Acta Neurochirurgica (2019) 161:1297–1304
https://doi.org/10.1007/s00701-019-03884-7

ORIGINAL ARTICLE - BRAIN TRAUMA

Standardized assessment of outcome and complications in chronic subdural hematoma: results from a large case series

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Received: 25 December 2018 / Accepted: 20 March 2019 / Published online: 20 May 2019
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Abstract

Introduction Chronic subdural hematomas (cSDH) are commonly deemed to have a benign prognosis. However, detailed and standardized data describing outcome and complications in a large prospective patient cohort is lacking.

Methods Retrospective analysis of prospectively collected data in our institutional patient registry on consecutive patients undergoing surgery for cSDH from 2013 to 2017. Complications were assessed according to the Clavien-Dindo grading system (CDG). The outcome was measured with respect to two endpoints: occurrence of a complication with CDG 3–5 and lack of improvement in Karnofsky Performance Status (KPS) at the last follow-up.

Results Out of 435 operations, 166 (38.3%) presented a complication until 3 months postoperative (CDG 1, 23 (5.3%); CDG 2, 62 (14.3%); CDG 3a, 7 (1.6%); CDG 3b, 64 (14.7%); CDG 4a, 2 (0.5%); and CDG 5, 8 (1.8%)). Higher CDG correlated with a lower KPS ($r_s = -0.27$, $p < 0.001$). A lack of improvement in KPS was associated with a Charlson Comorbidity Index (CCI) > 1 and the iso- or hypodense appearance of the cSDH.

Conclusions This study provides a reliable estimate of the rate of medical and surgical complications in cSDH surgery. Complications that required a surgical intervention turned out to be rare. Recording complications in a standardized and prospective fashion can therefore serve as a basis for assessing patient outcome and quality control within the department.

Keywords Clavien-Dindo classification system · Complications · Outcome measures · Chronic subdural hematoma

Abbreviations

ASA American Society of Anesthesiology Classification of Perioperative Risk
BMI Body mass index
CCI Charlson Comorbidity Index
CDG Clavien-Dindo grading system
cSDH Chronic subdural hematoma
GCS Glasgow Coma Scale
IQR Interquartile range
KPS Karnofsky Performance Status
mRS Modified Rankin Scale
NIHSS National Institute of Health Stroke Scale
SD Standard deviation

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This article is part of the Topical Collection on *Brain trauma*

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Introduction

Chronic subdural hematomas (cSDH) are a very common pathological entity. With an incidence of 1.7–18/100,000, which rises to 286/100,000 in the older population [1, 9, 12, 17], cSDH patients represent a relevant portion of all patients referred to neurosurgical departments. This is particularly true for modern western countries where an aging population leads to an even growing number of cSDH patients [14].

The prognosis of cSDH is generally considered to be good [9, 17], even for patients requiring surgical evacuation [4, 15]. However, there have been several studies indicating that cSDH may result in significant patient mortality and morbidity [8, 16]. The exact incidence and severity of surgical and medical complications after surgery for cSDH are still unclear. Available reports on the topic are, although numerous, very heterogeneous in terms of patient numbers, data collection methods, inclusion criteria, and criteria of reporting complications [17, 22]. This heterogeneity not only renders comparisons between centers difficult but also hampers the awareness of the problem. Data on large patient cohorts with standardized, rigorous, and prospective data collection are therefore desirable.

Since January 2013, all data concerning patients undergoing surgery at our department are prospectively collected in our institutional patient registry [23]. Among several clinical, radiological, and surgery-related variables, complications are systematically assessed according to the Clavien-Dindo grading (CDG), see Table 1, [7], a classification widely used in general surgery, which proved to be reliably applicable in neurosurgery as well and to be easy to handle and reproduce [6]. Similar registers are rare but available at other medical institutions, particularly in the Scandinavian countries [2–4, 11, 24].

The aim of our study is thus to report on the incidence of complications and on their impact on patient outcome in a large cohort of consecutive patients, undergoing surgery for cSDH at our institution. All complications were prospectively assessed in a standardized and easily reproducible manner. A special focus was set on identifying factors associated with the occurrence of a complication and the failure of clinical improvement after the surgical intervention.

Methods

Patients and data collection

Prospectively collected data of all patients undergoing surgical evacuation for cSDH at our institution between January 2013 and September 2017 were retrospectively analyzed. All data were extracted from our department's prospective database of complications and outcome [23]. Disease-specific data was added by reviewing electronic patient records.

