

Role of Tissue Oxygen Saturation Monitoring in Diagnosing Necrotizing Fasciitis of the Lower Limbs

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Study objective: We determine the utility of tissue oxygen saturation monitoring in diagnosing necrotizing fasciitis of the lower extremities.

Methods: We prospectively studied patients who met the criteria of soft tissue infection throughout the lower extremities by tissue oxygen saturation monitoring (with near-infrared spectroscopy) over the middle third of possible involved areas. Cases with evidence of chronic venous stasis, peripheral vascular disease, shock, and systemic hypoxia were excluded. Biceps and contralateral unaffected leg areas were measured as references. The tissue oxygen saturation reading for each area was compared with those finally diagnosed as necrotizing fasciitis and those with only simple soft tissue infection. The tissue oxygen saturation reading was presented as mean \pm SD. Receiver operating characteristic (ROC) curves were used to determine a cutoff value of tissue oxygen saturation reading for early diagnosis of necrotizing fasciitis.

Results: Two hundred thirty-four consecutive patients were enrolled. Nineteen patients (group N) were confirmed to have necrotizing fasciitis, whereas the remaining 215 patients (group C) had only cellulitis. The tissue oxygen saturation reading measured over the biceps muscle was $86\% \pm 11\%$ in group N and $85\% \pm 12\%$ in group C. In group N, the leg with necrotizing fasciitis had a tissue oxygen saturation reading of $52\% \pm 18\%$ throughout the involved site, whereas the tissue oxygen saturation reading measured in the comparative values found in group C was $84\% \pm 7\%$ (difference 95% confidence interval [CI] 22% to 29%). After fasciotomy, the tissue oxygen saturation reading of the leg with necrotizing fasciitis returned to $82\% \pm 17\%$ (95% CI 23% to 28% compared with prefasciotomy value) in group N. At the cutoff value of a tissue oxygen saturation reading less than 70% (area under the curve 0.883; 95% CI 0.817 to 0.949) defined by ROC curve, the test revealed a sensitivity of 100% (95% CI 82% to 100%), a specificity of 97% (95% CI 94% to 99%), and an accuracy of 97% (95% CI 95% to 99%).

Conclusion: The low tissue oxygen saturation reading values measured by near-infrared spectroscopy throughout the involved areas of the lower extremities are of value in identifying necrotizing fasciitis. This method may offer a reliable noninvasive method of assessing lower extremities at risk for necrotizing fasciitis, at least for a selected patient population.

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Editor's Capsule Summary*What is already known on this topic*

Early physical findings of necrotizing fasciitis are often subtle, and there are no simple, rapid tests to confirm the diagnosis.

What question this study addressed

Near-infrared spectroscopy was prospectively studied to identify necrotizing fasciitis among patients with soft tissue infections in the lower extremities.

What this study adds to our knowledge

Nineteen of 234 patients studied were confirmed to have necrotizing fasciitis. Tissue oxygen saturation measured by near-infrared spectroscopy was significantly lower in limbs affected by necrotizing fasciitis compared with normal limbs or limbs with simple cellulitis.

How this might change clinical practice

If the technique is validated in other studies, near-infrared spectroscopy may provide a rapid, noninvasive means to confirm suspected necrotizing fasciitis.

INTRODUCTION

Necrotizing fasciitis is a disease characterized by rapidly spreading gangrene of the skin and subcutaneous tissues above the fascial layer. The pathogenesis is most likely caused by the β -hemolytic streptococci group A (*Streptococcus pyogenes*)¹ and sometimes by other organisms or mixed infection.² Its clinical progression usually leads to acute compartment syndrome, septicemia, and even mortality.²

