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ORIGINAL SCIENTIFIC REPORT

Spontaneous Retroperitoneal and Rectus Sheath Hemorrhage—Management, Risk Factors and Outcomes

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Abstract

Background Spontaneous retroperitoneal and rectus sheath hemorrhage (SRRSH) is associated with high mortality in the literature, but studies on the subject are lacking. The objective of this study was to identify early predictors of the need for angiographic or surgical intervention (ASI) in patients with SRRSH and define risk factors for mortality.

Methods We conducted a retrospective cohort study at a tertiary academic hospital. All patients with computed tomography-identified SRRSH between 2012 to 2017 were included. Exclusion criteria were age below 18 years, possible mechanical cause of SRRSH, aortic aneurysm rupture or dissection, and traumatic or iatrogenic sources of SRRSH. The primary outcome was the incidence of ASI and/or mortality.

Results Of 100 patients included (median age 70 years, 52% males), 33% were transferred from another hospital, 82% patients were on therapeutic anticoagulation, and 90% had serious comorbidities. Overall mortality was 22%, but SRRSH-related mortality was only 6%. Sixteen patients underwent angiographic intervention (n = 10), surgical intervention (n = 5), or both (n = 1). Flank pain (OR 4.15, 95% CI 1.21–14.16, p = 0.023) and intravenous contrast extravasation (OR 3.89, 95% CI 1.23–12.27, p = 0.020) were independent predictors of ASI. Transfer from another hospital (OR 3.72, 95% CI 1.30–10.70, p = 0.015), age above 70 years (OR 4.24, 95% CI 1.25–14.32, p = 0.020), and systolic blood pressure below 110 mmHg at the time of diagnosis (OR 4.59, 95% CI 1.19–17.68, p = 0.027) were independent predictors of mortality.

Conclusions SRRSH is associated with high mortality but is typically not the direct cause. Most SRRSHs are self-limited and require no intervention. Pattern identification of ASI is hard.

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Introduction

Spontaneous retroperitoneal and rectus sheath hemorrhage (SRRSH) typically occurs in elderly patients with significant comorbidities and may cause exsanguination or abdominal compartment syndrome with associated devastating complications [1–3]. The diagnosis may be delayed due to the variability and vagueness of the symptoms [4]. Approximately two-thirds of SRRSHs are associated with therapeutic anticoagulation, and the remaining third is often related to hemodialysis, hemophilia, or abnormal retroperitoneal formations (cysts, lipomas, aneurysms, and tumors) [4]. The mortality rate of SRRSH patients has been

described only in small case series, and risk factors for SRRSH are not well described [5–7]. Timely intervention is desirable, but there is no clear guidance regarding which subgroup(s) of patients require an interventional method of bleeding control; many bleeding episodes stop spontaneously. The objective of this study was to identify early predictors of the need for angiographic or surgical intervention (ASI) in patients with SRRSH and define risk factors of mortality. We hypothesized that patients in need of ASI are defined by certain characteristics which can be identified early and thus guide early intervention.

Materials and methods

In this retrospective study, all patients older than 18 years of age admitted to our tertiary academic medical center from January 2012 to January 2017 with a SRRSH identified on computed tomography (CT) were included. We excluded patients with procedures performed within 14 days prior to the diagnosis of SRRSH in order to rule out a mechanical cause of bleeding. Patients with aortic rupture, a traumatic or iatrogenic source of SRRSH, and patients with a known SRRSH before the current admission were also excluded. Patients were identified through "Render," a prospective electronic registry of all patients who undergo angiography for suspected hemorrhage maintained by the Massachusetts General Hospital Division of Interventional Radiology. The registry was sought for CT scans containing a combination of the words "retroperitoneal," "extraperitoneal" or "rectus" and "hemorrhage,"" hematoma" or "bleed." The medical records of the identified patients were reviewed for the following variables: demographics, documented comorbidities, vital signs on presentation, specific signs and symptoms of SRRSH (flank ecchymosis, abdominal mass or pain, generalized weakness, symptoms attributed to low-volume state [lightheadedness or syncope], and/or dyspnea), laboratory findings closest to the time of diagnosis (international normalized ratio, prothrombin, activated clotting time, hemoglobin, platelet count, and activated partial thromboplastin time), use of therapeutic anticoagulation (including antiplatelet agents), history of transfusion, CT scan indication, CT diagnosis and description, CT-identified source of bleeding, interventions (transfusions, interruption of anticoagulants/antiplatelets, reversal of anticoagulants, interventional radiology, or surgery), and outcomes (intensive care unit (ICU) admission, ICU length of stay, hospital length of stay, and mortality). Cause of death was either based on clear documentation in the medical records or by a review of the data by the authors. The study protocol was approved by the institutional review board.