Patient data were routinely registered at admission, discharge, and 6 weeks postoperatively. Additional controls were scheduled if patients have any complications or if the cSDH was not yet sufficiently reabsorbed on CT scan. For the

Table 1 Clavien-Dindo grading system (CDG) of classifications [7]

CDG grade	Definition	Surgical complications 108/435 (24.8%)		Medical complications 58/435 (13.3%)	
Grade 1	Any deviation from the normal postoperative course, which can be treated without pharmaceutical, surgical, endoscopic, or radiological interventions. Excluded from these interventions are anti-emetics, antipyretics, analgesics, diuretics, electrolytes, and physiotherapy.	19 (4.4%)	16 recurrences, 1 optic hallucination (DD seizure), 1 shunt malfunction, 1 wound rebleeding	4 (0.7%)	1 decubitus, 1 urinary retention, 1 hypotension, 1 delirium
Grade 2	Requiring treatment with pharmaceutics other than the ones allowed in grade 1.	21 (4.8%)	20 epileptic seizures (first-time occurrence), 1 wound infection	41 (9.4%)	1 acute peripheral artery occlusion, 2 cardiac decompensations, 16 deliria, 1 gout relapse, 2 infection NOS, 1 thrombosis, 13 urinary tract infections, 1 gastric bleeding, 4 pneumonia
Grade 3	Requiring surgical, endoscopic, or radiological treatment				
Grade 3a	Intervention not under general anesthesia	4 (0.9%)	1 wound infection, 3 wound healing disorders	3 (0.7%)	1 ascites, 1 urinary retention, 1 thrombosis
Grade 3b	Intervention under general anesthesia	64 (14.7%)	1 hydrocephalus malresorptivus, 3 wound infections, 1 hematoma infection, 57 recurrences, 2 wound healing disorders		
Grade 4	Life-threatening complications requiring intensive care unit (ICU) management				
Grade 4a	Single-organ dysfunction			2 (0.5%)	1 asystole, 1 AVNRT
Grade 4b	Multi-organ dysfunction				
Grade 5	Death of the patient			8 (1.8%)	1 liver failure, 1 pneumonia, 2 sepses, 1 recurrence, 3 unknown

Grading, number, and type of complication until the last follow-up. *NOS*, not otherwise specified purpose of our study, if patients were not seen at the 3-month control, data from the last available follow-up were used.

Functional status of patients at each time point was measured using the Karnofsky Performance Status Scale (KPS), the modified Ranking Scale (mRS), and the National Institutes of Health Stroke Scale (NIHSS). Other collected patient-related variables were age, sex, body mass index (BMI), smoking habits, use of anticoagulant or antithrombotic drugs, American Society of Anesthesiology Classification of Perioperative risk (ASA), Glasgow Coma Scale (GCS), Charlson Comorbidity Index (CCI), and length of hospital stay. Disease-specific radiological criteria included maximum hematoma thickness (measured in mm in axial CT plane, only in unilateral hematoma), midline shift (measured in mm in axial CT plane), laterality of cSDH (bilateral vs unilateral), density (hypodense, isodense, hyperdense, or mixed), and presence of membranes. CCI score was retrospectively calculated.

Definition of complications

Any deviation from the normal postoperative course during the first 3 months after the operation was defined as a complication. Complications were graded from 1 to 5 according to the therapy-oriented Clavien-Dindo grading system (see Table 1) [7]. Complications were further classified as surgical if clearly related to the surgery (such as wound infections) and as medical if no relation to the surgery was apparent. Recurrence of cSDH was also considered a complication and was defined by radiological evidence of recurrence.

Primary and secondary endpoints

The primary endpoint was the occurrence of a CDG grade 3–5 complication during the first 3 months after the surgical evacuation of a cSDH. The secondary endpoint was a lack of improvement of KPS at the last follow-up after the operation.

Statistical analysis

Data are presented as median and interquartile range or mean and standard deviation for ordinal and metric variables and percentage for nominal variables. Comparisons of patient characteristics and disease-specific variables between study groups were done using Pearson chi-squared test for nominal variables, non-parametric tests (Mann-Whitney *U* test) for ordinal variables and Student's *t* tests (or Fisher's exact test as appropriate) for metric variables if data were distributed normally. To identify independent predictors of our primary and secondary endpoints, variables with significant differences in bivariate analysis were implemented in a multivariable logistic regression model. Comparison of outcome (KPS at follow-up, change of KPS between admission and follow-up, length of hospital stay) was done with non-parametric tests. Bonferroni corrections were applied for multiple testing. Spearman's rho was used to determine correlations between different variables. Missing data was excluded for each test separately. The software IBM SPSS Statistics for Windows, Version 24.0 was used for statistical analysis. Tests were done two-tailed and the level of significance was set at p values < 0.05.