Many new diagnostic tools, such as computed tomography³ (CT) and magnetic resonance imaging,^{4,5} have been recommended for the diagnosis of necrotizing fasciitis. Ultrasonography has also been used as a diagnostic method.⁶ However, these methods are either costly or technique dependent. Early diagnosis still rests on clinical alertness of physicians. Because necrotizing fasciitis is always accompanied by soft tissue necrosis and even compartment syndrome, in which elevated pressure in a closed fascial space reduces capillary filling below the critical level necessary for tissue perfusion, prompt treatment may prevent muscle and nerve ischemia and systemic organ dysfunction.^{7,8} Continuous and noninvasive monitoring of tissue oxygen saturation seems a reasonable method for early detection of patients with necrotizing fasciitis and compromised tissue perfusion. Transcutaneous oximetry uses light transmission and absorption to measure oxygen saturation and oxygenated and deoxygenated hemoglobin in tissue.⁹ Its light penetrates tissues and is absorbed by the chromophores (mainly hemoglobin and myoglobin) that have absorption

wavelengths in the near-infrared region (approximately 660 to 940 nm). The chromophores vary in their absorbance of the near-infrared spectrum, depending on the state of oxygenation. We performed a prospective, observational study to use near-infrared spectroscopy to measure the tissue oxygen saturation reading of the involved soft tissue to determine whether we could find a cutoff value that would be sensitive and specific to help in the diagnosis of lower extremity necrotizing fasciitis.

MATERIALS AND METHODS**Study Design**

This was a prospective observational study conducted from March 2000 through December 2002. This study was approved by our institutional review board.

Setting and Selection of Participants

Consecutive patients who visited the emergency department (ED) with soft tissue infection involving the lower extremities were enrolled in a university teaching hospital with a yearly ED census of more than 80,000. The cases were collected 24 hours a day, 7 days a week. To eliminate possible confusing data because of tissue oxygen saturation reading differences over different body parts, we included only patients having soft tissue infection throughout the lower extremities. Patients transferred from other facilities were, however, not excluded. The diagnostic criteria of soft tissue infection were derived from the definitions of the US Centers for Disease Control and Prevention (CDC).¹⁰ In summary, they were diagnosed as soft tissue infection by meeting at least 1 of the following criteria: (1) organism isolated from culture of tissue or drainage from affected site; (2) purulent drainage from affected site; (3) abscess or other evidence of infection seen during surgery or by histopathologic examination; or (4) localized pain or tenderness, swelling, redness, heat, and positive evidence of pathogen from blood. We excluded patients with evidence of chronic venous stasis, peripheral vascular disease, shock, and systemic hypoxia that possibly interfered with the tissue oxygen saturation readings.

