

Characteristics of Toxic Epidermal Necrolysis and Stevens-Johnson Syndrome: A 5-Year Retrospective Study

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Background: Toxic epidermal necrolysis (TEN) and Stevens-Johnson syndrome (SJS) are rare, unpredictable, life-threatening drug reaction with high mortality, and acute emergencies condition. There was no data about these patients in community base practice in Thailand.

Objective: To study the demography, causative drugs, laboratory features, treatments, complications, and mortality of TEN/SJS in Chonburi Hospital and compare factors associated with mortality between groups.

Material and Method: The medical records of TEN/SJS patients between 2005 and 2009 were retrospectively reviewed. Characteristics of the patients and factors associated with mortality were analyzed by SPSS version 19 for windows.

Results: There were 15 SJS and 9 TEN patients. The average age was 40.13±22 years. Male to female ratio was 1.4:1. The mean SCORTEN on day 1 was 1.54±1.1 and 1.79±1.59 on day 3. The overall mortality was 20.83%. Antibiotics were the commonest group of drugs causing TEN (55.6%) and SJS (66.7%). Septicemia and pulmonary infections were associated with higher mortality ($p<0.001$ and 0.004 respectively). Steroid treatment was associated with lower mortality 13.33% vs. 33.33%.

Conclusion: Antibiotics are the most common causative agents in SJS/TEN. Sepsis and pulmonary infections are associated with higher mortality. Steroid treatment may have some survival benefit.

Keywords: Stevens-Johnson syndrome, Toxic epidermal necrolysis

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Stevens-Johnson syndrome (SJS) and toxic epidermal necrolysis (TEN) are severe cutaneous drug reactions associated with high mortality⁽¹⁾. The majority of cases appear to be related to idiosyncratic drug reactions. SJS and TEN are both characterized by the detachment of dead epidermis and the erosions of mucous membranes. SJS occurs predominantly in children and adolescents, whereas TEN occurs in all ages, from premature infants to the elderly⁽²⁾. The incidence of TEN and drug reactions are 2.7 times higher in the elderly and TEN mortality is twice as high in elderly patients (51% vs. 25%)⁽³⁾. Genetic susceptibility to SJS and TEN is likely as exemplified by the strong association observed in Han Chinese between a genetic marker, the human leukocyte antigen HLA-B*1502, and SJS induced by carbamazepine⁽⁴⁾. Drugs, infections, vaccines, radiological contrasts,

vaginal suppositories, acrylonitrates, graft versus host reaction, and lupus erythematosus predisposed individuals result in immunologically mediated keratinocyte apoptosis, and hence, extensive necrosis and detachment of epidermis⁽⁵⁾. The incidence among Europeans of both SJS and TEN is approximately two per million people per year⁽⁶⁾. The incidence of TEN and drug reactions are higher in HIV-infected patients, particularly those with advanced disease. This retrospective study was done to study characteristics, causative drugs, duration of hospital stay, laboratory features, treatments, complications, and mortality in SJS/TEN in Chonburi Hospital.

Material and Method

All medical records of TEN/SJS patients between January 1, 2005 and December 31, 2009 in Chonburi Hospital were reviewed. The clinical diagnosis of SJS and TEN were made by dermatologists. Classification of SJS and TEN based on the degree of epidermal detachment. Epidermal detachment of less than 10% of the total body surface area is considered

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SJS, more than 30% as TEN, and between 10 and 30% as SJS/TEN overlapping. The patients should have at least two mucous membranes involvement with skin lesion and epidermal detachment. SCORTEN⁽⁷⁾ was used to assess severity of these illness and predicted mortality. The score is the sum of seven clinical variables, (1) age over 40 years, (2) heart rate >120 beats per minute, (3) the presence of cancer or hematologic malignancy, (4) epidermal detachment involving body surface area >10% on day one, (5) blood urea nitrogen >28 mg/dl, (6) glucose >252 mg/dL, and (7) bicarbonate <20 mEq/L. Of the 38 medical records, 24 with complete data were selected. Bastugi's criteria⁽⁸⁾ formed the basis for classifying these severe mucocutaneous reactions into SJS and TEN. Fourteen medical records were excluded because the patients had alternative diagnosis. Parameters included age, sex, period of hospital stay, duration of symptom, etiology, SCORTEN, investigations, treatment modalities, and outcome of these 24 patients were recorded and analyzed by SPSS for Window version 19. Independent t-test and Chi-square test were used as appropriate. The p-values of <0.05 were considered as statistically significant. The present study was approved by research ethic committee in Chonburi Hospital.