Results

Patient characteristics

A total of 435 operations from 371 patients undergoing surgery for cSDH were included in this study. Burr hole trepanation was performed in 404 (92.9%), whereas 31 (7.1%) required a craniotomy. Patient characteristics are reported in detail in Table 2. Median follow-up length was 57 days (IQR 45–88 days).

Complications and clinical outcome

After 166 (38.2%) operations, we observed a complication during the first 3 months postoperatively. Of those, 81 (18.6%) were graded as CDG 3 or higher. Six patients (1.4%) died within 30 days of surgery (CDG 5 and KPS 0). Table 1 shows the list of complications separated into medical and surgical complications and their corresponding CDG grading.

Median KPS at the last follow-up was 90 (IQR 80–100) in the whole cohort. Until follow-up, patients who did not experience complications had a higher median KPS than patients who did (100 vs 90, $p < 0.001$). Patients with CDG 2- and CDG 3b-complications showed significantly lower KPS compared to patients without complications (Fig. 1). Obviously, patients who died (CDG 5) had significantly lower KPS as well. There was an association between grades of CDG and KPS ($r_s = -0.339$, $p < 0.001$).

KPS at the last follow-up showed a median increase of 10 points (see Fig. 2) (IQR 0–+ 20) relative to KPS at admission. The median increase in KPS was significantly lower in the group with complications (median + 10, IQR 0–+ 20 vs +20, IQR + 10–+ 30, $p < 0.001$). Change in KPS correlated with CDG of complications ($r_s = -0.27$, $p < 0.001$).

When using mRS as a measure of the outcome at the last follow-up, we obtained similar results. Patients without complications had a median mRS of 0 (IQR 0–1), compared to a median value of 1 (IQR 0–3, $p < 0.001$) for those who had a complication. On the contrary, no difference in median NIHSS at the last follow-up appeared between patients with and without complications (median in both groups 0, IQR 0–0 vs IQR 0–2, $p < 0.001$).

Table 2 Comparison of patient characteristics between patients with and without improvement of KPS, with CDG 0–2 and CDG 3–5, and with recurrence or no recurrence at the last follow-up