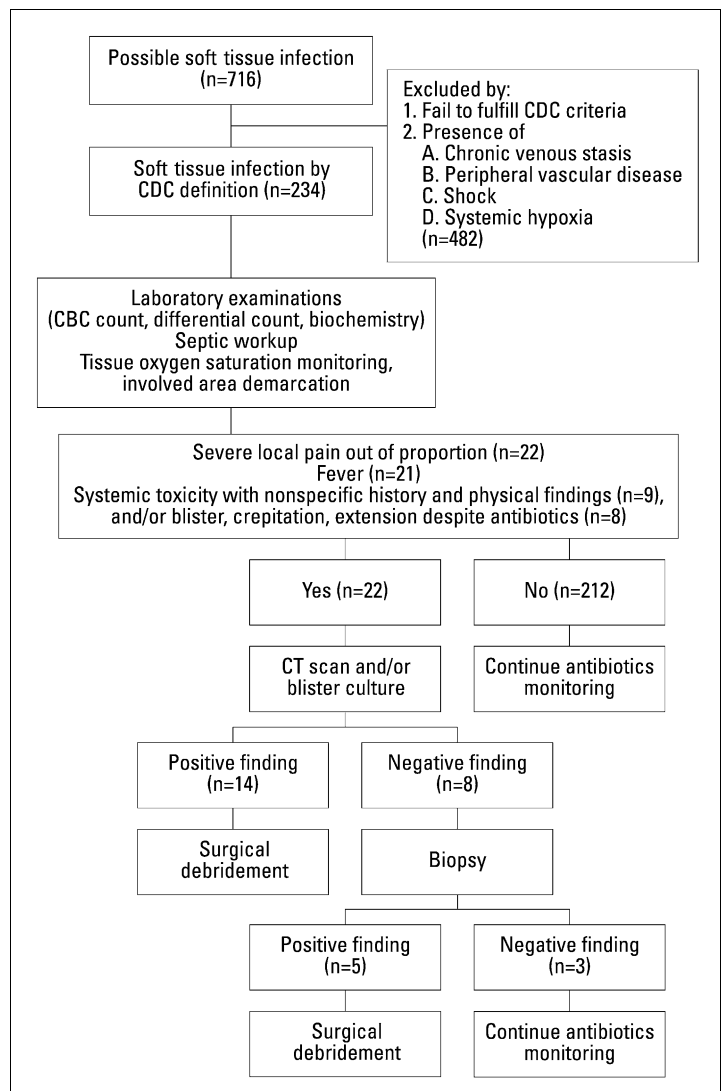
Methods of Measurement

All of the enrolled patients underwent a CBC count, WBC differential count, biochemistry test, and blood culture or cultures of other specimens. They were also monitored by area demarcation and tissue oxygen saturation throughout the involved leg and comparable part of the contralateral leg.

As depicted in Figure 1, the patient underwent CT scan or biopsy if there was any evidence of necrotizing fasciitis, such as persistent fever, severe local pain out of proportion to the clinical findings, systemic toxicity or blister formation, crepitation, or extension of the involved area after receipt of antibiotics. The decisionmaking was at the discretion of the emergency physician. Computed tomographic criteria for necrotizing fasciitis included fascial thickening, fat stranding, gas along fascial planes, and abscess formation. The final diagnosis of necrotizing fasciitis was made by pathologic findings for patients who underwent fasciotomy or biopsy. The remaining patients with no evidence of necrotizing fasciitis were assigned to group C. Specific details for all patients such as age, sex, associated medical illnesses, and causative organisms were recorded.

Oxygen saturation was measured using a continuous light source, dual-wavelength, near-infrared spectroscopy device (Runman CW2000; NIM, Inc., Philadelphia, PA) with good reliability.¹¹ The probe contained 2 small tungsten filament lamps, 6 cm apart, which emit white light, and 2 photo detectors with filters for 760- and 850-nm light, located between the lights. Light migrated through the tissue and was collected by the detectors at wavelengths set by 2 optical filters. Oxyhemoglobin has a greater absorbance at 850 nm than at 760 nm, with deoxyhemoglobin absorbing more at 760 nm than at 850 nm. The difference between the signal at 760 nm and 850 nm was used as the index of relative oxygen saturation. Hemoglobin and oxyhemoglobin are included in the equation $(\text{HbO}_2/[\text{HbO}_2+\text{Hb}] \times 100)$ to provide the tissue oxygenation saturation value.

Figure 1.
Management for patients with soft tissue infection.



In all the patients studied, tissue oxygen saturation readings were performed on the extremities at risk, as were control readings of the biceps muscle before CT and other procedures (Figure 1). Tissue oxygen saturation readings were taken on the middle third of the potentially involved areas underlying the soft tissue infection. Positions were selected to eliminate possible measurement errors. Areas with blisters were also avoided. Tissue oxygen saturation readings of the corresponding points of the uninvolved leg were also measured as comparisons. The biceps muscle readings were performed along the middle third of the center of the muscle. A sterile near-infrared transducer was placed on intact skin. The average depth of penetration of near-infrared light in skeletal muscle was estimated to be 2.5 cm. All of the measurements were performed by an independent researcher who was unaware of any clinical data, including CT findings. The treating physicians were blinded to the tissue oxygen saturation reading data.

Data Collection and Processing

Data were abstracted by one of the authors into a Microsoft Excel spreadsheet (Microsoft Corporation, Redmond, WA). When data were unclear or missing from the record, an author contacted the treating physician.

Primary Data Analysis

Values were presented as mean \pm SD. To select the cutoff value of the tissue oxygen saturation reading that had the best discriminatory power, the receiver operating characteristic (ROC) curves were measured. The test characteristics of tissue oxygen saturation reading, including sensitivity, specificity, positive predictive value, negative predictive value, accuracy, and likelihood ratios, were also examined. The difference between groups was presented as 95% confidence intervals (CIs). Statistics were examined by using a statistical software package (SPSS 8.0, SPSS, Inc., Chicago, IL).

