

# Clinical characteristics and risk factors of 267 patients having severe fever with thrombocytopenia syndrome—new epidemiological characteristics of fever with thrombocytopenia syndrome

## Epidemiological characteristics of SFTS

Yu Dong, MD<sup>a</sup>, Shao-hua Lin, MD<sup>b</sup>, Ling Jiang, MD<sup>c</sup>, Hui Liu, PhD<sup>d,\*</sup>

### Abstract

**Objective:** To analyze the epidemiological distribution, clinical characteristics, and prognostic risk factors of patients having severe fever with thrombocytopenia syndrome (SFTS).

**Methods:** We enrolled 790 patients with SFTS divided into the ordinary group and the severe group, analyzed the clinical characteristics, and screened the risk factors of serious patients by univariate logistic regression analysis.

**Results:** Most of the 790 patients (SFTS) are farmers (84.56%). The proportion of patients with fieldwork history was 72.41%, of which 21.27% had a clear history of a tick bite and 98.61% were sporadic cases. The annual peak season is from April to November. 16.33% patients were not accompanied by fever. The incidence of severe thrombocytopenia was 47.59%. They were statistically significant between the 2 groups in indicators such as age, hypertension, coronary heart disease, diabetes mellitus, bunyavirus nucleic acid load and mean platelet count ( $P < .05$ ). Multivariate non conditional Logistic regression analysis showed that the risk factors of the mild patients deteriorating severe disease were age ( $OR = 1.985, P \leq .003$ ), diabetes mellitus ( $OR = 1.702, P \leq .001$ ), coronary heart disease ( $OR = 1.381, P \leq .003$ ), platelet count ( $OR = 2.592, P \leq .001$ ), viral nucleic acid loading ( $OR = 3.908, P \leq .001$ ).

**Conclusion:** The incidence population and seasonal distribution characteristics of patients with SFTS are obvious. The risk factors for poor prognosis of severe patients are old age, multiple basic medical histories, high viral load, a serious decrease of mean platelet count, and delay of treatment time.

**Abbreviations:** SFTS = severe fever with thrombocytopenia syndrome.

**Keywords:** bunyavirus infection, prognosis, risk-factors, severe fever with thrombocytopenia syndrome

## 1. Introduction

Severe fever with thrombocytopenia syndrome (SFTS) is an acute infectious disease caused by a new Bunyavirus.<sup>[1,2]</sup> Severe fever and thrombocytopenia are the main clinical manifestations. The novel Bunyavirus belongs to the sandfly virus genus of the Bunyavirus family. Most patients are with elevated serum muscle enzyme and early nonspecific symptoms of the digestive system. Severe patients are with multiple organ function injuries, especially abnormal coagulation mechanisms and elevated liver enzymes.<sup>[3]</sup> The rapid deterioration of the disease of a few patients, changes in respiratory, circulatory system and

consciousness, and multiple organ failure leads to the increase of clinical mortality. The disease is self limited, most patients have a good prognosis. Some patients die because of acute disease onset and rapid deterioration and multiple organ failure. The clinical mortality is 10% to 40%.<sup>[4,5]</sup> At present, similar cases have been reported in the United States, Japan, and South Korea.<sup>[6]</sup> The clinical incidence rate has been increasing since the first case in China in 2010 with a different rate in various regions. In recent years, the number of SFTS has been increasing in Shandong province, China, where the hilly areas in Weihai, rank first.<sup>[7,8]</sup> To provide a basis for further effective prevention and treatment by analyzing the epidemiological

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The datasets generated during and/or analyzed during the current study are available from the corresponding author on reasonable request.

<sup>a</sup> Department of Gastroenterology, Shandong, Provincial hospital affiliated to Shandong First Medical University, P.R.China, <sup>b</sup> Department of Infectious Disease, Rongcheng Hospital Affiliated to Shandong First Medical University, Rongcheng, P.R.China, <sup>c</sup> Department of Clinical Laboratory Center, Rongcheng Hospital Affiliated to Shandong First Medical University, Rongcheng, P.R.China, <sup>d</sup> Department of Gastroenterology, Shandong, Provincial hospital affiliated to Shandong University, Jinan, P.R.China.