Statistical methods

Patients who underwent ASI were compared with those who did not to identify variables associated with ASI. Similarly, to identify variables associated with mortality, patients who died were compared to those who survived. For numerical variables, parametric data were reported as means with standard deviations (sd) and nonparametric data as medians with interquartile ranges [IQR]. Categorical variables were reported as frequencies and percentages. Univariate analyses were performed using the two-sided Student's t test or the Mann–Whitney U test for numerical variables as appropriate; the Pearson's Chi-squared test or the Fisher's exact test was used for categorical data. Statistical significance was set at a p value below 0.05. Multivariable logistic analyses controlled for clinically relevant variables were performed to identify independent predictors of the need for ASI and for mortality. Odds ratios (OR) and 95% confidence intervals (CI) were calculated for every independent predictor. The statistical analyses were performed using R Studio version 0.99.486. As the sample size was 100 patients, the numerical values and percentages were identical and as such we present one or the other, not both.

Results

A total of 476 CT scans with extraperitoneal hemorrhages were identified through the radiology records and screened for eligibility. As a result, 376 patients were excluded based on the above-mentioned exclusion criteria and the remaining 100 patients constituted the population of this study.

Of them, 70% had a spontaneous retroperitoneal hematoma, 27% had a spontaneous rectus sheath hematoma, and 3% had both. The detailed patient distribution can be seen in Fig. 1. The mean age was 68 (14) and 52% were male. SRRSH was the primary reason of admission in 59% and 33% were transfers from other hospitals.

Almost all patients (96%) had documented known comorbidities prior to presentation, with cardiac disease being the predominant comorbidity and therapeutic anticoagulation being the predominant medication present at admission (see Table 1). The most common symptom on presentation was abdominal pain (46%), followed by flank pain (18%), and symptoms related to hypovolemia (18%).

Interventions

ASI was performed in 16 patients. Embolization involved a lumbar artery in four patients, the inferior epigastric artery in three, a renal artery in three, an iliac artery in two, and