RESULTS

Characteristics of Study Subjects

Of 716 consecutive patients, 482 patients who had infection signs over lower limbs but did not meet the above criteria were excluded from the study, and none of them developed necrotizing fasciitis during follow-up. Another 234 patients were enrolled because of fulfillment of at least 1 of the following criteria: (1) organism isolated from culture of the tissue or drainage from the affected site (n=96); (2) purulent drainage from the affected site

(n=108); (3) abscess or other evidence of infection seen during surgery or by histopathologic examination (n=26); or (4) localized pain or tenderness, swelling, redness, heat, and positive evidence of pathogens from blood (n=55). Twenty-two patients underwent surgery. Nineteen patients (group N) had the diagnosis of necrotizing fasciitis confirmed (Figure 1). Three patients had a final diagnosis of deep vein thrombosis with soft tissue infection after biopsy. The remaining 212 patients were diagnosed as having cellulitis. As depicted in the Table, the age, sex, and underlying diseases were comparable between group N and those without necrotizing fasciitis (group C; n=215). In group N, *Staphylococcus aureus* was identified in 4 patients, streptococcal species in 8 patients, and *Vibrio* species in 5 patients. None of the infections were polymicrobial. Two patients had negative culture results and were diagnosed by typical pathologic findings of necrotizing fasciitis. The overall details of the patients' clinical data are depicted in Figure 1.

In group N, the biceps muscle tissue oxygen saturation reading was $86\% \pm 11\%$ before surgical intervention and $85\% \pm 10\%$ after operation. Group C revealed a mean tissue oxygen saturation reading of $86\% \pm 12\%$ over the biceps muscles during observation.

The leg area involved was evaluated before and after fasciotomy in patients with clinical suspicion of necrotizing fasciitis. The patients in group C had a mean tissue oxygen saturation reading of $84\% \pm 7\%$, whereas the prefasciotomy mean tissue oxygen saturation reading in group N was $52\% \pm 18\%$ (95% CI 22% to 29%; Figure 2). In addition, the postfasciotomy mean tissue oxygen

Table.

Clinical characteristics and the percentage of tissue oxygen saturation greater than 70% over the involved leg area (group N) or comparable compartment (group C).

Risk Factors	Group N (n=19)	Group C (n=215)
Characteristic, No. (%)		
Age, $y \pm$ SD	59 \pm 12	56 \pm 18
Male sex	12 (63)	128 (59)
Hypertension	3 (16)	43 (20)
Diabetes mellitus	5 (26)	47 (22)
Smoking	8 (42)	80 (37)
Chronic liver disease	3 (16)	32 (15)
Chronic renal disease	2 (10)	13 (6)
Malignancy	1 (5)	3 (1)
Tissue oxygen saturation reading, %		
<70%	19	6
\geq 70%	0	209

saturation reading was $82\% \pm 17\%$ (95% CI 23% to 28% compared with pre fasciotomy value) in group N. There was only 1 patient whose post fasciotomy tissue oxygen saturation reading did not improve to the control range because of late presentation and irreversible muscle ischemia.

The contralateral (healthy) legs of the patients in group N were assessed by tissue oxygen saturation readings of comparable areas before ($83\% \pm 12\%$) and after fasciotomy ($85\% \pm 9\%$). The difference between tissue oxygen saturation reading of the healthy legs and that of the involved leg compartments was 31% (95% CI 20% to 41%) in group N.

During tissue oxygen saturation reading measurements, only 2 patients in group N had blisters, 3 patients had additional crepitation, and other patients had only progressive induration that was indistinguishable from cellulitis.

The ROC curves of the tissue oxygen saturation reading values at 60%, 70%, and 80% are depicted in Figure 3. If a tissue oxygen saturation reading less than 70% (area under the curve 0.883; 95% CI 0.817 to 0.949) was selected as the cutoff value of the diagnosis (Table), the test revealed a reported sensitivity of 100% (95% CI 82% to 100%),

a specificity of 97% (95% CI 94% to 99%), a positive predictive value of 76% (95% CI 55% to 91%), a negative predictive value of 100% (95% CI 98% to 100%), and an accuracy of 97% (95% CI 95% to 99%). The positive likelihood ratio was 33, and the negative likelihood ratio was 0.

