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Original Research Article

Stevens-Johnson syndrome and toxic epidermal necrolysis prevalence and causative factors at Khartoum dermatology teaching hospital (2010-2020)

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ABSTRACT

Background: Cutaneous drug reactions mainly Stevens-Johnson Syndrome (SJS) and Toxic Epidermal Necrolysis (TEN) and their overlap are rare but potentially fatal reactions endangers patient's life, they are characterized by epidermal necrosis which causes erosions of the mucous membranes, extensive detachment of the epidermis. Drugs are the major causes of SJS/TEN. The types of the drugs depend on the prevalent diseases in the country and the protocols of management in that country. The aim of this study was to determine prevalence, causative factors and their correlation with SJS/TEN and their overlap, among patients admitted to Khartoum Dermatology and Venereology Hospital from January 2010 to September 2020.
Methods: This retrospective cross-sectional study investigated 295patients with severe cutaneous reactions. Information collected included participants' socio-demographic variables, clinical characteristics of the disease and the possible triggers. Data were analyzed using SPSS version 23.0.
Results: The main age distribution was between 20-40 years in (42.7%), 48.8% of the cases had SJS, 44.4% had TEN and only 6.8% had SJS\TEN overlap. Seventy-two percent of the patients had no past history of similar condition. Sixty-six percent of the patients developed cutaneous symptoms from first till the seventh day after drugs intake. Drugs were determined to be the causative agent in 90.5% followed by other risk factors 7.5% mainly; chicken pox and dukhan dermatitis, (2%) of cases were idiopathic. The most common drugs implicated were antibiotics (75.6%), followed by NSAIDs (37.6 %). Patients who passed away during the study period were 24/295 cases (8.1%), 16 patients due to TEN, 6 patients with SJS and 2 patients with SJS/TEN overlap.
Conclusions: SJS was the most common subtype of SJS/TEN in Khartoum Dermatology Hospital but most deaths occur among TEN patients. Women and persons aged 21–40 years were the most affected groups and was attributed to use of drugs, especially antibiotics (Ciprofloxacin), followed by NSAIDs (Diclofenac sodium).

Keywords: Antibiotics, NSAID, Stevens Johnson syndrome, Toxic epidermal necrolysis

INTRODUCTION

Adverse drug reactions (ADR) accounts for 6% of the total hospital admission, increases economic burden on healthcare system, results into withdrawal of drugs from market and death.[1,2] Among various ADR, cutaneous drug reactions mainly SJS and TEN are rare but potentially fatal reactions endangers patient's life. They are mucocutaneous immune complex-mediated hypersensitivity reactions, characterized by epidermal

detachment and mucositis.[3] The basic difference between SJS and TEN is the percentage of body surface affected and SJS affects, 10% of the body surface, SJS–TEN overlap involves 10%–30% of the body surface and TEN affects .30% of the body surface area.[4,5] The incidence of SJS and TEN is estimated 1 to 6 and 0.4 to 1.2 cases per million person years, respectively.[6,7] However, the incidence is higher among people living with HIV/AIDS. The mortality for SJS varies from 3% to 10% and for TEN from 20% to 40%.[8] In Sudan, a study done in 2012 indicated that SJS and TEN are the second cause of death (22.0%) among causes of mortality at Khartoum Dermatology Teaching Hospital.[8] The exact pathogenesis of SJS and TEN remains to be elucidated but apoptotic mechanisms, including involvement of cytotoxic T cells, tumor necrosis factor (TNF)-α and Fas (CD95), Fas ligand (FasL) interaction are considered to be relevant to these diseases.[9]

Drugs are found to be one of the important causes. More than 100 drugs have been implicated in causing SJS and TEN. Based on RegisSCAR/EuroSCAR registries, the highest risk drugs include allopurinol, carbamazepine, cotrimoxazole and other anti-infective sulfonamides, sulfasalazine, lamotrigine, nevirapine, oxicam-type non-steroidal anti-inflammatory drugs (NSAIDs), phenobarbital and phenytoin. Moderate risk drugs include cephalosporins, macrolides, quinolones, tetracyclines and acetic acid-type NSAIDs. Low-risk drugs, that in previous studies, were not associated with a measurable risk, including beta-blockers, angiotensin-converting enzyme inhibitors, calcium channel blockers, sulfonamide-based thiazide diuretics, sulfonylurea anti-diabetics, insulin and propionic acid–type NSAIDs.[10,11]