\* Correspondence: Hui Liu, Department of Gastroenterology, Shandong, Provincial hospital affiliated to Shandong University, Jinan 250021, P.R.China (e-mail: shaohuaself@163.com).

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distribution, clinical characteristics, and prognostic risk factors of patients having severe fever with thrombocytopenia syndrome.

## 2. Patient and Methods

### 2.1. Study Patients

790 patients (368 males, 422 females) with STFS (April 2016, November 2020), age (19~86), average age ( $56.52 \pm 10.91$ ). The diagnosis of SFTS is in line with the Chinese guidelines for the prevention and treatment of severe fever with thrombocytopenia syndrome (2010 Edition).

**2.1.1. Inclusion criteria.** ① body temperature  $\geq 37.3$  ° C; ② Peripheral platelet count  $\leq 100 \times 10^9/L$ ; ③ Positive SFTS virus nucleic acid.

**2.1.2. Exclusion criteria.** ① severe endocrine diseases such as hyperthyroidism; ② Sepsis and severe sepsis caused by other definite bacterial infections; ③ Patients with liver and kidney insufficiency and serious blood system diseases; ④ Patients with autoimmune diseases, malignant tumors and other diseases that can cause changes in platelet counts, as well as other recognized or determined viral infections.

**2.1.3. Criteria of cases from severe group.** The criteria of severe group were as follows: Aspartate transaminase or Alanine aminotransferase was 3 times more than the upper limit of normal value, and lactate dehydrogenase and Creatine kinase were 2 times more than the upper limit of normal value. Two conditions must be met in the above indexes, and there are 3 or more organ function injuries at the same time.

### 2.2. Ethics approval and consent to participate

The study conformed to the standards of ethical medical research with the approval of the Medical Ethics Committee of Rongcheng People's Hospital (Research Approval No. 2016-012). All of the investigations have been conducted under the guidance of the principles expressed in the Declaration of Helsinki. We guaranteed the right to know the disease of patients or their families and obtain their written consent.

## 3. Methods

We used an epidemiological case questionnaire to carry out regression statistics of the cases. The general clinical characteristics and laboratory data of the patients were analyzed. We used multivariate Logistic regression analysis to screen the risk factors of critically ill patients. Bunyavirus nucleic acid was detected by RNA real-time fluorescence quantitative detection, and the unit was expressed as  $\lg TCID_{50}/mL$ . The peripheral blood leukocyte count and platelet count were measured by Shenzhen Mindray MY300 automatic hematology analyzer.

### 3.1. Statistical analysis

The data were analyzed by SPSS 21.0 statistical software, the measurement data of normal distribution were expressed by ( $\bar{x} \pm s$ ), comparison between groups was performed by *t*-test. The measurement data of non-normal distribution were expressed as  $\{M (Q1, Q3)\}$ , and the Wilcoxon non-parametric test was used in the comparison between the 2 groups.  $\chi^2$ -test was used to compare the counting data which was expressed as  $[n, (\%)]$ , and Logistic regression was used to analyze the related risk factors of critically ill patients. The difference was statistically significant ( $P < .05$ ).

## 4. Results

### 4.1. Epidemiological characteristics

**4.1.1. Population distribution characteristics.** 790 patients (368 males, 422 females) with STFS ( $P > .05$ ) (April 2016, November 2020) living in the hilly area in Weihai, average age ( $56.52 \pm 10.91$ ), age (19~86), age of most patients (50~60). See Table 1, Figure 1A.