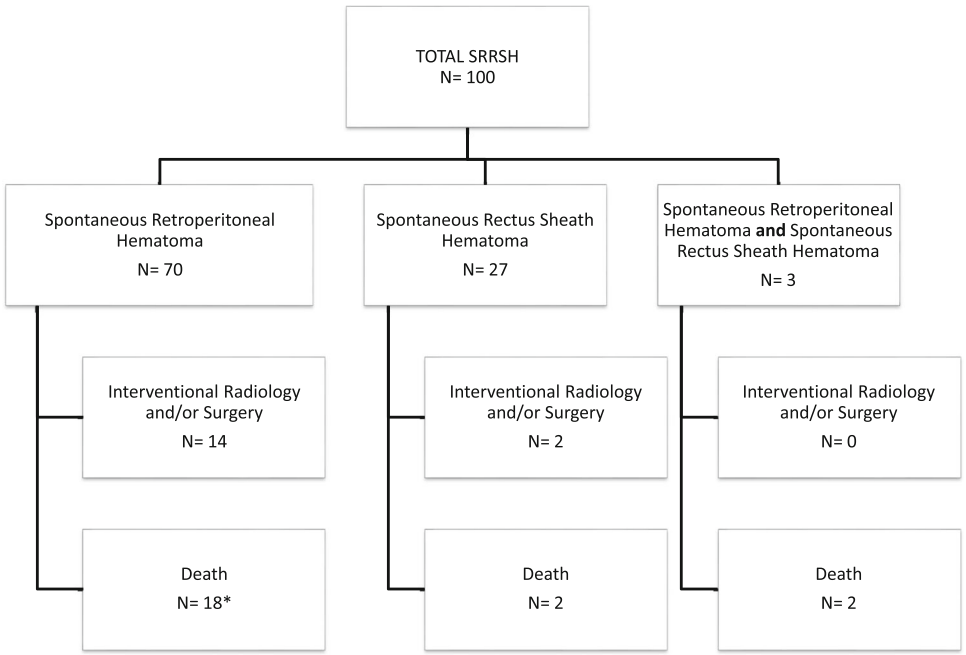

Fig. 1 Patient distribution and outcome. *Of these, two were judged to be secondary to the bleed

the iliolumbar artery in one. Surgical procedures included exploration and drainage of three hematomas (two retroperitoneal hematomas and one rectus sheath hematoma) and exploration and packing of one pelvic hematoma. Furthermore, one patient with indicators of hemorrhagic pancreatitis underwent emergent IR coil embolization of two splenic artery pseudoaneurysms. However, a large amount of clot and debris remained in his lesser sac causing gastric outlet obstruction and an aggressive, ongoing inflammatory response; for this reason, he underwent operative necrosectomy. Finally, one patient with an anterior abdominal wall hematoma underwent both interventional radiology (embolization of the superficial iliac circumflex artery) and surgery (subsequent evacuation and drain placement). Two variables were significantly different between patients who did and did not undergo ASI (see Table 2), and both were found to be independent predictors of ASI: flank pain (OR 4.15, 95% CI 1.12–14.16, $p = 0.023$) and active intravenous contrast extravasation on CT (OR 3.89, 95% CI 1.23–12.27, p = 0.020) (see Table 3).

Mortality

In-hospital mortality was 22%. However, 11 (50%) deaths were clearly documented as being unrelated to the bleed (five patients had descriptions of a well-controlled bleed at the time of death; three died due to pulmonary aspiration; one died due to an unsuccessful cardiac transplant; one died due to congestive heart failure; and one died secondary to an intracranial parenchymal bleed). In five cases, the cause of death was unclear, as available information was too sparse to judge the cause of death.

In the remaining six (27%) patients who died, the cause of death was found to be secondary to the bleed (one patient did not wish to receive any intervention and died of kidney failure due to persistent hypotension; one patient developed hemorrhagic shock secondary to the bleed and was passed on to comfort measures; an extensive bleed led to development of compartment syndrome in a third patient who was a poor surgical candidate; a fourth patient developed disseminated intravascular coagulation and was too unwell to be offered interventional radiology; a fifth patient with non-small cell lung cancer developed factor 8 inhibition leading to a massive retroperitoneal bleed that could not be medically controlled; a sixth patient had a stroke that was described to be secondary to the retroperitoneal hemorrhage).

The following variables were significantly different between patients who died and those who did not: transfer from another hospital, age above 70 years, systolic blood pressure below 110 mmHg at the time of diagnosis, and the need for ICU admission (see Table 4).

Independent predictors of mortality were transfer from another hospital (OR 3.72, 95% CI 1.30–10.70, $p = 0.015$), age above 70 years (OR 4.24, 95% CI 1.25–14.32, $p = 0.020$), and a systolic blood pressure below 110 mmHg at the time of diagnosis (OR 4.59, 95% CI 1.19–17.68, $p = 0.027$) (see Table 3).