Besides drugs, vaccines, radiological contrasts, infections, ulcerative colitis, etc. are the other important causes leading to significant morbidity and mortality.[12] Clinically these reactions are characterized by mucocutaneous tenderness, typically hemorrhagic erosions, erythema with more or less severe epidermal detachment presenting as macules, papules, plaque, vesicles and bullae affecting distal extremities with positive Nikolsky's sign. Mucosal surface is involved in the form of erosion or ulceration and areas of denuded skin.[13] Immediate cessation of an offending drug and adequate supportive care in intensive care unit remain the mainstay of management of SJS/TEN. There is no specific treatment strategy available for this condition. Systemic corticosteroids, IVIG and other immunosuppressive therapy are used for its management.[14] Despite the fact that the incidence of SJS or TEN is acute life-threatening; the condition may also lead to significant financial consequences for the patients.[15] Therefore, identification and withdrawal of drugs suspected to cause SJS or TEN are important.[16] In SUDAN, however, little work has been conducted to identify the prevalence, causative drugs, thus this retrospective study is aiming to identify the offending drugs causing SJS/TEN as well as the associated morbidity and mortality.[17]

METHODS

Study design

Retrospective, descriptive, cross-sectional, hospital based study.

Study place

The study was conducted at Khartoum dermatology and Venereal Diseases Teaching Hospital, located near El Mek Nimir street, at Khartoum locality, the main locality of Khartoum state (KDVTH), which is considered as tertiary hospital in Sudan receiving about 300-500 patients daily from Khartoum State and other parts of the country. It is working 24 hours/7 days a week with regular clinics during the day time (8:30 AM–1.30 am, 3:00 pm–9 pm) and emergency clinic at the rest of the day – These involved general and specialized clinics. There is psoriasis clinic every week, caring of all psoriatic patients newly diagnosed and follows up, in addition to leprosy clinic. The hospital now has clinic and services for andrology and sexual transmitted diseases (STDS) including (AIDS). Other hospital facilities include (Lab serving the outpatient and inpatients), laser and PUVA clinics, pharmacy providing most of the needs of the patients, small theater for minor operations, wards for males, females and pediatrics with a capacity of about 50 beds, education center including library and lecture rooms

Study duration

A retrospective study covering the period from January 2010 to September 2020 using the patient's medical records.

Study population

All patients with (SJS/TEN) were admitted to (KTHSVD) during the study period.

Inclusion criteria

All admitted patients diagnosed as SJS, TEN and SJS/TEN overlap at Khartoum Dermatology Teaching Hospital during the study period.

Exclusion criteria

All files with incomplete data or unclear diagnosis.

Sample size

A total number of 345 patients were admitted in the period from January 2010 to September 2020.A sample

size of 295 was included in the study, 50 files were missed or has incomplete data.

Data collection

The data were collected from in-patients records (files) at the Medical Records Department (Archive). For a patient to be diagnosed as having SJS they must have had symptoms of acute erythematous mucosal and skin erosions or bullae which are target-like in appearance extending to <10% of the body surface area.For SJS/TEN overlap the patient should have had similar lesions covering 10–30% of the B.S.A and for T.E.N they should have had extensive epidermal detachment of >30% B.S.A in addition to the above symptoms.

Electronic questionnaire designed with Epi Info7 program was used to collect patient's demographics, causative drugs, time period between drug intake and onset of skin lesion (lag period), relevant past medical history, coexisting conditions, mucosal involvement, percentage of B.S.A involvement on admission, Biopsy and HIV status and clinical outcome. The data collection was collected by the researcher through comprehensive structured check list.

Data analysis

Data was interpreted, cleaned and analyzed using SPSS VERSION 23.0.

Ethical consideration

The study was approved from ethical committee in Arab board office in Sudan medical specialization Board. Consent was obtained from administration of Khartoum dermatology teaching hospital to conduct the study. The patient's files used for data collection will not be used other than the research objectives.

RESULTS

The number of patients who were diagnosed as SJS were144 patients (48.8%), 131patients (44.4%) with TEN and 20 patients (6.8%) SJS, TEN, SJS-TEN overlaps. Sociodemographic characteristics of patients are diverse as shown in Table 1. The total number of patients who used drugs was 267 (90%), while 22 patients (8%) reported other causes and 6 patients were idiopathic (2%) Table 2, Table 3. Single drug usage was accounted in 154 patients (58%), multiple drugs were the cause in 113 patients (42%). Skin as initial site of involvement or mucous membranes varied depending on diagnosis Table 4.

Table 1: Demographics characteristics of SJS, TEN and SJS-TEN overlap patients admitted at KDTH from 2010-2020.