LIMITATIONS

There are some limitations in this study. First, the small sample size, single center, and selected population in this study limits the generalizability of our findings to the entire population of patients with necrotizing fasciitis. Additional studies to validate the reliability of this device are required in various subpopulations such as patients with shock, anemia, and systemic hypoxemia. Second, some of the patients who had other diseases, such as deep venous thrombosis, could also manifest reduced tissue oxygen saturation like those in this report. Many other diseases, such as peripheral arterial disease,¹² may also affect tissue oxygen saturation readings of extremities. Tissue oxygen saturation readings might not provide an accurate diagnosis for a heterogeneous population, although we tried to exclude such cases in this study.

Figure 2.

Baseline tissue oxygen saturation reading throughout the involved leg areas (N1), unaffected leg areas (N2), and biceps compartments (N3) in group N, and the comparable compartments (C1, C2, C3) in group C. The median is labeled within each box, and the upper and lower whiskers mean 75th percentile and 25th percentile, respectively.

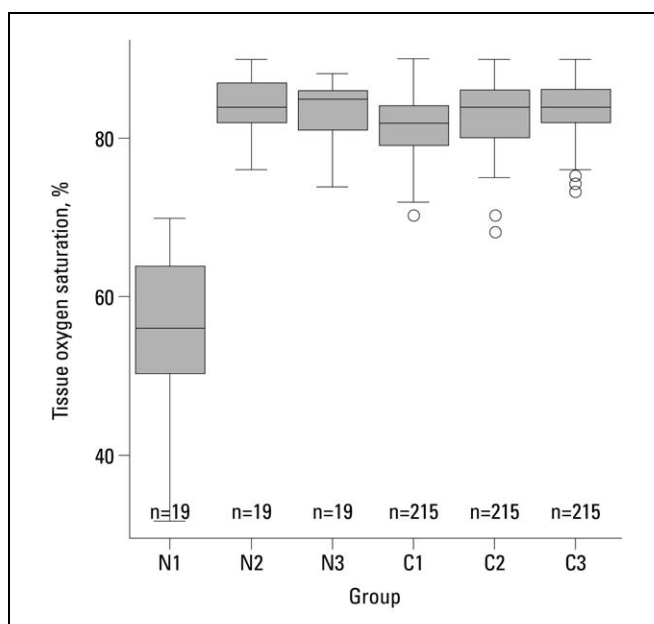
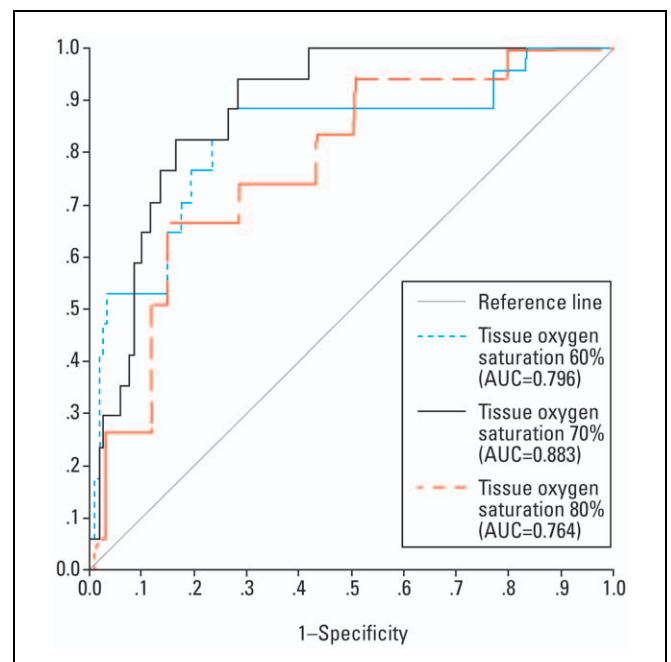


Figure 3.

The ROC curves of tissue oxygen saturation readings at 60%, 70%, and 80% for discriminating necrotizing fasciitis from other soft tissue infection. AUC, area under the curve.



Third, the depth of measurement may be another interfering factor, especially for extremely large or thin patients. However, our patients weighed 60 to 80 kg, and therefore errors might have been eliminated. Finally, the impact of tissue oxygen saturation readings on the outcomes of patients with necrotizing fasciitis was not investigated.