Results

There were 24 patients including 15 SJS patients, seven TEN patients, and two overlapping SJS/TEN patients. Two patients in SJS/TEN overlap group were included in TEN groups for analysis. The profiles of all the patients are shown in Table 1 and characteristics of TEN and SJS patients are shown in Table 2.

Etiology

Drug as an etiology was established in all cases except one case of TEN that was suspected to be due to dimenhydrinate. The major group of drugs causing SJS/TEN was antibiotics 15/24 (62.5%), followed by allopurinol 4/24 (16.67%), and anti-convulsant 3/24 (12.5%). The drugs that were implicated in causing SJS/TEN in these patients are shown in Fig. 1.

Laboratory investigations

Laboratory parameters in both groups were not significantly different. Patients with TEN tended to have higher serum creatinine (1.45 ± 0.96 vs. 0.95 ± 0.31 mg/dL $p = 0.08$) and transaminase

(103.22 ± 95.76 vs. 49.67 ± 33.87 U/L $p = 0.09$) levels than SJS patients. High eosinophil count was found in both groups with non-significant higher eosinophil count in SJS patients. Two patients in TEN group and six patients in SJS group had anti-HIV positive.

Complications during admission

The most common complication in both groups was septicemia (33.33%), followed by skin infection (20.83%), shock (8.33%) and multi-organ failure (8.33%). Non-survivors had a higher incidence of pulmonary infection and septicemia than survivors (Chi-square 8.29 $p = 0.004$, Chi-square 12.63 $p < 0.001$ respectively). Fig. 2 shows the complications during admission in TEN and SJS.

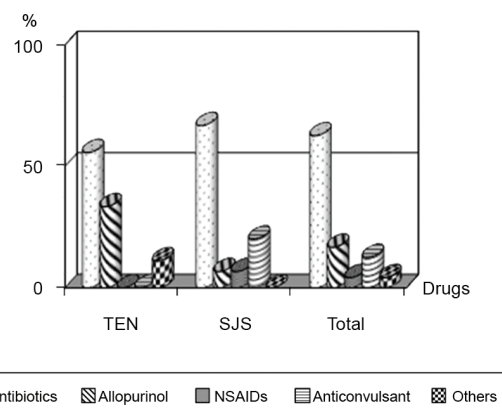


Fig. 1 The causative drugs in TEN and SJS. The major groups of drugs causing TEN were antibiotics (55.56%), followed by allopurinol (33.33%) and dimenhydrinate (11.11%). The major groups of drugs causing SJS were antibiotics (66.67%), anticonvulsant (20%), allopurinol (6.67%) and NSAIDs (6.67%).