Table 1 Baseline characteristics of 100 patients with spontaneous retroperitoneal and rectus sheath hemorrhage (SRRSH)

Male (%)	52
Transfer from another hospital (%)	33
SEH primary reason for admission (%)	59
Age (years), mean (sd)	68.4 (14.4)
BMI, body mass index, mean (sd)	32.3 (9.8)
Presentation characteristics	
Systolic blood pressure	109.5 [92.8, 131.2]
Heart rate	90.0 [76.0, 104.0]
Saturation	97.0 [95.0, 98.0]
Respiratory rate	18.0 [16.0, 20.0]
Days from onset	1.0 [0.0, 2.0]
Flank pain (%)	18
Flank ecchymosis (%)	1
Abdominal mass (%)	1
Abdominal pain (%)	46
Hip pain (%)	5
Back pain (%)	7
Weakness (%)	4
Low-volume state (%)	18
Dyspnea (%)	6
Laboratory values	
Creatinine	1.4 [0.8, 1.9]
Hemoglobin	7.6 [6.7, 9.8]
Hematocrit	24.0 [21.7, 30.7]
Platelet	203.0 [138.2, 288.5]
INR	1.4 [1.2, 2.3]
Prothrombin time (s)	16.9 [14.5, 26.4]
Activated partial thromboplastin time (s)	39.8 [30.2, 56.5]
Comorbidities	*%*
Hemophilia	7
DVT	14
CAD	31
Atrial fibrillation	42
Anticoagulation medication	79
Non-reversible	19
Reversible	60
Antiplatelet medication	18
Management	*%*
Any intervention	79
Surgery	6
Interventional radiology	11
Both	1
Transfusion	45
Anticoagulation reversal	18
Anticoagulation held	36
Anticoagulation and antiplatelet held	5
Anticoagulation or antiplatelet therapy held	49
Outcomes	
Hospital length of stay	9.5 [5.0, 18.0]
ICU length of stay	0.0 [0.0, 2.8]
Mortality (%)	22

Results are presented medians with [IQR] or as otherwise indicated

IQR interquartile range, *DVT* deep venous thrombosis, *CAD* coronary artery disease, *ICU* intensive care unit

Discussion

In this study of 100 SRRSH patients, we documented that most SRRSHs are self-limited: only 16% required ASI and of those, two-thirds were managed by angiographic embolization alone. Surgical treatment of the SRRSH was performed in only 6%.

ASI

While our observed rate of surgical intervention ties in well with previous research [4, 8], the proportion of angiographic interventions has previously been found to be higher. For example, Smithson et al. and Sunga et al. reported that between 20.8 to 24.7% SRRSH patients underwent angiographic intervention [4, 9], and Caleo et al. [8] found the incidence to be as high as 48.1%. Of note, however, the study by Caleo only included patients with a clinical suspicion of SRRSH, and thus, less severe cases (where SRRSH was found incidentally on CT) may have been excluded.

Unfortunately, the retrospective nature and lack of detail in these studies makes it is difficult to evaluate whether these differences are insignificant or whether indeed fewer patients need angiographic intervention.

Furthermore, although some of our results indicate beneficial effects of ASI, such as reduced rates of transfusion, others indicate disadvantageous effects, such as prolonged hospital length of stays, and as such recommendations are hard to make.

Mortality

In this study, we found a high in-hospital mortality of 22%. To what extent the bleeds contributed, even remotely, to the demise of these often multi-morbid patients cannot be accurately evaluated. However, based on our retrospective assessment, the majority (73%) of deaths was not directly attributable to the SRRSH, and only six deaths were found to be caused directly by the spontaneous bleed.

Table 2 Comparison of patients who required angiographic or surgical interventions (ASI) with those who did not