DISCUSSION

Early intervention remains the only method of reducing morbidity and mortality of necrotizing fasciitis.^{1,2,8} However, the early diagnosis of necrotizing fasciitis is often difficult. Reliable and convenient tools allowing for rapid establishment of a definite diagnosis are essential. Our results have shown that tissue oxygen saturation readings measured by near-infrared spectroscopy provide a reliable screening tool for diagnosing necrotizing fasciitis. Its sensitivity and specificity are 100% and 96%, respectively. The high negative predictive value and intermediate positive predictive value suggest tissue oxygen saturation reading as a good screening method for necrotizing fasciitis.

The principal finding of this study was that tissue oxygen saturation reading values were significantly less than control values in the leg with necrotizing fasciitis and dramatically recovered after fasciotomy. Tissue oxygenation can be measured because hemoglobin and myoglobin are the only biological compounds that vary significantly in their absorbance of near-infrared light with differences in oxygenation.^{13,14} Clinical uses of near-infrared spectroscopy in managing hemorrhagic shock,¹⁵ compartment syndrome,¹² peripheral vascular disease,¹⁶ and neonatal resuscitation¹⁷ have been described before. Changes of tissue oxygen saturation reading throughout the lower extremities were also demonstrated under many circumstances such as leg elevation,¹⁸ exercise,¹⁹ and chronic compartment syndrome.²⁰ It is thus well known that tissue oxygen saturation reading correlates well with tissue (such as muscle) oxygenation.

Necrotizing fasciitis initially causes severe inflammation along the fascia and then spreads either to soft tissue above the fascia or to the muscles underlying the fascia. The tissue hypoxia may be multifactorial. First, the process of necrosis decreases tissue oxygenation rapidly. Second, gas-forming bacteria interfere with tissue oxygenation because of their low oxygen tension and its deteriorating effects on intramuscular vasculature.^{1,2,21} Third, the necrotizing characteristics of these infections

result in early thrombosis of small vessels, leading to further low oxygenation of the involved muscles. Fourth, the increased compartment pressure also impairs tissue oxygenation. All of these pathologic sequences of necrotizing fasciitis may explain high sensitivity and specificity of tissue oxygen saturation reading in early diagnosis of the disease from our data.

Previous reports suggested that shunting as a result of loss of extraction for irreversibly damaged muscle might contribute to the normal tissue oxygen saturation readings in some victims of acute compartment syndrome.^{15,22} In this study, no case of necrotizing fasciitis had tissue oxygen saturation reading values greater than 70%. This might suggest that the patients enrolled in this study had neither delayed diagnoses nor any evidence of acute compartment syndrome. The other possible explanation is that the low tissue oxygen saturation reading values measured in the necrotizing fasciitis were not mediated (at least not completely) by the mechanisms of compartment syndrome. Muscular necrosis itself and early thrombosis of small vessels should be taken into consideration instead.

On the other hand, the tissue oxygen saturation reading always detects the light absorbance at 20 mm and could not reflect the oxygenation of deep muscles.^{18-20,22} Necrotizing fasciitis initially progresses along the fascia, especially the superficial side. The superficial tissue (including soft tissue and muscle) may thus be involved earlier than the deeper layer. In our series, the computed tomographic findings for patients with necrotizing fasciitis consistently confirmed that the superficial fascia was involved. No one with necrotizing fasciitis had only necrosis of the deeper fascia. Tissue oxygen saturation readings can therefore be reliably used because it monitors the oxygen level of the involved tissues within its range of detection.

The use of the tissue oxygen saturation reading in diagnosing necrotizing fasciitis can provide many benefits in the ED. First, it can permit continuous monitoring, which cannot be accomplished by other diagnostic tools such as CT and magnetic resonance imaging. Second, it is completely noninvasive and tolerable. Third, the tissue oxygen saturation reading is technique independent, which is different from ultrasonography. The simple application method requires little training of personnel. Fourth, the near-infrared spectroscopy devices are small, portable, and usually cost between \$25,000 and \$50,000 (depending on the channels available and accessories). All of these factors make tissue oxygen saturation readings a convenient and reliable method to screen necrotizing fasciitis.