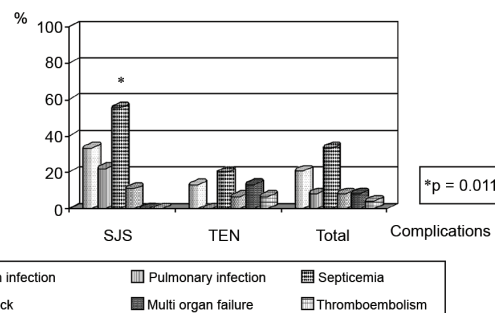


Fig. 2 Complications in TEN and SJS during admission. * $p = 0.011$

Table 1. The profile of all patients

Patient No.	Age (year)/sex	Presence of malignancy	Heart rate (bpm)	Epidermal detachment (%)	BUN (mg/dl)	Blood sugar (mg/dL)	Bicarbonate (mEq/L)	Suspected cause	SCORTEN	Treatment	Result
1	47/F	No	100	4	20	120	22	Ibuprofen	1	Steroid	Improve
2	20/M	No	80	4	12	100	22	Phenytoin	0	Supportive	Improve
3	32/F	No	60	4	10	80	22	Phenytoin	0	Steroid	Improve
4	18/F	No	120	4	10	80	21	Amoxicillin	1	Supportive	Improve
5	21/M	No	60	4	10	70	22	Phenytoin	0	Steroid	Improve
6	38/F	No	80	4	10	80	22	Bactrim	0	Steroid	Improve
7	7/F	No	100	5	30	80	18	Erythromycin	2	IVIg	Death
8	79/F	No	80	5	15	140	14	Dicloxacillin	2	Steroid	Improve
9	12/F	No	100	5	10	80	23	Lamotigine	0	Steroid	Improve
10	44/M	No	80	5	8	90	23	Bactrim	1	Steroid	Improve
11	41/M	No	80	5	14	90	27	Bactrim	1	Supportive	Improve
12	83/F	No	120	5	35	96	30	Ceftriaxone	3	Supportive	Death
13	42/M	No	120	5	14	100	17	Bactrim	3	Supportive	Death
14	44/M	Acute leukemia	130	6	10	88	27	Cefoperazone/sulbactam	2	Steroid	Death
15	28/M	Lymphoma	140	8	12	100	21	Bactrim	2	Supportive	Improve
16	35/M	No	80	25	12	100	26	Allopurinol	1	Steroid	Improve
17	74/M	No	100	25	20	70	16	Ceftriaxone	3	Steroid	Improve
18	41/M	No	100	30	20	80	13	Bactrim	3	Supportive	Improve
19	66/F	No	80	35	35	140	21	Piperacillin/tazobactam	3	Steroid	Improve
20	37/M	No	100	35	24	120	21	Dimenhydrinate	1	Supportive	Improve
21	66/M	No	80	40	18	80	31	Piperacillin/tazobactam	2	Steroid	Improve
22	35/M	No	100	45	12	120	26	Allopurinol	1	Steroid	Improve
23	32/M	No	140	50	24	120	25	Bactrim	2	Steroid	Improve
24	61/F	No	100	72	88	120	23	Allopurinol	3	Steroid	Death

Table 2. The characteristics of TEN and SJS patients

Parameters	TEN (9)		SJS (15)		Total	
	Mean	SD	Mean	SD	Mean	SD
Age (years)	49.67	16.70	34.40	23.29	40.13	22.00
Sex (male:female)	3.5:1		0.87:1		1.4:1	
Hospital day (day)	10.89	3.79	13.27	18.24	12.38	14.46
Duration before admission (day)	2.86	2.11	4.21	3.28	3.76	2.96
Result (survive:dead)	8.0:1		2.75:1		3.8:1	
SCORTEN day 1	2.11	0.93	1.20	1.08	1.54	1.10
SCORTEN day 3	3.00	1.50	1.07	1.16	1.79	1.59

Comparison between survivor and non-survivor patients

The present study classified patients into survived or non-survived groups. There were 19 patients who survived and five patients in the non-survived group. Most of the patient characteristics were not significantly different between groups except for SCORTEN on the first day and third day in the non-survived group, which were significantly higher than the survived group (1.26 ± 1.04 , 2.6 ± 0.54 , $p = 0.012$; 1.42 ± 1.5 , 3.2 ± 1.09 , $p = 0.02$). Absolute eosinophil counts tend to be higher in the non-survived group. There was only one patient in the non-survived group who had anti-HIV positive and seven patients in the survived group had anti-HIV positive. The most common complication in the non-survived group was septicemia (100%) followed by pulmonary infection (40%), skin infection (20%), shock (20%), and multiorgan failure (20%). The predicted mortality of all patients according to the given SCORTEN was lower than actual mortality (12.8% vs. 20.80%). The characteristics of patients in the survived and non-survived groups are shown in Table 3 and Fig. 3.

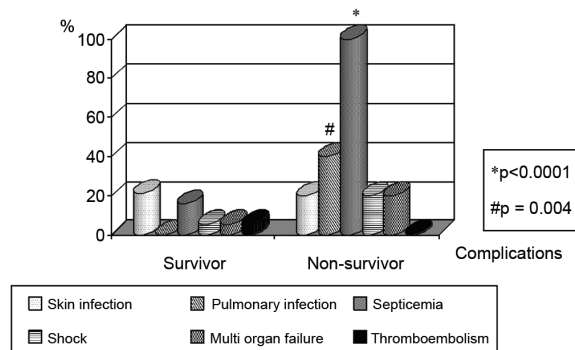


Fig. 3 The complications in survived and non-survived group.