	ASI (n = 16)	No ASI (n = 84)	p value
Female	7 (43.8)	41 (48.8)	0.92
Transfer from another hospital	7 (43.8)	26 (31.0)	0.48
Active extravasation described on CT	8 (50.0)	20 (23.8)	0.067
SEH primary reason for admission	15 (93.8)	44 (52.4)	0.0050
Age (years), mean (sd)	66.1 (11.1)	68.8 (14.9)	0.49
BMI, body mass index, mean (sd)	30.7 (8.3)	32.7 (10.2)	0.64
Size of hematoma (cm^3)	1415.0 [630.2, 2667.0]	936.0 [454.0, 1920.0]	0.26
Presentation characteristics			
Systolic blood pressure	103.0 [87.5, 113.0]	110.0 [97.0, 132.0]	0.18
Heart rate	91.0 [76.5, 106.5]	87.5 [76.0, 103.2]	0.75
Saturation	96.0 [93.2, 98.2]	97.0 [96.0, 98.0]	0.39
Respiratory rate	19.0 [17.0, 20.0]	18.0 [16.0, 20.0]	0.76
Days from onset	1.5 [0.0, 2.8]	1.0 [0.0, 2.0]	0.40
Flank pain	6 (37.5)	12 (14.3)	0.063
Flank ecchymosis	0 (0.0)	1 (1.2)	1.0
Abdominal mass	0 (0.0)	1 (1.2)	1.0
Abdominal pain	7 (43.8)	39 (46.4)	1.0
Hip pain	1 (6.2)	4 (4.8)	1.0
Back pain	1 (6.2)	6 (7.1)	1.0
Weakness	1 (6.2)	3 (3.6)	1.0
Low-volume state	4 (25.0)	14 (16.7)	0.66
Dyspnea	3 (18.8)	3 (3.6)	0.077
Laboratory values			
Creatinine	1.4 [1.0, 1.8]	1.4 [0.8, 1.9]	0.54
Hemoglobin	7.6 [7.0, 9.2]	7.7 [6.7, 9.9]	0.69
Hematocrit	24.6 [21.8, 28.4]	23.8 [21.7, 31.0]	0.93
Platelet	212.0 [173.0, 304.8]	201.5 [131.0, 288.5]	0.34
INR	1.4 [1.2, 1.8]	1.4 [1.2, 2.3]	0.69
Prothrombin time (s)	16.5 [14.6, 20.4]	16.9 [14.6, 26.5]	0.78
Activated partial thromboplastin time (s)	38.1 [29.4, 39.9]	41.1 [31.3, 57.1]	0.41
Comorbidities			
Hemophilia	1 (6.2)	6 (7.1)	1.0
DVT	1 (6.2)	13 (15.5)	0.56
CAD	6 (37.5)	25 (29.8)	0.75
Atrial fibrillation	5 (31.2)	37 (44.0)	0.50
Reversible anticoagulant	7 (11.7)	53 (88.3)	0.15
Non-reversible anticoagulant	5 (26.3)	14 (73.7)	
Management	No (%)		
Anticoagulation reversal	12 (75.0)	70 (83.3)	0.66
Anticoagulation held	1 (6.2)	17 (20.2)	0.33
Anticoagulation and antiplatelet held	0 (0.0)	5 (6.0)	0.71
Anticoagulation OR antiplatelet therapy held	2 (12.5)	47 (56.0)	0.004
Any intervention	16 (100)	63 (75.0)	0.06
Both	1 (6.2)	0 (0.0)	0.35
Transfusion	3 (18.8)	42 (50.0)	0.04
Anticoagulation reversal	2 (12.5)	16 (19.0)	0.79
Anticoagulation held	0 (0.0)	36 (42.9)	0.0028

Table 2 continued

	ASI (n = 16)	No ASI (n = 84)	p value
Outcomes			
Hospital length of stay	10.0 [6.8, 15.0]	9.5 [5.0, 18.0]	0.98
ICU length of stay	2.0 [2.0, 2.0]	0.0 [0.0, 3.0]	0.42
Mortality, no (%)	1 (6.2)	21 (25.0)	0.18

Results are presented as numbers with percentages (%), medians with [IQR] or as otherwise indicated

CT computed tomography, *IQR* interquartile range, *DVT* deep venous thrombosis, *CAD* coronary artery disease, *ICU* intensive care unit

Table 3 Independent predictors of angiographic or surgical intervention (ASI) and mortality

