

Case Report

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A confirmed case of menstrual cup-associated toxic shock syndrome: A Philippine perspective

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Abstract:

Menstrual toxic shock syndrome (TSS) is a severe, fatal, superantigen toxin-mediated illness, which leads to multiorgan system failure early in its course. At the time of writing, there are no local data available on menstrual cup-associated TSS. Reported is a 30-year-old healthy Filipino, diagnosed as a case of menstrual cup-associated TSS. Diagnosis was confirmed by case definition criteria and supported by vaginal discharge culture of methicillin-resistant *Staphylococcus aureus*. The patient was treated empirically with antibiotics that led to successful treatment outcomes with no recurrence. At present, when women empowerment is of utmost importance, we support women's decisions pertaining to their health, including their choice of menstrual hygiene products. This case is reported to raise awareness, promote wellness and safety among menstrual cup users and to educate clinicians on the course and management of menstrual cup associated toxic shock syndrome to prevent its catastrophic sequelae.

Keywords:

Menstrual cup, methicillin-resistant *Staphylococcus aureus*, toxic shock syndrome

Introduction

Toxic shock syndrome (TSS) was first introduced in 1978 in a *Lancet* publication describing the disease to occur in children 8–17 years of age presenting as an acute fatal febrile illness.^[1] It was in 1980 when TSS was associated with young menstruating women; thus, it was further categorized into two: menstrual and nonmenstrual TSS.^[2]

Menstrual TSS is a severe, superantigen toxin-mediated, multiorgan system disease, whose sequelae are shock and multiorgan system failure early in its clinical course. It is highly associated with the use of highly absorbent tampons among young healthy women, with more than 90% having *Staphylococcus aureus* isolates in their vaginal cultures. It was postulated that the

root cause of disease is the inflammatory response to the toxin produced by *S. aureus* which is the TSS toxin 1.^[3]

The incidence of menstrual and nonmenstrual TSS is estimated to be around 0.8–3.4 per 100,000 with menstrual cases accounting for 74% of total cases in the United States. However, at present, there are no local statistics available with no published case at the time of writing.^[4]

In lieu of advancements of menstrual hygiene products, the menstrual cup was invented and slowly introduced worldwide including the Philippines. The menstrual cup is a menstrual hygiene device, made of silicone, rubber, or thermoplastic isomer in the shape of a cup or bell whose main purpose is to collect menstrual blood. It is found to be more convenient, ergonomic, and cost-effective than the traditional napkin pads and tampons.^[5] It is also said

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to be safer than tampons due to the very rare incidence of menstrual TSS associated with its use.^[6,7]

Reported here is a case of a 30-year-old, nulligravid diagnosed as a confirmed case of menstrual cup-associated TSS treated with clindamycin and meropenem, which led to successful treatment outcome.

Case Report

This is a case of a 30-year-old Filipino, nulligravid, with no known present comorbidities. She is allergic to ranitidine and cotton napkin pads. No allergies to food, latex, rubber, and other medications were noted. She is a resident physician, a nonsmoker, and nonalcoholic beverage drinker. The patient menstruates regularly and has been using a 25cc silicone menstrual cup for 6 years, following manufacturer's recommendations of using it for less than 12 h, washing the cup with tap water in between use, and sterilizing it by boiling for 5 min daily. She also replaces the cup yearly.

The patient consulted our emergency room due to high-grade fever. History started 1-month prior; on her 2nd day of menses, she noted macular rashes on bilateral palms, arms, and shoulders, which were erythematous and pruritic. The patient self-medicated with cetirizine 10 mg/tablet which afforded relief of symptoms and clearing of rashes; no consult was done.

Three days before consult, the patient experienced headache, body malaise, and anorexia. This was on her 3rd day of menses where she also reported unintentional prolonged use of menstrual cup, of more than 12 h [Figure 1]. No consult was done and no medications were taken. The following day, symptoms persisted, now with associated arthralgia, myalgia, and high-grade fever Tmax of 39.3°C. Now, the pruritic macular rashes in her palms were noted to desquamate



Figure 1: Actual photograph of menstrual cup used by the index patient

as well. She self-medicated with paracetamol 500 mg/tablet every 4 h which only provided temporary relief of symptoms.