Treatment

All patients received the supportive treatment and stopped the causative agents in hospital. The patients received immuno-modulatory therapy in the form of dexamethasone (7 patients), prednisolone (7 patients), methylprednisolone (1 patient), and IVIG (1 patient). Systemic steroid was used in TEN group more than SJS group (77% vs. 53.33%). The patients in survived group received systemic steroid more than non-survived group (68.42% vs. 40%). A 7-year-old girl with SJS received IVIG but did not survive. When comparing effect of steroid treatment on patients' outcome, the authors found that steroid therapy was associated with non-significance survival benefit as shown in Fig. 4.

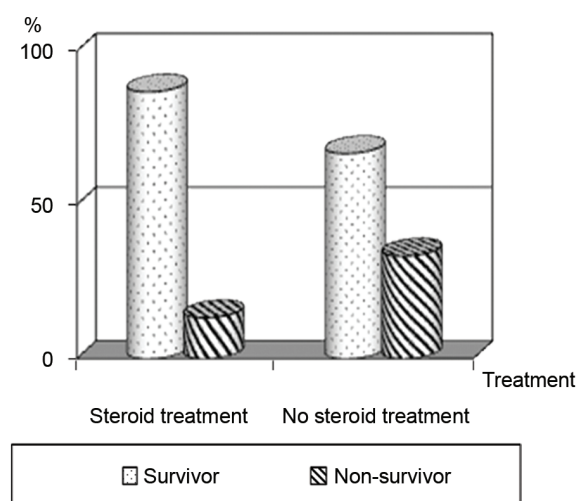


Fig. 4 The steroid treatment in survived and non-survived group. Shows TEN/SJS patients survival in those who receive steroid versus no steroid treatment. Those who receive steroid had non-significant survival benefit (86.7 vs. 66.7%).

Table 3. characteristics of patients in survived and non-survived group

Parameters	Survivor (19)		Non-survivor (5)		p-value
	Mean	SD	Mean	SD	
Age (year)	40.31	18.94	39.40	34.19	0.930
Sex male:female	2:3	-	12:7	-	-
Hospital day (day)	10.00	9.60	39.40	34.19	0.379
Duration before admission (day)	3.87	3.20	3.40	2.07	0.763
SCORTEN day 1	1.26	1.04	2.60	0.54	0.012
SCORTEN day 3	1.42	1.50	3.20	1.09	0.022
Sodium (mmol/L)	134.05	7.94	133.60	5.12	0.900
Potassium (mmol/L)	4.11	0.65	4.02	0.82	0.790
Chloride (mmol/L)	102.11	7.50	100.60	3.28	0.670
Bicarbonate (mmol/L)	21.83	4.52	23.00	5.61	0.632
Creatinine (mg/dl)	1.076	0.50	1.42	1.16	0.328
SGOT (U/L)	99.50	81.89	97.80	72.69	0.967
SGPT (U/L)	74.75	78.25	65.80	46.27	0.813
Hematocrit (%)	34.28	7.77	38.16	9.50	0.358
Absolute eosinophil (cell/ml)	251.44	326.88	532.66	371.05	0.187
Absolute neutrophil (cell/ml)	5,996.12	4,231.20	5,239.00	1,313.38	0.701
WBC count (cell/ml)	8,523.88	4,415.00	9,950.00	7,415.92	0.588
Anti HIV positive (patients)	7	-	1	-	-

Discussion

TEN and SJS are rare but serious and potentially life-threatening. The condition can be associated with major metabolic abnormalities, sepsis, multi-organ failure, pulmonary infection or embolism and gastrointestinal hemorrhage⁽⁸⁾. The present study presented cases of SJS/TEN in Chonburi Hospital, a referral center in the Eastern part of Thailand.

The present study had 24 patients, TEN (9 patients) less than SJS (15 patients), contrasting to the other studies that were done in a tertiary care hospital^(9,10). The mean age of patients in the present study was 40.13±22 years. Patients in TEN group were older than SJS group, similar to another study done in West Germany⁽¹¹⁾. The mean age group of both SJS and TEN group in the present study was lower than another study in Asia⁽¹²⁾.