Variable	Total number of cases ($n = 435$)	KPS at the last follow-up ($n = 435$)			CDG at the last follow-up ($n = 378 = 354 + 24$)			Recurrence at the last follow-up ($n = 435$)		
		Improvement of KPS ($n = 321$, 74%)	No improvement/worsening of KPS ($n = 114$, 26%)	*p* value	CDG 0–2 ($n = 354$, 94%)	CDG 3–5 ($n = 23$, 6%)	*p* value	No recurrence ($n = 378$, 86%)	Recurrence ($n = 57$, 14%)	*p* value
Female sex	115 (26.4%)	85 (26.5%)	30 (26.3%)	1.000	97 (27.4%)	5 (21.7%)	0.726	102 (27.1%)	13 (22.0%)	0.505
Age	76 (68–82)	75 (67–82)	76 (68.75–81.25)	0.613	76 (68–82)	73 (60–85)	0.690	75.5 (67.0–82.0)	76 (69–80)	0.970
KPS at admission	80 (5–8)	80 (5–8)	80 (6–9)	< 0.001	80 (60–80)	70 (50–90)	0.488	80 (60–80)	80 (50–80)	0.304
mRS at admission	2 (1–3)	2 (2–3)	2 (1–3)	< 0.001	2 (1–3)	2 (1–3)	0.684	2 (1–3)	2 (2–3)	0.407
NIHSS at admission > 0	304 (71.9%)	235 (75.3%)	69 (62.2%)	0.012	247 (71.6%)	13 (59.1%)	0.313	260 (71.0%)	44 (77.2%)	0.422
ASA > 3	39 (9%)	26 (8.1%)	13 (11.4%)	0.384	27 (7.6%)	5 (21.7%)	0.036	31 (8.2%)	8 (13.6%)	0.279
CCI > 1	146 (33.6%)	97 (30.2%)	49 (43.0%)	0.018	112 (31.6%)	9 (39.1%)	0.606	121 (32.2%)	25 (42.4%)	0.164
GCS	15 (14–15)	15 (14–15)	15 (14–15)	0.345	15 (14–15)	14 (14–15)	0.008	15 (14–15)	15 (14–15)	0.928
Anticoagulant drugs at time of diagnosis	96 (22.1%)	68 (21.2%)	28 (24.6%)	0.538	81 (22.9%)	6 (26.1%)	0.922	87 (23.1%)	9 (15.3%)	0.235
Antithrombotic drugs at time of diagnosis	98 (22.5%)	78 (24.3%)	20 (17.5%)	0.176	80 (22.6%)	5 (21.7%)	1.000	84 (22.3%)	14 (23.7%)	0.944
Smoking	53 (12.4%)	36 (11.5%)	17 (15.0%)	0.417	44 (12.8%)	6 (26.1%)	0.106	50 (13.6%)	3 (5.1%)	0.103
BMI, kg/m^2	25.0 (3.8)	25.1 (3.8)	24.6 (3.6)	0.231	25.1 (3.8)	25.2 (3.5)	0.907	25.08 (3.8)	24.23 (3.7)	0.114
Burr hole trepanation (vs craniotomy)	404 (92.9%)	298 (92.8%)	106 (93.0%)	1.000	328 (92.7%)	23 (100%)	0.388	350 (93.1%)	54 (91.5%)	0.593
Bilateral hematoma	128 (29.4%)	90 (28.0%)	38 (33.3%)	0.344	100 (28.2%)	9 (39.1%)	0.380	109 (29.0%)	19 (32.2%)	0.726
Hematoma thickness, mm	24.03 (7.2)	24.16 (7.3)	23.63 (6.7)	0.574	24.1 (7.4)	24.0 (6.1)	0.980	24.02 (7.3)	24.13 (6.3)	0.930
Midline shift	7.0 (3.0–10.0)	7.0 (3.5–11.0)	5.0 (2.0–9.0)	0.002	7.0 (3.0–10.0)	6.0 (3.0–10.0)	0.800	7.0 (3.0–10.0)	7.0 (4.0–10.0)	0.740
Hypo-/isodense hematoma (vs mixed/hyperdense)	153 (35.3%)	100 (31.2%)	53 (46.9%)	0.004	112 (31.6%)	9 (39.1%)	0.606	120 (31.9%)	33 (56.9%)	< 0.001
Membranes	148 (34.1%)	116 (36.1%)	32 (28.3%)	0.164	126 (35.6%)	7 (30.4%)	0.782	133 (35.4%)	15 (25.9%)	0.203

Data is presented as count (percent) for categorical variables, mean (standard deviation (SD)) for variables on an interval scale, and median (interquartile range (IQR)) for variables on an ordinal scale. ASA, American Society of Anesthesiology Classification of Perioperative Risk; *BMI*, body mass index; *CCI*, Charlson Comorbidity Index; *CDG*, Clavien-Dindo grading; *GCS*, Glasgow Coma Scale; *KPS*, Karnofsky Performance Status Scale; *mRS*, modified Rankin Scale; *NIHSS*, National Institute of Health Stroke Scale; *SD*, standard deviation

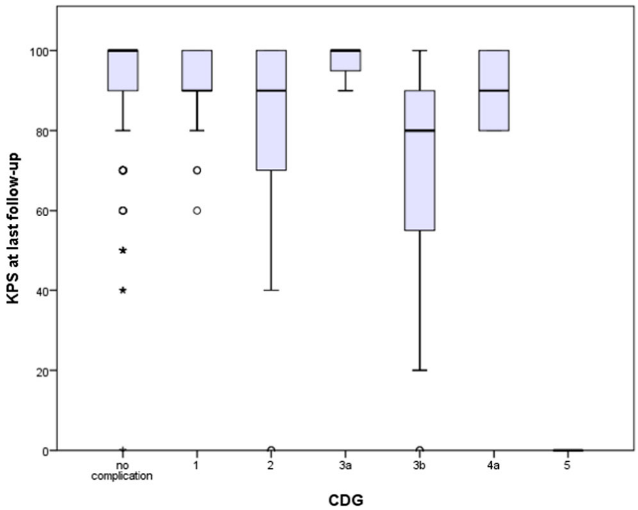

Fig. 1 KPS at the last follow-up according to CDG. Patients with CDG 2-, CDG 3b-, and CDG 5-complications showed significantly lower KPS compared to patients without complications. Boxplots represent quartiles (25%, 75%); horizontal lines represent medians; whiskers show ranges up to 1.5 times the interquartile range; dots above whiskers show outliers. CDG, Clavien-Dindo grading; KPS, Karnofsky Performance Status Scale

The length of hospital stay was significantly longer for patients with complications than for those without complications (6 vs 5 days, $p < 0.001$) and correlated with the CDG ($r_s = 0.209$, $p < 0.001$), as expected for a therapy-oriented grading scheme.