Angiographic or surgical intervention (ASI)					In-hospital mortality				
	OR	95% CI	p value	Missing data		OR	95% CI	p value	Missing data
Flank pain	4.15	1.21–14.16	0.023	0	Age > 70[a]	4.24	1.25–14.32	0.020	0
Active extravasation described on CT[b]	3.89	1.23–14.16	0.020	0	Transfer from outside hospital[a]	3.72	1.30–10.70	0.015	0
					Systolic blood pressure < 110 mmHg[b]	4.59	1.19–17.68	0.027	16

OR odds ratio, *95% CI* 95% confidence interval, *CT* computed tomography

[a]Holding age and hemoglobin constant

[b]Holding systolic bloodpressure and hemoglobin constant

Detailed literature on the mortality after SRRSH is limited. Ivascu et al. and Sunga et al. found mortality rates between 10 to 12% [4, 10], and smaller studies have shown similar results [8, 11]. However, none of these studies consider the extent to which the bleeds may have contributed to the deaths. Nevertheless, efforts should be taken to understand the impact of a SRRSH, as it appears to be a marker of high mortality.

Independent predictors of ASI

While previous literature does describe common signs and symptoms in relation to SRRSH [4, 10, 12], our study is the first to identify independent predictors of the need for ASI: flank pain and extravasation of contrast on CT. Arguably, however, extravasation of contrast on CT may be a self-fulfilling prophecy and make surgeons more likely to perform ASI, whether needed or not. Furthermore, our results should be interpreted cautiously as our confidence intervals are rather wide, perhaps owing to the small study population. The only other attempt to identify predictors of ASI we are aware of was made by Smithson et al. [9] who studied 24 SRRSH patients and found the use of low molecular weight heparin, hypovolemic shock, need for blood transfusion as well as length of hospitalization to be significant predictors of interventional treatment on univariate analysis.

Independent predictors of mortality

In this study, we found age above 70 years, transfers from an outside hospital and a systolic blood pressure below 110 mmHg on presentation to be independent predictors of mortality. Again, however, the confidence intervals are wide, and the results should be interpreted with caution. Several previous studies have looked for predictors of mortality in SRRSH patients without significant findings [4, 10, 11, 13].

All in all, it seems that predictors of ASI and mortality in SRRSH patients are extremely hard to identify, and perhaps a high index of clinical suspicion in the elderly, anticoagulated population is the only tool we have. Given the significant mortality in this population, and the increasing elderly population, this condition warrants further, preferably prospective, investigation.

Limitations

Limitations of this study must be noted. First, it represents a single-center experience, and the results may not be generalizable to other institutions. Furthermore, symptom description in a retrospective chart analysis is assumed to be imprecise as not all symptoms will be included. Likewise, several relevant laboratory tests such as the arterial blood gas analyses will not always be available. Moreover, the indications for ASI are difficult to determine in

Table 4 Comparison of patients with spontaneous retroperitoneal or rectus sheath hematoma (SRRSH) who died and survived