	Diagnosis			Total (%)	P value (%)
	SJS (%)	TEN (%)	SJS-TEN overlaps (%)		
Gender					
Male	56 (18.9)	41 (13.8)	2 (0.7)	99 (33.6)	
Female	88 (29.8)	90 (30.5)	18 (6.1)	196 (66.4)	0.029*
Total	144 (48.8)	131 (44.4)	20 (6.8)	295 (100)	
Age (years)					
<20	28 (9.5)	6 (2.0)	5 (1.7)	39 (13.2	
20-40	68 (23)	54 (18.3)	4 (1.4)	126 (42.7)	
41-60	35 (11.8)	51 (17.6)	9 (3.1)	95 (32.5)	0.002*
>60	13 (4.4)	19 (6.5)	2 (0.7)	34 (11.6)	
Total	144 (48.8)	131 (44.4)	20 (6.8)	295 (100)	
Residence					
Al Gadarif	1 (0.3)	7 (2.4)	2 (0.7)	10 (3.4)	
Al jazerah	12 (4.1)	5 (1.7)	6 (2)	23 (7.8)	
East Darfour	0	2 (0.7)	0	2 (0.7)	
Kasala	0	2 (0.7)	0	2 (0.7)	
Khartoum	106 (35.6)	57 (19.3)	7 (2.4)	170 (57.6)	
Mid Darfur	0	2 (0.7)	0	2 (0.7)	
Nile River	5 (1.7)	7 (2.4)	2 (0.7)	14 (4.7)	0.00*
North Kordofan	6 (2)	19 (6.4)	1 (0.3)	26 (8.8)	
Sinnar	2 (0.7)	3 (1)	0	5 (1.7)	
South Darfour	2 (0.7)	2 (0.7)	0	4 (1.4)	
South Kordofan	3 (1)	2 (0.7)	2 (0.7)	7 (2.4)	
West Kordofan	4 (1.4)	0	0	4 (1.4)	
White Nile	3 (1)	23 (7.8)	0	26 (8.8)	
Total	144 (48.8)	131 (44.4)	20 (6.8)	295 (100)	

*Statistically significant.

Table 2: Drugs implicated in SJS, TEN, SJS-TEN overlap patients admitted at KDTH from 2010-2020.

Drugs	Frequency	%
Antibiotics	202	75.6
Penecillins injections	18	6.6
Amoxicillin-clavulanic acid tabs	33	12.3
Ampicillin+cloxacillin tabs	2	0.7
Ciprofloxacin tabs	48	17.9
Norfloxacin tabs	7	2.6
Clarlthromycin tabs	6	2.2
Azithromycin tabs	8	2.9
Doxycycline caps	10	3.7
Tetracycline tabs	5	1.8
Ceforuxime tabs	2	0.7
Cefixime tabs	6	2.2
Ceftriaxone injections	23	8.6
Cefedoxime tabs	5	1.8
Co-trimoxazole tabs	10	3.7
Streptomycin injections	8	2.9
Metronidazole tabs	11	4.1
Analgesics	130	48.6
Unknown analgesic tabs	77	28.8
Diclofenac sodium tabs	14	5.2
Ibuprofen tabs	4	1.4
Mefnamic acid tabs	10	3.7
Meloxicam tabs	11	4.1
Piroxicam tabs	10	3.7
Paracetamol tabs	4	1.4
Antimalarials	75	28.1
Artemether injections	56	20.9
Artesunate tabs	9	3.3
Sulfadoxine and pyrimethamin	4	1.4
Quartem tabs	6	2.2
Allupurinol tabs	35	13.1
Anticonvulsants	25	9.3
Carbamazepine tabs	14	5.2
Clonazepam tabs	2	0.7
Lamotrigen tabs	7	2.6
Phenytoin tabs	1	0.3
Levetiracetam tabs	1	0.3
Continue		
Proton pump inhibitors (p.p.I)	5	1.8
Omeprazole tabs	5	1.8
Antiparasitic	4	1.4
Albendazole tabs	4	1.4
Antifungals	4	1.4
Fluconazole tabs	4	1.4
Antipsychotics	3	1.1
Risperidone tabs	3	1.1
Antiviral	1	0.3
Acyclovir tabs	1	0.3

Table 3: Frequency and percentage of other causative factors of SJS, TEN and SJS-TEN overlap patients admitted at KDTH from2010-2020.

If yes	Frequency	%
Carcinoma of the ovaries	1	0.3
Chicken pox	5	1.7

Continued.