Two hours before consult, on her 5th day of menses, symptoms persisted now with associated myalgia, vomiting, and erythematous tongue; thus, she consulted the emergency room.

The patient was seen conscious and coherent but hypotensive and febrile with initial blood pressure range of 80–90/60 mmHg and temperature of 39°C, nontachypneic, and nontachycardic. She was initially managed with fluid bolus hydration with crystalloids and intravenous (IV) antipyretics, which elevated her blood pressure to 100/60 mmHg and decreased her temperature to 37°C. On physical examination, her skin was warm and supple, with note of bilateral erythematous palms with desquamation. There were no other rashes on the rest of her body [Figure 2a]. Her tongue was noted to be erythematous with prominent papules [Figure 2b]. Bilateral lung fields were clear, and cardiovascular findings were unremarkable. Her abdomen was flat, soft with no areas of tenderness. Pelvic examination was done revealing normal external genitalia. Speculum examination showed a hyperemic vaginal canal with rugae, noted copious amount of whitish-yellow foul-smelling vaginal discharge within the canal. The cervix was hyperemic, smooth with no lesions. On internal examination, the cervix was firm and smooth with cervical motion tenderness, uterus was small, retroverted not enlarged, and no bilateral adnexal masses or tenderness was noted. On rectovaginal examination, her anal sphincter tone was intact, parametria were smooth and pliable, and the cul-de-sac was not full.

Her blood picture revealed septicemia with neutrophilic predominance. Inflammatory markers of erythrocyte sedimentation rate and procalcitonin levels were elevated. Electrolytes, blood chemistry, bleeding parameters, 12-lead electrocardiogram, 2D echocardiogram,



Figure 2: (a) Bilateral erythematous palms, with desquamation. (b) Erythematous tongue with prominent papules

COVID-19 swab, transvaginal sonogram, and chest X-ray all revealed normal findings [Table 1]. Urine, blood, and vaginal cultures were also collected at the emergency room. At this time, her working impression is to consider menstrual cup-associated TSS, with possible pelvic inflammatory disease. With above findings, the patient was referred to an infectious disease specialist for comanagement. She was immediately started on clindamycin 600 mg and meropenem 1 g IV every 8 hours, as well as paracetamol 300 mg and metoclopramide 10 mg IV every 8 h for fever and vomiting. Hydration was maintained with crystalloids. She was monitored for any signs of deterioration such as neurologic changes, chest pain, dyspnea, fever, and recurrence of hypotension.

On her 2nd hospital day, the patient was stable; however, she still complained of headache, anorexia, myalgia, and pruritus of both palms which were erythematous and desquamative. There were no episodes of fever, hypotension, chest pain, dyspnea, or any neurologic changes. Cultures were released; her urine and blood culture of both arms showed no growth after 48 h of incubation. Vaginal discharge Gram stain revealed the presence of 2+ Gram-positive cells and Gram-positive bacilli 3+. Vaginal discharge culture sensitivity isolated heavy growth of methicillin-resistant *S. aureus*, resistant to oxacillin and penicillin, and sensitive to clindamycin, cotrimoxazole, erythromycin, linezolid, tetracycline, and vancomycin. She was referred to dermatology service for the comanagement of skin lesions whose initial impression was cutaneous manifestation of menstrual TSS. Supportive management was advised with hypoallergenic diet and started on levocetirizine 5 mg/tablet once at bedtime and beclomethasone ointment twice daily. Infectious disease specialist advised to complete 5 days of IV antibiotics. Meticulous monitoring and supportive management were continued.

On the 5th hospital day, the patient was well, stable, and improved. She was discharged with the following home medications; co-amoxiclav 625 mg/tablet 2× a day and clindamycin 300 mg/capsule 4× daily for 1 week, naproxen 550 mg/tablet twice daily for joint pains, desloratadine 5 mg/tablet once daily, betamethasone dipropionate ointment twice daily, and calcium + Vitamin D3 once daily. The patient was counseled well on perineal hygiene care and discontinuation of menstrual cup use. She was advised strict monthly follow-up and to observe for any signs of recurrence.