In conclusion, tissue oxygen saturation values measured by near-infrared spectroscopy are often diminished in the lower extremities of patients with necrotizing fasciitis compared with control limbs and return to normal after fasciotomy. Tissue oxygen saturation readings can thus offer a rapid, noninvasive method to continuously monitor extremities at risk and avoid delayed diagnosis.

Author contributions: Both authors participated in conception and design of the study. TLW acquired, analyzed, and completed initial interpretation of the data. CRH provided critical revisions of the manuscript. TLW takes responsibility for the paper as a whole.

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care, preventative and occupational medicine, drug screening, and epidemiologic and public health issues (eg, norovirus, severe acute respiratory syndrome). Issues specific to the many crew nationalities and cultures that we treat are always a challenge. Critical decisionmaking regarding the most appropriate and logistically feasible means of evacuation is often required.

The physician functions in a very tight social system, requiring an understanding of the hierarchy of the officers and the function of numerous departments. The cruise lines are not in the medical business, they are in the travel business. If you think patient satisfaction is an issue in your emergency department (ED), you have never worked on a cruise ship. The Americans With Disabilities Act has created quite a challenge, attempting to meet the needs of respirator-dependent and other passengers with disabilities while not compromising safety.

There is no residency in cruise medicine. Our physicians are independent contractors. We do not control how they practice or their medical decisionmaking. However, I am fortunate, as chairman of an ED that has a residency program, to disseminate cutting-edge information to our physicians. Additionally, in 2002, we started the annual Institute of Cruise Ship Medicine in Miami, Florida, which is currently open to all of our ships' physicians.

Continuity encourages many cruise ship lines to prefer that physicians work for extended periods. The crew gets to know the physician, and the physician can build confidence. Unfortunately, the US system has rarely provided quality physicians who are willing to work for 6 to 8 months or longer. I predict the continued deterioration of reimbursement and the medical care system in our country will lead to an increasing number of highly qualified emergency physicians who are willing to work more than the occasional 2-week tenure. I would encourage physicians who are looking for a tremendous challenge, one requiring a significant broadening of their emergency skill set, to consider time as a ship's physician to be a worthwhile experience, not only socially and culturally, but also intellectually.

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Tissue Oxygen Saturation Monitoring in Diagnosing Necrotizing Fasciitis of the Lower Limb: A Valuable Tool but Only for a Select Few

To the Editor:

I read with interest the article by Wang and Hung¹ published in the September 2004 issue of *Annals*. Necrotizing

fasciitis is perhaps the deadliest soft tissue infection known to humankind, and early diagnosis and aggressive debridement have been proven to improve survival.²⁻⁴ I think this article would contribute to the development of a focused and targeted approach in the management of necrotizing fasciitis by helping in the detection of early cases of necrotizing fasciitis. While I applaud this effort, I would like to raise some points that I hope will help in the potential application of this work.

The first matter is regarding terminology. The authors used the term fasciotomy as a treatment of necrotizing fasciitis. Fasciotomy is a treatment for compartment syndrome where there is acute or chronic elevation of intracompartment pressure. It is doubtful that increased intracompartment pressure has any role in necrotizing fasciitis. The authors themselves mentioned this in passing in their discussion. The pathological process in necrotizing fasciitis is liquefactive necrosis with thrombosis of the perforating vessels supplying the skin. Although the authors mentioned that several factors may be responsible for their clinical observation, I believe that this is the primary reason for their observation of decreased tissue saturation. The correct term should be excisional debridement of the necrotic fascia. Aggressive removal of all infected tissue, especially the superficial fascia, not fasciotomy, is the only way to halt and control the infection.

Another issue that critically compromised the utility of this article clinically is the patient selection for the study. All patients with chronic venous stasis, peripheral vascular disease, shock, and systemic hypoxia were excluded from the study. This is understandable because most patients with these conditions would have impaired tissue perfusion and oxygen saturation and, thus, would give a false-positive result. However, most patients who develop necrotizing fasciitis have underlying predisposing conditions that make them susceptible to the development of this condition. In my review of 89 consecutive patients, predisposing conditions such as diabetes, peripheral vascular disease, or chronic liver disease were present in 87% of patients. In addition, patients presenting with necrotizing fasciitis with multi-organ failure and shock (eg, streptococcal toxic shock syndrome) would not have interpretable results. Therefore, a majority of patients susceptible to necrotizing fasciitis would have been excluded from this study. This is a pity, because this is a group of patients in whom early diagnosis would profoundly affect outcome. Still, in the select group of patients (namely healthy patients), tissue oxygen saturation monitoring may potentially be a valuable diagnostic adjunct.

