained by the need to transport patients from PVD to the neurosurgical department of the RVC, which was not always possible due to the risk of worsening the patient's condition and, accordingly, reflected on recommendations for patient management tactics. The second reason for the lower frequency of surgical treatment could be a more frequent location of the hematoma in the subcortical region in patients of the Group 2. Due to the small number of patients operated on, the analysis of this subgroup was not informative.

The lack of randomization is a significant limitation of our study, which led to an imbalance of the groups according to the initial characteristics, so the results of the study may be biased. However, multivariate analysis did not reveal a significant effect of the imbalance of the groups according to the initial signs on the primary endpoint of the study. Nevertheless, such a large difference in mortality between the RVC and PVD raises the question of clarifying the indications for transferring patients with ICHg to a higher level medical institution. To date, there is insufficient evidence that could establish the criteria for transferring patients with ICHg to the next stage of medical care. Current recommendations include extremely broad and inaccurate parameters [9]. Further randomized clinical trials using telemedicine technologies are needed to clarify the indications for transferring patients with ICHg to the higher level of medical organizations.

CONCLUSION

At the current level of development of medicine and information technology, telemedicine cannot fully replace the traditional (at the patient's bedside) consultation of an expert level neurosurgeon and neuroresuscitator in patients with intracerebral hematomas.

REFERENCES

1. McLean S, Sheikh A, Cresswell K, Nurmatov U, Mukherjee M, Hemmi A, et al. The impact of telehealthcare on the quality and safety of care: a systematic overview. *PLoS One*. 2013;8(8):e71238. http://doi.org/10.1371/journal.pone.0071238
2. Badaev FI, Alasheev AM, Belkin AA, Chadova EA. Case-Control Study of Impact of Telemedicine Consultations on the Outcome of Patients with Intracerebral Hemorrhage. *Journal of Ural Medical Academic Science* 2015;4(55):4–6. (In Russ.)
3. Badaev FI, Alasheev AM, Belkin AA, Gadzhieva NSh, Kuznetsov YuV, Levit AL, et al. Pomekhi videokonferentssvyazi vo vremya neyroreanimatsionnykh robotizirovannykh telekonsul'tatsiy. *Intensivnaya terapiya i anesteziya*. 2014;(1):36–39. (In Russ.)
4. Badaev FI, Alasheev AM, Belkin AA, Gadzhieva NS, Kuznetsov YV, Levit AL, et al. Organization of neurological critical care robotic teleconsulting for remote monitoring of patients with acute cerebral failure in Sverdlov region. *Information technologies for the Physician*. 2014;(1):65–74. (In Russ.)
5. Steiner T, Al-Shahi Salman R, Beer R, Christensen H, Cordonnier C, Csiba L, et al. European Stroke Organisation (ESO) guidelines for the management of spontaneous intracerebral hemorrhage. *Int J Stroke*. 2014;9(7):840–855. PMID: 25156220 http://doi.org/10.1111/ijs.12309
6. Hemphill JC, Bonovich DC, Besmertis L, Manley GT, Johnston SC. The ICH score: a simple, reliable grading scale for intracerebral hemorrhage. *Stroke*. 2001;32(4):891–897. PMID: 11283388 http://doi.org/ 10.1161/01.STR.32.4.891
7. Macellari F, Paciaroni M, Agnelli G, Caso V. Neuroimaging in intracerebral hemorrhage. *Stroke*. 2014;45(3):903–908. PMID: 24425128 http://doi.org/10.1161/STROKEAHA.113.003701
8. Tunes da Silva G, Logan BR, Klein JP. Methods for equivalence and noninferiority testing. *Biol Blood Marrow Transplant*. 2009;15(1Suppl):120–127. PMID: 19147090 http://doi.org/10.1016/j.bbmt.2008.10.004
9. Vahidy FS, Meyer EG, Bambhroliya AB, Meeks JR, Begley CE, Wu TC, et al. Rationale and Design of a Statewide Cohort to examine efficient resource utilization for patients with Intracerebral hemorrhage (EnRICH). *BMC Neurol*. 2018;18(1):31. PMID: 29562884 http://doi.org/10.1186/s12883-018-1036-1

Received on 26.03.2019

Accepted on 24.04.2019