	Died (n = 22)	Survived (n = 78)	p value
Female, no. (%)	10 (45.5)	38 (48.7)	0.98
Transfer from another hospital	12 (54.5)	21 (26.9)	0.029
Size of hematoma (cm^3), median [IQR]	1747.0 [958.0, 3549.0]	845.5 [366.8, 1884.0]	0.0096
Active extravasation described on CT	7 (31.8)	21 (26.9)	0.85
SEH primary reason for admission	11 (50.0)	48 (61.5)	0.47
Age (years)	75.5 [68.5, 81.0]	69.0 [57.5, 77.8]	0.030
BMI, body mass index	32.7 [29.3, 35.6]	29.5 [24.6, 37.1]	0.67
Presentation characteristics			
Systolic blood pressure	100 [84.5, 109.0]	111.0 [97.0, 138.0]	0.0089
Heart rate,	87.0 [76.2, 104.0]	90.5 [75.2, 102.8]	0.43
Saturation	96.0 [94.0, 98.0]	97.0 [96.0, 98.0]	0.16
Respiratory rate	20.0 [18.0, 25.5]	18.0 [16.0, 20.0]	0.012
Days from onset	1.0 [0.2, 1.8]	1.0 [0.0, 2.0]	0.44
Flank pain	4 (18.2)	14 (17.9)	1.0
Flank ecchymosis	0 (0.0)	1 (1.3)	1.0
Abdominal mass	0 (0.0)	1 (1.3)	1.0
Abdominal pain	12 (54.5)	34 (43.6)	0.50
Hip pain	1 (4.5)	4 (5.1)	1.0
Back pain	2 (9.1)	5 (6.4)	1.0
Weakness	0 (0.0)	4 (5.1)	0.64
Low-volume state	4 (18.2)	14 (17.9)	1.0
Dyspnea	1 (4.5)	5 (6.4)	1.0
Laboratory values			
Creatinine	1.5 [1.3, 1.9]	1.3 [0.8, 1.9]	0.72
Hemoglobin	7.3 [6.5, 9.1]	7.8 [7.1, 10.3]	0.09
Hematocrit	22.7 [20.1, 27.1]	24.5 [22.1, 31.3]	0.049
Platelet	245.5 [115.0, 303.8]	201.5 [143.8, 279.8]	0.57
INR	1.4 [1.2, 1.9]	1.4 [1.2, 2.3]	0.83
Prothrombin time (s)	16.6 [14.8, 21.5]	17.0 [14.5, 26.8]	0.75
Activated partial thromboplastin time (s)	50.4 [37.5, 63.8]	38.1 [28.1, 53.9]	0.090
Comorbidities			
Hemophilia	1 (4.5)	6 (7.7)	0.97
DVT	1 (4.5)	13 (16.7)	0.27
CAD	7 (31.8)	24 (30.8)	1.0
Atrial fibrillation	12 (54.5)	30 (38.5)	0.27
Management	No (%)		
Anticoagulation	19 (86.4)	63 (80.8)	0.77
Antiplatelet	6 (27.3)	12 (15.4)	0.33
Anticoagulation and antiplatelet medication	1 (4.5)	4 (5.1)	1.0
Anticoagulation or antiplatelet medication	13 (59.1)	36 (46.2)	0.41
Any intervention	18 (81.8)	61 (78.2)	0.94
Surgery	0 (0.0)	6 (7.7)	0.40
Interventional radiology	1 (4.5)	10 (12.8)	0.48
Both	0 (0.0)	1 (1.3)	1.0
Transfusion	13 (59.1)	32 (41.0)	0.21

Table 4 continued

	Died (n = 22)	Survived (n = 78)	p value
Anticoagulation reversal	6 (27.3)	12 (15.4)	0.33
Anticoagulation held	8 (36.4)	28 (35.9)	1.0
Outcomes			
ICU length of stay	4.0 [3.0, 8.0]	0.0 [0.0, 0.0]	0.0090
Hospital length of stay	15.0 [7.0, 22.0]	9.0 [5.0, 17.0]	0.13

Results are presented as numbers with percentages (%), medians with [IQR] or as otherwise indicated

IQR interquartile range, *CT* computed tomography, *DVT* deep venous thrombosis, *CAD* coronary artery disease, *ICU* intensive care unit

retrospect and thus a randomized setup is needed to correctly assess when and why ASI is required.

The three-dimensional sizes of the hematomas were available in 61% of cases and insignificant on multivariate analysis. It is plausible that missing measurements account for smaller hematomas or very large hematomas for which intervention was initiated without a prior CT scan and that this variable is therefore unreliable. Finally, the reported in-hospital mortality, instead of 30-day mortality, is a limitation commonly seen in the literature that must also be acknowledged, as information on recovery and other hospitalizations is crucial to accurately understand the impact of a SRRSH.

Conclusion

SRRSH is associated with high mortality but is typically not the direct cause of death. Most SRRSHs are self-limited and require no intervention, but pattern identification of ASI is difficult. Larger, prospective studies are warranted to study the best management strategies for patients with SRRSH.

Compliance with ethical standards

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

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