If yes	Frequency	%
Chronic lymphcytic leukemia	1	0.3
Contact dermatitis	2	0.7
Dukhan dermatitis	7	2.4
Herpes labialis	2	0.7
Non-Hodgkin lymphoma	2	0.7
Vaccination against meningitis	2	0.7
Total	22	7.5

Table 4: Distribution of initial site to be involved in SJS, TEN and SJS-TEN overlap patients admitted at KDTH from 2010-2020.

First site	Diagnosis			Total (%)	P value
	SJS (%)	TEN (%)	SJS-TEN overlaps (%)		
Mucous membranes	71 (24.1)	39 (13.2)	6 (2.0)	116 (39.3)	0.003
Skin	58 (19.6)	66 (22.4)	14 (4.7)	133 (46.8)	
Both	15 (5.1)	26 (8.8)	0 (0.0)	41 (13.9)	
Total	144 (48.8)	131 (44.4)	20 (6.8)	295 (100)	

Table 5: Distribution of prognosis of SJS, TEN and SJS-TEN overlap patients admitted at KDTH from 2010-2020.

Prognosis	Diagnosis			Total (%)	P value
	SJS (%)	TEN (%)	SJS-TEN overlaps (%)		
Improved	118 (40)	91 (30.8)	16 (5.4)	225 (76.3)	0.00
Referred	10 (3.4)	24 (8.1)	2 (0.7)	36 (12.2)	
Escaped	10 (3.4)	0 (0.00)	0 (0.0)	10 (3.4)	
Death	6 (2)	16 (5.4)	2 (0.7)	24 (8.1)	
Total	144 (48.8)	131 (44.4)	20 (6.8)	295 (100)	
Referred			Frequency		
Referred due to C.V.A			2	5.5	
Referred due to septic shock			7	19.5	
Referred. due to renal impairment			11	30.6	
Referred due to uncontrolled D.M			5	13.8	
Referred. due to ocular complication			11	30.6	
Total			36	100	

Table 6: Correlation between single or multiple drugs administered and prognosis of SJS, TEN and SJS-TEN overlap patients admitted at KDTH from 2010-2020.

Prognosis	Number of drugs		Total (%)	P value
	Single (%)	Multiple (%)		
Improved	131 (49.1)	80 (30)	211 (79.1)	0.00
Referred	8 (3)	15 (5.6)	23 (8.6)	
Escaped	4 (1.5)	5 (1.8)	9 (3.3)	
Death	11 (4.2)	13 (4.8)	24 (9)	
Total	154 (57.8)	113 (42.2)	267 (100)	

Eventually, most of patients had mucous membranes and systemic involvement accounted in 277 patients (93.9%), 207 patients (67.2%) respectively. Systemic involvement accounted in 207 patients (67.2%), mainly genitourinary among 118 patients (40%), gastrointestinal in100 patients (33.9%), respiratory in 73 patients (24.7%), musculoskeletal in 53 patients (18.0%), cardiovascular in 52 (17.6%), central nervous in 28 patients (9.5%). Thirty patients only had their SCORETEN calculated (10%). Regarding the prognosis, 225 patients (76.3%) improved, 10 patients (3.4%) escaped, 24 patients (8.1%) passed away and 36 patients (12.2%) were referred due to development of various complications Table 5, Table 6.

DISCUSSION

There was a total of 295 patients, admitted at (KDTH) and diagnosed as SJS, TEN and SJS-TEN overlap from January 2010 till September 2020. The least number of cases diagnosed were in 2010, after which there was

dramatic increase, reaching the maximum in 2015 and 2016, then stable and sharply decreased in the last two years, especially 2020, most probably due to the covid-19 virus lock down and political issues. Research done at KDTH studying SJS, TEN and SJS-TEN overlap in 2010 done by Dr. Shaza, the number of patients enrolled within the study was 60, which is far less than the researcher study (295) patients although the number of years was the same (10) years.

This sharp rise in the number of patients could be due to economic issues and increase in complications of chronic diseases e.g., DM and HTN. Sixty-six percent of cases were women, while 33.6% were men. This female predominance is similar to findings from other studies 18-20. While a similar ten years study done in China, had male to female ratio 1.77:1 showing male predominance over the disease subtypes 21, this may be due to men preferring herbal medicine over drugs.