Primary endpoint: occurrence of complication CDG ≥ 3

After excluding cases with cSDH recurrence, 24 complications CDG ≥ 3 were registered. Patients with CDG complication ≥ 3 more frequently had an ASA score > 3 ($p = 0.036$,)

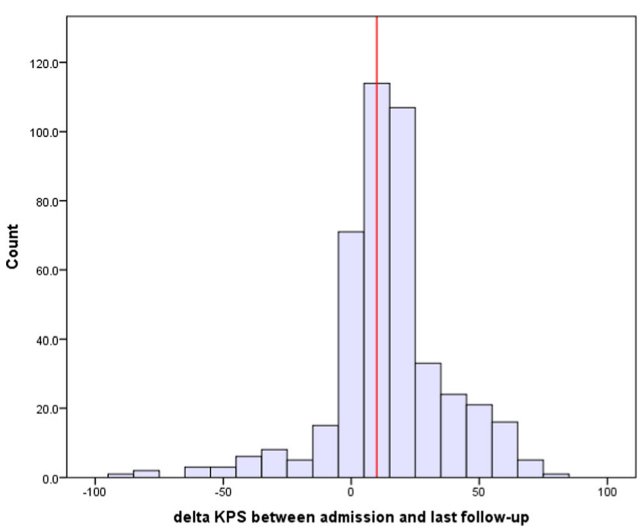

Fig. 2 Distribution of the difference in KPS between admission and the last follow-up. The median is + 10 (red line)

and a lower median GCS at admission ($p = 0.008$) (Table 2). However, in the multivariable logistic regression model, these factors were not significant independent predictors for a complication with CDG ≥ 3 (see Table 3).

Secondary endpoint: lack of improvement in KPS

A KPS improvement at the last follow-up could be shown in 321 (73.8%) operations. KPS at admission, mRS at admission, NIHSS > 0 at admission, CCI > 1, median midline shift, and hematoma density were significantly different distributed between patients with improvement and those without (see Table 2). Multivariable logistic regression, however, showed only CCI > 1 and hypo-/isodense hematoma (vs hyperdense/mixed hematoma) as independent predictors for lack of improvement in KPS (see Table 3). To be complete, we included the analysis of predictors for the occurrence of recurrence (see Tables 2 and 3). As this was not one of our endpoints, we refrained from further discussion.

Discussion

Our study aimed to report surgical complications in a standardized manner, to identify the rate of medical and surgical complication in a prospective cohort of consecutive patients undergoing surgery for cSDH, and to identify risk factors associated with the occurrence of a complication. Our study showed that the incidence of complications in our patient cohort was higher than in many published studies, possibly because we considered any deviation from the normal postoperative course as a complication. However, complications other than recurrence requiring re-operation or worse (CDG ≥ 3) were rare (5%). Second, we could show that the occurrence of a complication had an impact on clinical outcome, which correlated with the CDG grading of complications. Third, patients with a CCI > 1 and a hypo- or isodense appearance of the cSDH of the CT scan had a higher risk for lack of improvement of KPS and mRS.

Complications and outcome

Reported complication rates in the literature after surgery for cSDH vary between 6 and 32% [5, 10, 13, 19, 22]. Our complication rate (38.2%) seems thus to be slightly higher than commonly reported. We believe, however, that this is due to our definition of a complication being particularly strict since it includes any deviation from the normal, expected postoperative course. Including complications that occurred within 3 months after surgery and the high quality of our prospectively and systematically collected data might further explain higher complication rates than previously reported. Lastly, we

Table 3 Logistic regression analysis on predictors of lack of improvement of KPS, of CDG 3–5 complications, and of recurrence of cSDH at the last follow-up

	Variable	Odds ratio (95% confidence interval)	*p* value
Predictors of CDG 3–5 complications	GCS (per point)	0.931 (0.709–1.224)	0.610
	ASA > 3 (vs 1–3)	2.831 (0.788–10.171)	0.111
Predictors of lack of improvement of KPS	KPS at admission (per 10 points)	1.026 (0.769–1.369)	0.862
	mRS at admission (per 1 point)	0.675 (0.426–1.068)	0.093
	NIHSS at admission > 0 point (vs 0 point)	0.880 (0.507–1.527)	0.648
	CCI > 1 point (vs 0–1 point)	2.110 (1.300–3.425)	0.003
	Midline shift (per mm)	0.959 (0.912–1.008)	0.100
	hypo-/isodense Hematoma (vs mixed/hyperdense)	1.809 (1.145–2.858)	0.011
Predictors of recurrence of cSDH	hypo-/isodense hematoma (vs hyperdense/mixed)	2.816 (1.604–4.945)	< 0.001