The sex ratio shows male more than female (1.4:1), the same as the study from West Germany⁽¹¹⁾ and the study from India⁽¹³⁾. The total mortality rate was 20%, lower than the European studies^(9,10) but higher than the study from China⁽¹⁴⁾. The overall actual mortality rate in the present study was higher than predicted mortality according to SCORTEN (20.8% vs. 12.8%).

Antibiotics were the most common cause of TEN/SJS (62.5%), followed by allopurinol (16.67%), anticonvulsant (12.25%), and NSAIDs (4.17%). Those were the same as the other studies in Thai children⁽¹⁵⁾, Indian⁽¹⁶⁾, and French⁽¹⁷⁾. This study is contrasting to a study from Singapore⁽¹⁸⁾ in which they found anticonvulsant (35.7%) were the most common implicated drugs followed by antibiotics (28.7%), NSAIDs (14.3%), allopurinol (7.1%), and traditional Chinese medicine (7.1%). This finding might be caused from genotypic difference between patient subgroup. The HLA-B*1502 allele was present in 100% of 51 Han Chinese patients experiencing severe cutaneous reactions to allopurinol, but it was present in only 15% of 135 tolerant patients⁽¹⁹⁾. Similarly, the study in a Thai population⁽²⁰⁾, all 27 (100%) allopurinol induced SJS/TEN patients who were examined carried HLA-B*5801 whereas only seven (12.96%) of the control patients had this allele. If the screening test of genetic analysis was done in a Thai population before prescribing these drugs, the severe cutaneous drug eruption might be decrease.

The mean period of the first symptom to the admission was 3.76±2.96 days, less than the other study from Europe⁽¹⁰⁾. The non-survived group had

the mean period of the first symptom to the admission more than the survived group. The period of the first symptom to admission may associate with treatment outcome since TEN/SJS patients should receive immediate diagnosis, stop causative drugs and appropriate treatment. The mean duration of hospital stay of the patients was 12.38 ± 14.46 days. This duration was shorter than the finding from the studies of Barvaliya M et al⁽¹⁶⁾ SJS had duration of hospital stay more than TEN (13.27 ± 18.24 vs. 10.89 ± 3.79 days). The duration of hospital stay could not predicted the mortality.

Most of the patients had elevated liver enzymes, similar to the study of Yaman et al⁽¹²⁾ and Abarna Devi S et al⁽¹³⁾. The TEN patients had mean serum transaminase levels higher than SJS patients, but not statistically significant. Creatinine and absolute eosinophil counts were non-significantly higher in the non-survived group more than the survived group. The study suggested that hepatitis is commonly found in both TEN and SJS, high absolute eosinophil count and creatinine level may associate with higher mortality.

The most common complication in the present study was septicemia (33.33%) similar to the other studies^(13,16). TEN patients had higher incidence of multiorgan failure than SJS patients ($p = 0.01$). Every death case in the present study had septicemia followed by pulmonary infection (40%), which were significantly associated with poor outcome ($p = 0.004$, <0.001 respectively). These data suggested that if the TEN/SJS patient had septicemia, pulmonary infection or multiorgan failure, the patient is at increased risk for death outcome.

Fifteen out of 24 patients received steroid treatment in the form of dexamethasone, methylprednisolone, or prednisolone. Steroid was used in TEN group more than SJS group (77%, 53.3%). The patients who received steroid treatment had a non-significant survival benefit (86.7 vs. 66.7%). This study was similar to the study of Moniz P et al⁽⁹⁾ in which they found lower mortality in the patients treated with steroid (42.8 vs. 66.7%). Chen J et al⁽¹⁴⁾ found that early application of corticosteroids presented beneficial effects on SJS/TEN, and combination therapy of corticosteroid with IVIG achieved a better therapeutic effect than the administration of corticosteroid alone. A systemic review of treatment of drug-induced Stevens-Johnson syndrome and toxic epidermal necrolysis in children⁽²¹⁾, there were four main treatment modalities, IVIG, steroid, dressing with or without surgical debridement,

and supportive treatment alone. Steroid and IVIG seem to improve the outcome of SJS and TEN patients. Patients treated only with supportive care seem to have higher morbidity and mortality⁽²¹⁾. The present study also found no significant benefit of the steroid treatment group.