Furthermore, to categorize the relationship between the disease and geographical areas in Sudan, we concluded that most cases came from Khartoum state (57.6%), which is expected due to the large population and most of health facilities being located there. This finding differs from the previous study done in Sudan where most of cases were from the western region (48.2%), which may be attributed to low infrastructure and community awareness about drug use there.[18] This study revealed that probable causes of SJS, TEN, SJS-TEN overlap were mostly drugs, accounting for 90.5% which goes well with the reported data in the international studies.[18-22] Thirty eight percent of our patients had SJS/TEN attributable to the use of more than one drug. In Sudan drug prescription practices are not well controlled and there is a lack of awareness amongst doctors of the risk of adverse drug reactions.

The major contribution of drugs were antibiotics (75.6%), followed by analgesics (48.6%), antimalarial (28.1%) and allopurinol (13.1%). This matches the results from the other studies done in Sudan, Saudi Arabia, China, Kenya and U.S.A where antibiotics were the most common culprit drugs.[19-22] The most common antibiotics was ciprofloxacin (17.9%), which is contrary to the finding from Dr. Sami study done at the same hospital six years ago where ant malarial were the culprit drugs.[18] This may be explained by increase number of infectious diseases and the consumption of multiple antibiotics for single disease.

Allopurinol was used by (13.1%) of the patients, unlike a study from Europe has shown that Allopurinol is the commonest cause of SJS/TEN.[23] Two hundred fourteen of the patients had no past history of similar condition, making the possibility of sensitization less likely and postulate immune reactions process with different mechanism. Seven percent of the patients denied the use of any drug but reported association of dukhan dermatitis in 7patients (2.4%), chicken pox in 5 patients (1.7%), in addition to herpes labials, non-Hodgkin lymphoma and vaccination against meningitis in 2 patients (0.7%). Only six patients (2%) of the study population reported idiopathic presentation with no apparent causal factors, compared to Chinese study where 19% of patients did not have definite or possible relationship with drugs.[21] Regarding the correlation between the disease subtypes and socio-economic status, the greater numbers of patients were of low status (55.9%); this could be attributed to inability of poor income individuals to afford physician fees and full medical services in addition to easily access to medications at pharmacies and stores with no prescription needed.

Among patients admitted to KDTH, 225 were discharged in good condition (76.3%), 118 of them were diagnosed as SJS, 91 as TEN and 2 patients SJS/TEN overlap. Thirty-six patients were referred due to deterioration and complications, 24 patients of them were TEN, 10 SJS and 2 patients SJS-TEN overlap. Among the referred group, 15 patients reported the use of multiple drugs while 8 patients had single drug.

This could explain the effect of multiple drugs usage especially in T.E.N patients. The main causes of referral were renal impairment and ocular complications in 11 patients (3.7%), which is contrary to previous study done in Sudan where sepsis was the most common complication among patients, which imply the need of early assessment and close follow up by ophthalmologists and internal medicine physicians.[19] Ten patients (3.4%) escaped from the hospital, as it may be explained by preference of some patients to seek herbal and traditional methods of treatment instead.

The total number of deceased patients in the study was 24(8.1%). This result is lower than international records (30%) and also lower than the death rates in both previous studies done in Sudan reporting (26.3%) and (16%) respectively, attributed to early hospitalization, effective treatment and good supportive care.[18,19] Also, mortality rates were low in studies done over ten years in China (5.4%) and USA (14%).[21,22]

Among deceased patients, majority of them were due to TEN (16) patients distributed over the study period, which is similar to other studies.[18,19,21] This could be related to the larger area of skin detached of TEN patients and more prone to life threating complications. Also females were more affected (66.7%) and the commonest age group ranged from 20-40 years in (70.8%) of cases, which disagrees with findings in China where they had male predominance and the affected age ranged from 51-94 years.

This could be explained by the younger age group in our study being more mobile and prone to infections. Also, this age group are more educated and using the social media a lot as a source for medical information and advice.[21]

Limitations

The limitations of this study include its retrospective single-center design and reliance on medical record documentation, which may have led to incomplete data and possible information bias. Identification of causative agents was based mainly on clinical records and patient history, particularly in cases of multiple medications. In addition, the findings may not be generalizable beyond the study setting. Nevertheless, the study provides important epidemiological data on SJS/TEN in Sudan.

CONCLUSION

SJS/TEN cases admitted at KDTH from 2010 till 2020 are almost equal in number. Over 90% of SJS/TEN cases included in this study were drug induced. The most implicated drugs were antibiotics followed by NSAIDs then antimalarial and lastly allopurinol. Mortality rate due to SJS/TEN was 8% mainly among TEN patients, which is considerably lower than the international records.

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