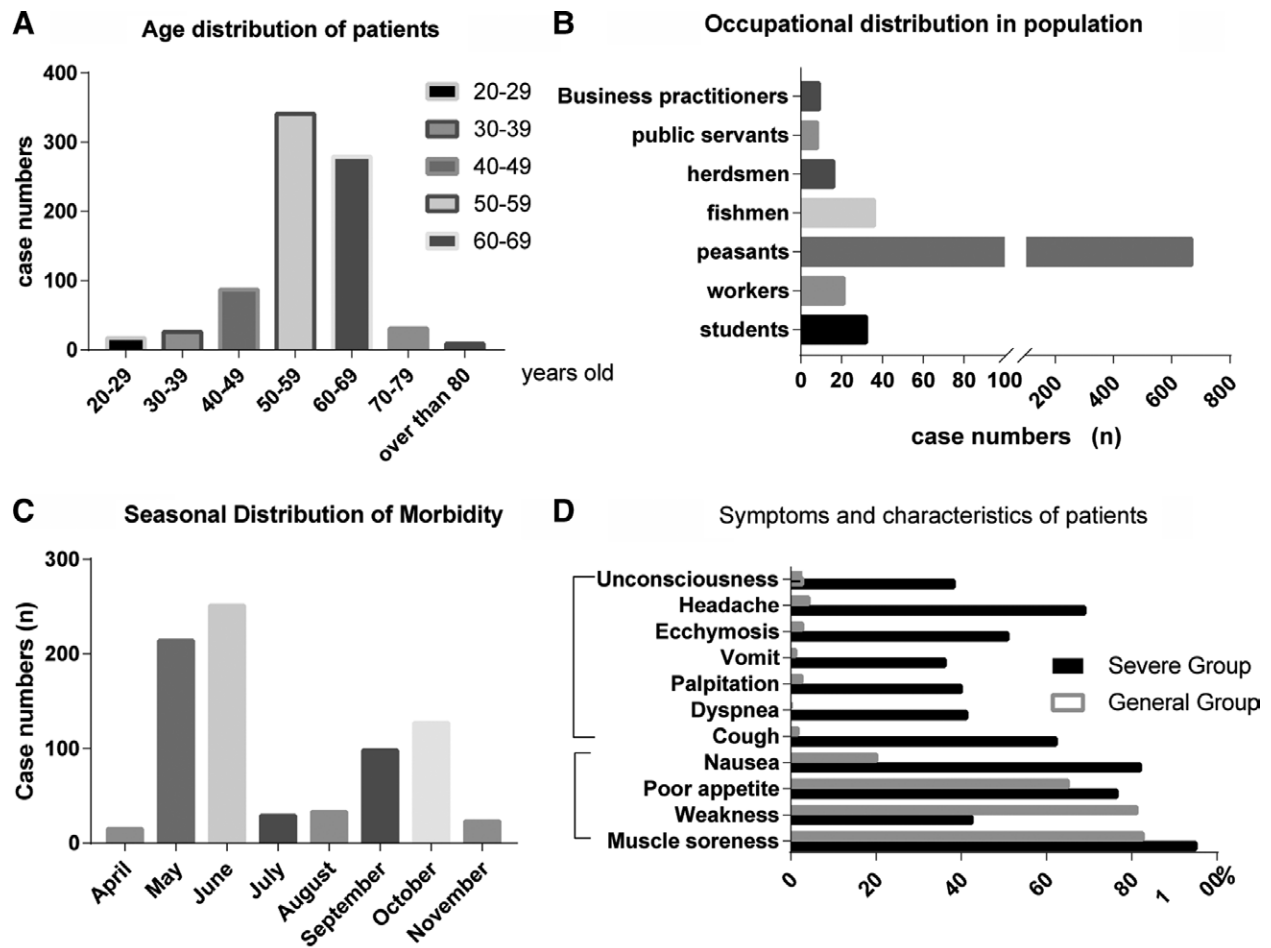
**4.1.2. Characteristics of occupational distribution.** Most of the patients were farmers (668/790, 84.56%), others were 32 students (4.05%), 21 workers (2.66%), 36 fishermen (4.56%), 16 herdsman (2.03%), 8 civil servants (1.01%) and 9 Commercial employees (1.14%)(See Fig. 1B), of which 72.41% (572/790) had some experiences of fieldwork within the first half month before the disease, 21.27% (168/790) had a clear tick bite, 98.61% (779/790) were sporadic cases and 1.39%