Case Discussion

Menstrual TSS is a severe, acute, superantigen, toxin-mediated disease, characterized by rapid-onset

Table 1: Laboratory results from initial assessment

Parameter	Normal range	Result
White blood cell count (10 ³ /L)	4.4-11	25.5
Neutrophils (%)	56.0-65.0	91
Lymphocytes (%)	25.0-35	2
Monocytes (%)	2.0-8.0	1
Eosinophils (%)	1.0-5.0	6
Hemoglobin (g/dL)	12-16	11.3
Hematocrit (%)	37.0-45	33.6
Platelet count (10 ³ /L)	150-450	320
Infectious parameters		
Erythrocyte sedimentation (mm/h)	0-2	37
C-reactive protein (ug/mL)	0.19-9.14	6.0
Procalcitonin (ug/L)	<0.5	1.66
SARS COV-2 RTPCR OPS/NPS		Not detected
Bleeding parameters		
Protime (s)	10-14	11.4
Protime control (s)		13.1
Protime % activity (%)		91.5
Activated Prothrombin Time (s)		30.3
Prothrombin Time control (s)		25
Blood chemistry		
Alanine aminotransferase (U/L)	0-34	21
Aspartate aminotransferase (U/L)	14.0-59.0	24
Blood urea nitrogen (mg/dL)	7.0-2.0	12.7
Creatinine (mg/dL)	0.52-1.25	0.70
Sodium (mmol/L)	137-150	137
Ionized calcium (mmol/L)	1.2-1.32	1.05
Magnesium (mg/dL)	1.60-2.30	1.99
Potassium (mmol/L)	3.6-5.0	3.67
Chloride (mmol/L)	98-111	101.1
Culture results		
Urine culture		
No growth after 48 h of incubation		
Blood culture		
Right arm: No growth after 48 h of incubation		
Left arm: No growth after 48 h of incubation		
Vaginal discharge culture sensitivity		
Heavy growth of methicillin-resistant <i>Staphylococcus aureus</i>		
Resistant: Oxacillin and penicillin		
Sensitive: Clindamycin, cotrimoxazole, erythromycin, linezolid, tetracycline, and vancomycin		
Vaginal discharge gram stain		
Polymorphonuclear cells 2+		
Gram positive cells 2+		
Gram positive bacilli 3+		
Negative for Gram-negative diplococci		
Transvaginal ultrasound		
Normal-sized retroverted uterus with proliferative phase endometrium. No myometrial lesions. Normal ovaries with follicles.		
Normal cervix. No fluid in the cul-de-sac		
Chest X-ray		
Unremarkable lung fields		
12-lead electrocardiogram		
Sinus rhythm, normal axis, low voltage, poor R wave progression		
Two-dimensional echocardiogram		
Normal left ventricular dimension with good wall motion and normal systolic function. Left ventricular ejection fraction of 66.8%		

Contd...

Table 1: Contd...

Parameter	Normal range	Result
by Simpson's biplane. Normal left ventricular diastolic function, normal right ventricular dimension, and contractility. Normal left and right atria. Structurally normal valves. Normal pulmonary artery pressure		

SARS COV-2 RTPCR OPS/NPS, Severe Acute Respiratory Syndrome Corona Virus 2 Reverse Transcription Polymerase Chain Reaction Oropharyngeal Swab/ Nasopharyngeal swab

hypotension, fever, and rash, which rapidly progresses to multiple-organ system failure and lethal shock. It is frequently preceded by a prodromal period involving fever, chills, myalgia, and gastrointestinal upset.^[8] The overall rates of TSS in the United States have remained relatively stable since the late 1980s and are now presently in the range of 0.8–3.4 per 100,000 adults, with 74% attributed to menstrual TSS and mortality rates ranging from 1.8% to 12%. The peak of incidence, morbidity, and mortality of Menstrual TSS was associated mainly to the increased usage of highly absorbent tampons. However, after thorough patient education and withdrawal of ultra-absorbent tampons from the market, a significant decline in incidence and case fatality rates was observed from 5.5% in 1979–1980 to 1.8% in 1987–1996.^[4]