ASA, American Society of Anesthesiology Classification of Perioperative Risk; *CCI*, Charlson Comorbidity Index; *CDG*, Clavien-Dindo grading; *cSDH*, chronic subdural hematoma; *GCS*, Glasgow Coma Scale; *KPS*, Karnofsky Performance Status Scale; *mRS*, modified Rankin Scale; *NIHSS*, National Institute of Health Stroke Scale

considered the recurrence of cSDH as a complication as well. The reason for such strict criteria is that patients harboring a cSDH are often in need of postoperatively restart anti-aggregation or anticoagulant therapy. The radiological evidence of recurrence of a cSDH may influence the decision to restart anti-aggregation or anticoagulation, a decision which in turn may have clinically relevant effects. This means that our criteria for reporting a complication are more inclusive than those commonly adopted in the literature, and therefore represent a more realistic assessment of expected complication in cSDH surgery [10, 13, 17–19].

To our knowledge, the present study is one of the very few using a standardized classification system to report complications [2]. Objective reporting of complications is needed in order to constantly and reproducibly monitor its own surgical results and to efficiently compare them among different centers. It represents, however, a tough task, since the reliability of every single score used to objectivize complications is ultimately dependent on the physician assessing it, no matter how restrictive the definition of each score may be. In the case of the CDG, this applies particularly to CDG complications grades 1 and 2, where the concept of "any deviation from normal postoperative course" leaves open the question of how a normal postoperative course should look like. Moreover, a minor complication may be either under or over diagnosed depending not only on the physician but also on the method used to assess it (i.e., clinical vs instrumental diagnosis). We chose the widely used CDG score for grading of complications, which have already been validated in multiple studies in general surgery as well as in neurosurgery [6, 7]. However, we chose to focus our primary outcome on CDG > 3, this means on those complications where the possibility of under- or overdiagnosis is reduced. We strongly believe that the use of a standardized validated classification improves the reliability of reporting complications and allows easier comparisons between different series. Indeed, our complications rate is similar to those shown in the only other study [2] reporting complications in a standardized fashion.

Importantly, patients in our series generally had a good outcome and showed an improvement in KPS after the operation even if they suffered from a complication. These results are consistent with the findings in other studies [9, 10, 17]. However, overall, the occurrence of a complication still had an impact on patients' outcome, which correlated with the grade of complication according to the CDG. This finding further validates the utility of the CDG in neurosurgery, notwithstanding the fact that the CDG is conceived to reflect more the resources needed to treat a complication rather than the severity of a complication itself (see Table 1). This implies that, at least in the case of cSDH, the two criteria go along with each other.

Predictors of complications and outcome

In literature [2], CCI > 1 and a GCS of 3–12 are reported as independent predictors of severe complications, a finding that we could not replicate. However, in bivariate analysis, we could show a significantly lower median GCS and a significantly higher number of patients with an ASA score > 3 in the group with CDG ≥ 3. This finding is in line with several studies in neurosurgery and general surgery, which found that patients with a higher ASA score have higher postoperative morbidity and mortality rates [20, 21, 25]. CCI > 1 was an independent predictor for a lack of improvement in KPS, together with an iso- or hypodense cSDH appearance in preoperative CT scan. This finding suggests that patients with multiple comorbidities do not recover as well as patients without.

Conclusions

Our study provides a reliable estimate of the rate of medical and surgical complications in cSDH surgery. While complications other than recurrence requiring revision surgery were rare, the occurrence and severity of a complication correlated with clinical outcome and length of hospital stay. Recording complications in a standardized and prospective fashion can therefore serve as a basis for assessing patient outcome and quality control within the department.

Acknowledgements The authors thank all resident and staff physicians of the department, who prospectively collected and verified the data that is the basis of the current analysis.

Compliance with ethical standards

Conflict of interest The authors declare that they have no conflict interests.

Ethical approval All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards. The local ethics committee (Kantonale Ethikkommission KEK-ZH 2012–0244) approved the prospective data collection in the patient registry.

Informed consent Informed consent was obtained from all individual participants included in the study.

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