Conclusion

Antibiotics, allopurinol, and anticonvulsants are common causes of SJS/TEN. SCORTEN is a good predictor of mortality. The period of the first symptom to admission may be predicted mortality. The treatment with steroid seems to improve outcome of SJS/TEN. Septicemia is the most common complication and is associated with poor outcome. Further study is needed to reduce mortality in these diseases.

Potential conflicts of interest

None.

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การศึกษาย้อนหลัง 5 ปีในผู้ป่วย *toxic epidermal necrolysis* และ *Stevens-Johnson syndrome*

จิรนุช ธรรมคำภีร์, สมชาย ยงศิริ

ภูมิหลัง: โรค *toxic epidermal necrolysis (TEN)* และ *Stevens-Johnson syndrome (SJS)* เป็นภาวะที่พบน้อย แต่มีความรุนแรง อัตราการตายสูง จำเป็นต้องได้รับการวินิจฉัยและให้การรักษาย่างทันที่เพื่อลดอัตราความพิการและอัตราการตาย ยังไม่มีข้อมูลเกี่ยวกับลักษณะผู้ป่วยและปัจจัยที่มีผลต่ออัตราการรอดชีวิตของผู้ป่วยกลุ่มนี้ในภาคตะวันออกเฉียงของประเทศไทย

วัตถุประสงค์: เพื่อศึกษาลักษณะผู้ป่วย ยาที่เป็นสาเหตุ ผลการตรวจทางห้องปฏิบัติการ *SCORTEN* การรักษาภาวะแทรกซ้อน และอัตราการตายในผู้ป่วย *TEN* และ *SJS* ในโรงพยาบาลชลบุรี และเปรียบเทียบปัจจัยที่มีผลต่ออัตราการเสียชีวิต

วัสดุและวิธีการ: ผู้นิพนธ์ทบทวนเวชระเบียนผู้ป่วยที่ได้รับการวินิจฉัยว่าเป็นโรค *TEN/SJS* ในโรงพยาบาลชลบุรีตั้งแต่ปี พ.ศ. 2548-2552 เก็บข้อมูลเกี่ยวกับลักษณะผู้ป่วย การรักษา ภาวะแทรกซ้อน *SCORTEN* และผลการรักษา วิเคราะห์หาปัจจัยที่มีผลต่ออัตราการรอดชีวิตด้วยโปรแกรม *SPSS for Windows version 19*

ผลการศึกษา: มีผู้ป่วยทั้งสิ้น 24 ราย เป็น *SJS* 15 ราย และ *TEN* 9 ราย อายุเฉลี่ย 40.13 ± 22 ปี พบผู้ป่วยเพศชายมากกว่าเพศหญิงในอัตรา 1.4 ต่อ 1 คะแนนเฉลี่ย *SCORTEN* วันแรก 1.54 ± 1.1 เพิ่มขึ้น 1.79 ± 1.59 ในวันที่ 3 อัตราการตาย 20.83% ยาปฏิชีวนะเป็นสาเหตุบ่อยที่สุดของการแพ้ยาแบบ *TEN* (55.6%) และ *SJS* (66.7%) ภาวะแทรกซ้อนที่พบบ่อยที่สุดคือการติดเชื้อในกระแสเลือด (33.33%) และการติดเชื้อที่ปอด (20.83%) ซึ่งสัมพันธ์กับการเสียชีวิตอย่างมีนัยสำคัญ ($p < 0.001$ และ $p = 0.004$ ตามลำดับ) ผู้ป่วยที่ได้รับยาสเตียรอยด์มีอัตราการรอดชีวิตสูงกว่าผู้ที่ไม่ได้รับยาแต่ไม่มีนัยสำคัญทางสถิติ (13.33% vs. 33.33%)

สรุป: ยาปฏิชีวนะเป็นสาเหตุของ *TEN* และ *SJS* ที่พบบ่อยที่สุด การติดเชื้อในกระแสเลือดและปอดอักเสบสัมพันธ์กับอัตราการตายที่สูงขึ้น การรักษาด้วยยาสเตียรอยด์อาจช่วยลดอัตราการตาย