Menstrual cups are menstrual hygiene products that are made of silicone, rubber, or latex, which are thermoplastic isomer that are increasingly used as a popular alternative to tampons. They are advertised to be ergonomic, convenient, and most of all safer than tampons.^[9] In a study by Juma *et al.* in 2017,^[6] they assessed women using female barrier methods, which similarly uses medical grade silicone or latex products, and the incidence of menstrual TSS is very low and was determined to be 2.25 cases per 100,000 users per year.^[6]

Central to the pathophysiology of menstrual TSS is in association with the use of highly absorbent tampons. Tierno *et al.*^[10] explained that, as menstrual blood accumulates in the polyester foam, it chips of carboxymethylcellulose, which in turn would produce carbon dioxide and increase vaginal pH during menses from the usual 4.2 to approximately 7.4. These factors provide a conducive environment for *S. aureus* growth, which is the organism responsible for the production of an exotoxin within the super antigen family, the TSS toxin 1. Toxin-mediated superantigen may induce clonal T-cell proliferation, resulting in massive cytokine release, subsequently causing cytokine storm that leads to fever, rash, capillary leakage, subsequent hypotension, and organ damage.^[11] On the other hand, pathogenesis of TSS associated with menstrual cups is still unclear and may be multifactorial, since silicone itself does not promote microbial growth. It is hypothesized that the accumulation of blood provides a good medium for bacterial growth. In detail, an *in vitro* trial by Nonfoux

et al. in 2018 postulated that air inserted into the vagina along with the cup favors *S. aureus* growth and subsequent TSS toxin 1 production in the menstrual blood collected in the cup. When the amount of menstrual blood exceeds that of the menstrual cup, the TSS toxin 1 produced in the fluid is in contact with the vaginal mucosa, resulting in toxin transcytosis into the blood which leads to menstrual TSS. It was also noted in their study that women may reinsert a contaminated cup following the manufacturer's instructions that the cup may be removed, emptied, and rinsed with tap water before reinserting. It was found that a significant amount of biofilm of *S. aureus* remained in the menstrual cup after 8 h and 3 washes regardless of model and composition; thus, this study recommends the use of small menstrual cups to avoid entry of air, and it emphasized boiling of menstrual cups in between uses.^[12]

Diagnosis of TSS as defined by the Centers for Disease Control is divided into two categories: the probable case, where the laboratory criteria and four of the five clinical criteria described below are present, and the confirmed case, which is a case that meets the laboratory criteria and all five of the clinical criteria described are present, including desquamation, unless the patient dies before desquamation occurs^[13] [Table 2].

At present, there is no stern clinical guideline with regard to the treatment of menstrual TSS; however, to prevent the fatal consequence, once with clinical suspicion, it is mandated to start empiric antibiotics while awaiting culture results. The recommended treatment regimen is a combination of clindamycin 600–900 mg IV every 8 h together with a penicillin plus beta-lactamase inhibitor or carbapenem in the form of meropenem 1 g IV every 8 h or imipenem 1 g IV every 6 h.^[14]

Clindamycin is an antibiotic used in the treatment of serious anaerobic, *Staphylococcus*, and *Streptococcus* infections, whose main mode of action is suppression of bacterial protein synthesis. More importantly, it is central to the treatment of menstrual TSS for its ability to suppress synthesis of TSS toxin 1.^[15]

There is no clinical study to dictate treatment duration for menstrual TSS; the present recommendation is to continue treatment at least 48–72 h until patients are clinically and hemodynamically stable.^[16]

Summary

As correlated with our index patient, she is a known silicone menstrual cup user for 6 years with an unintentional usage of more than 12 h on day 3 of menses. She presented with the classic signs and symptoms of menstrual TSS, and her diagnosis was

Table 2: Centers for Disease Control and Prevention, 2011, Georgia, USA, case definition for toxic shock syndrome (other than *Streptococcus*)