**Table 1**

**Clinical characteristics of patients with SFTS.**

Clinical features	Total	Severe group	General group	P
Numbers (Male/Female)	790 (368/422)	238 (107/131)	552 (261/291)	.608
Age [yrs. $\{M (Q1, Q3)\}$ ]	56 (31, 71)	64 (47, 79)	49 (22, 63)	.000
Time from onset to admission (d, $\bar{x} \pm s$ )	5.4 $\pm$ 3.2	6.7 $\pm$ 3.4	4.8 $\pm$ 2.1	.000
History of tick bite [n, (%)]	168 (21.27%)	59 (24.79)	109(19.75)	.134
Fever [n, (%)]	661 (83.67%)	221 (92.86)	440 (79.71)	.000
Muscle soreness [n, (%)]	682 (86.33%)	226 (94.96)	456 (82.61)	0.000
Weakness [n, (%)]	549 (69.49%)	101 (42.44)	448 (81.16)	0.000
Poor appetite [n, (%)]	541 (68.48%)	182 (76.47)	359 (65.04)	.001
Nausea [n, (%)]	306 (38.73%)	195 (81.93)	111 (20.11)	.000
Headache [n, (%)]	187 (23.67%)	164 (68.91)	23 (4.17)	.000
Cough [n, (%)]	157 (19.87%)	148 (62.18)	9 (1.63)	.000
Dyspnea [n, (%)]	98 (12.41%)	98 (41.18)	0	.000
Palpitation [n, (%)]	109 (13.80%)	95 (39.92)	14 (2.54)	.000
Vomit [n, (%)]	92 (11.65%)	86 (36.13)	6 (1.09)	.000
Ecchymosis [n, (%)]	136 (17.22%)	121 (50.84)	15 (2.72)	.000
Unconsciousness [n, (%)]	106 (13.42%)	91 (38.23)	15 (2.72)	.000
Drowsiness [n, (%)]	141 (17.85%)	84 (35.30)	57 (10.33)	.000
lethargy [n, (%)]	130 (16.46%)	130 (54.62)	0	.000
Coma [n, (%)]	27 (3.42%)	27 (11.84)	0	.000
Convulsions [n, (%)]	17 (2.15%)	17 (7.14)	0	.000
Superficial lymphadenopathy with tenderness [n, (%)]	196 (24.81%)	76 (31.93)	120 (21.74)	.003

SFTS = severe fever with thrombocytopenia syndrome.



**Figure 1.** (A) Age distribution characteristics of patients. It shows that the elderly aged 50 to 69 are susceptible to the disease. (B) Occupational distribution in population. It shows that farmers are the main sick population. (C) Seasonal distribution of morbidity. It shows that the annual peak season is from April to November, especially in May, June, September, and October. (D) Symptoms and characteristics of patients. It shows that the severe cases were mostly accompanied by cough, headache, ecchymosis, vomiting, palpitation, skin ecchymosis, disturbance of consciousness.

(11/790) were clustered cases that were close contacts of 2 death showing the characteristics of family aggregation.

**4.1.3. Season of disease.** The onset time of each year is from April to November, especially in May, June, September, and October (See Fig. 1C).

**4.2. Clinical Features**

There were 552 patients in the general group and 238 patients in the severe group. The mortality was 10.25% (81/790). The main clinical manifestations were fever (661/790, 83.67%), muscle soreness (682/790, 86.33%), fatigue (549/790, 69.49%), anorexia (541/790, 68.48%), nausea (306/790, 38.73%), headache (187/790, 23.67%). 24.81% (196/790) patients could touch the superficial lymph nodes with tenderness, and 16.33% (129/790) patients were not accompanied by fever. Severe cases were mostly accompanied by cough (157/238, 65.97%), vomiting (92/238, 38.66%), skin ecchymosis (136/238, 57.14%), disturbance of consciousness (47/238, 19.75%) (See Table 1, Fig. 1D).

**4.3. Comparison between the severe group and the ordinary group**

There were significant differences in age, hypertension, coronary heart disease, diabetes, Bunyavirus nucleic acid load, and

average platelet count between this 2 groups ( $P < .05$ ) (See Table 2)

**4.4. Risk factor analysis**

The risk factors of fever with SFTs by multivariate Logistic regression analysis: age ( $OR = 2.685, P \leq .001$ ), hypertension ( $OR = 1.093, P \leq .001$ ), diabetes mellitus ( $OR = 2.074, P \leq .001$ ), coronary heart disease ( $OR = 1.473, P \leq .003$ ), mean platelet count ( $OR = 1.047, P \leq .003$ ), viral nucleic acid load ( $OR = 2.687, P \leq .001$ ), the time from onset to treatment of disease ( $OR = 1.732, P \leq .001$ ) (As shown in Table 3).