Our group has been interested in the early recognition of necrotizing fasciitis. We compared laboratory tests for patients with necrotizing fasciitis and severe soft tissue infections and analyzed routinely performed tests for the assessment of severe soft tissue infections (ie, CBC count, electrolytes, erythrocyte sedimentation rate, C-reactive protein). A numeric score based on the relative significance of the laboratory parameters called the laboratory risk indicator for necrotizing fasciitis (LRINEC)

score was devised.⁵ We think this is capable of detecting even nascent cases of necrotizing fasciitis and can potentially be a valuable diagnostic adjunct in the assessment of potential necrotizing fasciitis.

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In reply:

I appreciate Dr. Wong's comments. As to the terminology, I agree that "excision debridement of the necrotizing fascia," which describes more informatively the surgical procedure, would be a preferred term instead of the term "fasciotomy," which we used in our article.¹ The other issue raised by Dr. Wong is that the patient selection might critically compromise the clinical implications of our study. We excluded patients with chronic venous stasis, peripheral vascular disease, shock, and systemic hypoxia and might raise the question of whether tissue oxygen saturation also works well to differentiate necrotizing fasciitis from cellulitis or other soft tissue infection among patients with these underlying diseases. I still have no definite data to answer this question. However, the above exclusion criteria have been used to find a homogenous study population. It does not mean that tissue oxygen saturation did not play any role in early diagnosis of necrotizing fasciitis for these patients. Theoretically, tissue oxygen saturation should become lowest over the limbs involved in necrotizing fasciitis even when the patient has concomitant presence of the conditions for exclusion. However, I believe the cut-off value of tissue oxygen saturation would be lower than 70%, which we concluded in the present study. The possible problem that should be considered is that peripheral vascular disease or other conditions can result in a low tissue oxygen saturation that falls below the cut-off value we used to detect fasciitis.

Tissue oxygen saturation provides repeated noninvasive measurements; therefore, dynamic changes, such as continuous

decline at the target limb areas, can still provide clinical clues for early diagnosis of fasciitis even in those with peripheral vascular diseases.

I have also reviewed the article concerning the laboratory risk indicator for necrotizing fasciitis (LRINEC) score developed by Wong et al.² I think the LRINEC score is an important finding in diagnosing necrotizing fasciitis. The LRINEC is reported to have high positive and negative predictive values. Accordingly, the sensitivity and specificity should also be high. However, when I try to apply the scoring to the subjects in our study, the positive predictive value is 40% and the negative predictive value is 95%.

One explanation is that our cohort population are victims of necrotizing fasciitis at a very early stage. To my knowledge, the score was developed according to the clinical data from a retrospective population and then proved in the consecutive validation cohort. The limitation will be that a retrospective population may provide a higher specificity and a lower sensitivity of the scoring. The laboratory data used in developing the scoring should therein be critically limited in those measured in an early phase of fasciitis. It may be difficult to define the phases with a retrospective review of the medical record. It is also difficult to apply the randomization process to a retrospective population. A scoring system is best validated in consecutive patients with no predetermination or diagnosis. The sensitivity, specificity, and positive and negative predictive values would be drawn by analyzing the differences between presumed and final diagnoses. Otherwise, the clinical implication of the model will be critically limited to full-blown diseases instead of early diagnosis. I believe that the LRINEC score will be a good indicator for full-blown necrotizing fasciitis, but its role in early detection should be determined in advance. Some other reports demonstrated the pitfalls in diagnosing necrotizing fasciitis by conventional blood tests and even suggested that the diagnosis depends on frozen section biopsy.³⁻⁶ We have the same difficulties and thus have tried to use tissue oxygen saturation to resolve the dilemma. The combination of tissue oxygenation saturation data and the predictive scoring system such as the LRINEC score may be a consideration to the issues mentioned above.

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