Clinical criteria
An illness with the following clinical manifestations
Fever: Temperature $\geq 38.9^{\circ}\text{C}$ ($\geq 102.0^{\circ}\text{F}$)
Rash: Diffuse macular erythroderma
Desquamation: 1-2 weeks after onset of rash
Hypotension: Systolic blood pressure ≤ 90 mmHg for adults or less than fifth percentile for children <16 years of age
Multisystem involvement
Gastrointestinal: Vomiting or diarrhea at the onset of illness
Muscular: Severe myalgia or creatine phosphokinase level at least twice the upper limit of normal
Mucous membrane: Vaginal oropharyngeal or conjunctival hyperemia
Renal: blood urea nitrogen or creatinine level at least twice the upper limit of normal for laboratory or urinary sediment with pyuria (≥ 5 leukocytes per high power field) in the absence of urinary tract infection
Hepatic: Total bilirubin, alanine aminotransferase enzyme or aspartate aminotransferase enzyme levels at least twice the upper limit of normal for laboratory
Hematological: platelets $<100,000/\text{mm}^3$
Central nervous system: Disorientation or alterations in consciousness without focal neurological signs when fever and hypotension are absent
Laboratory criteria for diagnosis
Negative results on the following tests if obtained
Blood or cerebrospinal fluid cultures, blood may be positive for <i>Staphylococcus aureus</i>
Negative serologies for Rocky Mountain spotted fever, leptospirosis or measles

confirmed through case definition criteria set by the Centers for Disease Control 2011 where she fulfilled five of the clinical criteria: fever, rash, desquamation, and hypotension, with the presence of multisystem involvement - vomiting, myalgia, and vaginal and oropharyngeal hyperemia. This was further supported by the heavy growth of methicillin-resistant *S. aureus* in her vaginal discharge culture. She was treated with clindamycin 600 mg and meropenem 1 g IV every 8 h for 5 days, which led to successful treatment outcomes. There was no recurrence of hypotension or any signs of shock upon timely initiation of empiric antibiotic regimen. On discharge, all symptoms have been resolved. The patient was advised to discontinue use of menstrual cups; furthermore, clindamycin 300 mg/capsule every 6 h was continued and she was started on co-amoxiclav 625 mg/tablet every 12 h for 1 week as step down for meropenem. Continuation of antibiotics was done as preventive measure to avoid recurrence of menstrual TSS. At present, on her 4th month follow-up, there are no signs of recurrence. A study by Davis *et al.* stated that recurrence may occur in the absence of tampon use. Recurrence of menstrual TSS was observed in 5 out of 30 women despite discontinued tampon

use during menses in a 5-month period after the initial episode.^[14] Despite an established high recurrence rate, few recommendations regarding antibiotic prophylaxis in women previously treated for menstrual TSS have been proposed including clindamycin, rifampicin and penicillin plus beta-lactamase inhibitor. Another possible approach is the use of oral contraceptives, which prevents menstruation, thus reducing the risk of recurrence.^[17] It is emphasized to discontinue menstrual cups and to administer additional oral antibiotics, to remove the carrier state of *S. aureus* which were all employed in our index patient.

At this day and age, when women empowerment is of utmost importance, we give women the freedom to choose what is right and appropriate for them, including the choice of sanitary menstrual hygiene products. It is a personal decision often influenced by cultural acceptability, user preferences, and affordable options. It is our responsibility as obstetricians and gynecologists to lead the way of awareness to promote wellness among Filipino women. To our knowledge, at present, there are only three international journals under the specialty of Internal Medicine who have published case reports of menstrual cup-associated TSS. In the local setting, there is rare if not limited knowledge in terms of incidence, morbidity, and mortality rate of this disease and our index patient may be the first Philippine reported case of menstrual cup-associated TSS treated with clindamycin and meropenem, which led to successful treatment outcomes. This paper is written to raise awareness, promote knowledge, and support women with their choice of menstrual hygiene products at the same time advocating wellness and safety.

Declaration of patient consent

The authors certify that they have obtained all appropriate patient consent forms. In the form, the patient(s) has/have given his/her/their consent for his/her/their images and other clinical information to be reported in the journal. The patients understand that their names and initials will not be published and due efforts will be made to conceal their identity, but anonymity cannot be guaranteed.

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Conflicts of interest

There are no conflicts of interest.

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