**5. Discussion**

Severe fever with thrombocytopenia syndrome is a novel natural epidemic infectious disease that has emerged in recent years. The initial case occurred in Xinyang, Henan Province, China. Chinese scholars isolated a novel bunyavirus, also known as SFTs bunyavirus, from a patient in 2011.<sup>[9-11]</sup> The clinical features are severe fever accompanied by a decrease in the number of platelets. Most patients can recover, and a few patients die of rapid disease deterioration and multi-visceral failure leading to death.<sup>[12]</sup> Epidemiological analyses have found distinct geographical characteristics for the onset of fever with thrombocytopenia syndrome. In China, cases are mostly found in eastern regions, mainly concentrated in

**Table 2****Comparison of clinical characteristics between severe group and general group.**

Group	N	Age (yrs)	Hypertension [n, (%)]	Coronary heart disease [n, (%)]	Diabetes mellitus [n, (%)]	virus nucleic acid load (lgTCID50/mL)	Mean platelet count ( $\times 10^9/L$ )
Severe group	238	65.03 $\pm$ 4.37	159/238, 66.81%	102/238, 42.86%	97/238, 40.76%	6.94 $\pm$ 0.81	37.80 $\pm$ 7.92
General Group	552	50.93 $\pm$ 5.74	174/552, 31.52%	73/552, 13.22%	65/552, 11.78%	2.68 $\pm$ 0.46	85.48 $\pm$ 11.49
$t/\chi^2$	-	33.89	84.91	82.97	83.91	93.49	58.31
<i>p</i>	-	< .000	.000	.000	.000	< .000	< .000

**Table 3****Logistic regression analysis of novel bunyavirus infection in SFTS.**

Variables	Regression coefficient	Standard error	Waldx <sup>2</sup>	<i>p</i>	OR	95%CI (lower limit–upper limit)
Age	12.905	3.905	18.9722	.000	2.685	2.207–3.275
Time from onset to admission	9.804	3.261	21.905	.000	1.732	1.498–2.239
Diabetes mellitus	11.792	5.496	17.397	.001	2.074	1.784–2.438
Coronary heart disease	10.673	6.017	14.209	.003	1.473	1.098–1.870
Hypertension	8.705	4.218	8.984	.005	1.093	0.998–1.437
Mean platelet count	10.116	4.892	6.893	.003	1.047	0.953–1.350
Virus nucleic acid load	11.378	5.983	9.903	.000	2.678	1.872–2.964

SFTS = severe fever with thrombocytopenia syndrome.

mountainous areas of Henan, Hubei, Anhui, Shandong, and Liaoning provinces.<sup>[13]</sup>

In the past 5 years, 50% of the statistically reported cases are concentrated in Shandong Province, where about 50% of cases are concentrated in Weihai and Yantai. The reported cases in Weihai have their characteristics, unlike that in Korea in 2013 mostly concentrated in the relatively warm southern cities.<sup>[14–17]</sup> First, although the number of female patients is more than that of male, there was no significant difference in the male to female incidence ratio and no difference in the proportion who developed severe disease. Previous data considered fever as the most common and early presenting symptom of the disease.<sup>[18,19]</sup> The results of this analysis revealed that most patients had a fever, muscle soreness, and nonspecific gastrointestinal symptoms. However, about 20% of patients are afebrile at an early age and only develop nonspecific gastrointestinal and thrombocytopenia symptoms, with myoenzymatic and hepatic enzyme impairment. Second, the transmission of host-virus for the disease is currently unknown, but previous clinical reports show that most patients with SFTS have tick bites.<sup>[20]</sup> 21.27% of patients had definite tick bites, indicating that ticks may be one of the main vectors of SFTSV, but most patients did not have tick bites within 2 weeks, suggesting that there may be other vectors temporarily unidentified in the region. Most patients are farmers, and the diseases are between April and November, which are the same as the reports in the literature.<sup>[21–23]</sup> Meanwhile, there are early peak between May and June and second peak between September and October in Weihai, Shandong province, China. The higher incidence of SFTS may be related to the frequent fieldwork of farmers during the 4 months. The less fieldwork in hot weather between July and August may lead to a reduced incidence.

Ticks are common bloodsucking ectoparasites in the hill areas in Weihai, mostly parasitizing on the surface of mammals and sucking blood for growth, but are also found in meadows or jungles. Previous bites by ticks have been relatively common in local populations, and consequently, there is insufficient awareness regarding the risk as well as prevention. So, prevention and risk education of tick bites should be enhanced for farmers in the area. Because ticks are often parasitic on pets such as cats and dogs, we should keep pets clean and take more tick repellent

measures. A large proportion of patients had fieldwork without protections although they were not bitten by ticks. So protections working outside should be enhanced during high incidence seasons to minimize the bare skin (such as tightening the ends of trousers and taking spray of insect repellent) to avoid the bites of mosquitos with bunyavirus causing morbidity.

Severe fever with thrombocytopenia syndrome belongs to the self-limited disease without effective treatments for patients, most of which can self-heal, but some can worsen swiftly, even die. The clinical fatality rate of the literature reports ranges from 10% to 40%, and that of the study is 10.25%.<sup>[24,25]</sup> According to the 2011 expert consensus on fever with thrombocytopenia syndrome in China, we classified the disease into common and severe forms, and this study found by comparison that the older the patient, the higher the case fatality rate. The case fatality rate of patients with diabetes mellitus, hypertension, and coronary heart disease was significantly higher, which may be due to reduced organ function and poor reserve, which are also the most underlying causes of preexisting conditions.

Viremia of SFTS can lead to immune injury and further failure of multiple organ functions.<sup>[26]</sup> The damage is superimposed by multiple adverse interactions. New Bunyavirus RNA can be detected in patients with SFTS, and the degree of organ function damage affects the viral load varying with the severity of the disease, the highest load appears in the period of multiple organ dysfunction. The decreased platelet count is associated with immune injury. Critically ill patients are clinically complicated by acute inflammatory response syndrome, higher levels of immune-inflammatory stress in the body, more severe secondary inflammatory blow injury, and multi-visceral functional injury. Therefore, prompt monitoring of viral load and platelet count changes in the serum of patients is required to guide the prognosis of patients. Recovering volume, reducing inflammatory mediator reaction, and protecting organ function is the clinical treatments in the early stage.

Early nonspecific gastrointestinal symptoms are the most common, the damage may be caused by the digestive tract organ as the earliest target organ of the new Bunyavirus, and the infected target organ may cause coagulation disorder. Severe patients with SFTS are often accompanied by injury of the lung and nervous system, Unconsciousness is the main index of



critical illness and the early warning index of increased clinical mortality. They often have basic complicated diseases and insufficient functional reserve of cardiopulmonary organs, which lead multiple organ failure and high mortality. Besides the laboratory tests, the delay of visit time of patient is another risk factor for the prognosis of severe patients, which will a significant increase in mortality.

Although the pathogenesis of severe cases of new Bunyavirus infection is not clear, it may be related to several factors, such as continuous high-level replication, direct damage to tissue cells, extensive immune damage to tissues and organs of the virus RNA in patients and strong immune response of the virus-host.<sup>[27,28]</sup> Studying the risk factors of severe fever with thrombocytopenia syndrome by new bunyavirus can help improve clinical cure rates. Age, diabetes mellitus, coronary heart disease, hypertension, high viral load, a significant decrease in mean platelet count, and visit time delay of patients are the risk factors of severe fever with thrombocytopenia syndrome with new bunyavirus infection by multivariate unconditional logistic regression analysis. The findings suggest that protection against tick bites for people working outside should be enhanced, and especially for the older with multiple diseases to reduce the occurrence of clinically sporadic cases.

In summary, the population and seasonal distribution of severe fever with thrombocytopenia syndromes are distinct. High age, multiple underlying diseases, high viral load, severe platelet count reduction, and delayed visit time of patients are risk factors for a poor outcome of severe patients.

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## Author contributions

All authors read and approval the final version.

**Conceptualization:** Hui Liu.

**Investigation:** Yu Dong, Ling Jiang.

**Methodology:** Yu Dong, Shao-hua Lin.

**Software:** Shao-hua Lin.

**Writing – original draft:** Yu Dong.

**Writing – review and editing:** Hui Liu.

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