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Possible profiles of professional liability with reference to two cases

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Necrotizing fasciitis. Possible profiles of professional liability with reference to two cases.

Necrotizing fasciitis is one of the most dangerous complication of an abscess and it is still a disease with a high mortality. In this work, we decided to consider two cases: the first one concerns a male subject, aged 66, deceased because of a fatal necrotizing fasciitis associated to a cervical descending mediastinitis, which evolved from a primary peritonsillar abscess; the second is about a 50-year-old woman with a perineal abscess, then evolved into necrotizing fasciitis associated to a fatal septis shock. After a systematic consideration of necrotizing fasciitis as pathology and an analysis of the possible related risks to a diagnostic or therapeutic delay, we analyzed the particular history of both cases to underline the possible critical issues in professional behavior of the medical staff intervened.

KEY WORDS: Abscess, Medical malpractice, Mortality, Necrotizing fasciitis, Professional liability

Introduction

The term necrotizing fasciitis (NF) was first introduced by Wilson in 1952, describing a severe soft tissue infection with necrosis of fascia [1]. It is considered one of the most dangerous complication of an abscess, an infection that occurs with low frequency, albeit with high lethality. NF is usually produced by toxins of microorganisms like *Streptococcus* spp., *Staphylococcus* spp., *Fusobacterium* spp. and others [2]. however, some researchers have shown possible presence of mixed synergistic infection [3]. The natural evolution of inadequately treated FN is life threatening septic shock [4] with a mortality rate of 29% in the largest series [5]. From an anatomo-pathological point of view, this infection is characterized by a wide necrosis, spreading through superficial levels and deeper bands to the subcutaneous fat and to the muscular plans. The necrosis of the superficial fascia produces a watery fluid called "dishwater pus", probably caused by bacterial enzymes, deteriorating fascia and fat, resulting in liquefactive necrosis [6]. The histologic findings of NF include necrosis of the superficial fascia and fat, blood vessels thrombosis and inflammatory cell infiltrate characterized by a majority of neutrophils [7].

The greater part of FN cases, especially when misdiagnosed or not properly treated, have as natural pathophysiological evolution the septic shock. Early diagnosis, proper surgical intervention and prompt medical therapies are essential to avoid the devastating consequences of this severe soft tissue infection [8]. Purpose of this paper is to highlight, considering the notions commonly found in scientific literature and the findings from the two cases under consideration, the most common elements of

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criticality in the diagnosis and treatment of this dangerous nosological entity, in order to eliminate or minimize the impact of these on possible profiles of medical malpractice.

Report of Two Cases

Case 1

A 66-year-old male, with positive pathological anamnesis for diabetes mellitus in insulin therapy and atherosclerotic coronary diseases with sub-critical stenosis, arrived in emergency department because of a painful pharyngeal symptomatology arising from about 4 days, with fever and inspiratory dyspnea. Because of this clinical presentation, on advice of his doctor, the subject has already practiced empirical antibiotic therapy without any substantial improvement.
At the entrance in the emergency room, the clinical framework objectified by the doctor on duty, was a swelling of the right tonsil; at the following ENT visit was noted the presence of a right peritonsillar abscess, suggesting hospitalization. At the time of admission to the ward, the subject's vital signs measurement showed an absence of fever (T.C.: 36,4 °C) although the laboratory tests showed an increase of the inflammatory markers, particularly with strong neutrophilia and rising of VES. The next day, after performing an ultrasound examination of the neck, he was submitted, as an outpatient, to surgical incision and drainage of the right tonsil. However, after 48 hours, a chest x-ray showed a thickening of interstitial plot, with signs of an overall inflammatory bronchopulmonary framework; however, the clinical condition of the patient had a drastic worsening with the onset of acute retrosternal pain combined with a decline of sensory, with the presence of respiratory distress, documented by evidence of hypoxia on the blood gas analysis. Therefore, it was performed a CT with contrast, which documented the presence of a subcutaneous emphysema in continuity with the tonsillar abscess, with fluid material visible in the surrounding tissues; the phlogistic material extended in peri-pharyngeal region, with increased density of the mediastinal tissue, in particular in the right paratracheal region, thus placing diagnosis of descending mediastinitis.
Given the particular gravity of this clinical presentation, combined with progressive deterioration of the general condition of the subject, the transfer to another hospital structure was opted for the placement of two drainages, in correspondence of the pleural cavities, in order to drain the effusion. However, due to the consistently low blood pressure, progressive oliguria and progressive respiratory failure, all elements that indicated the diagnosis of multi-organ failure by septic shock, a few hours later the patient died for an acute cardio-circulatory arrest.
At autopsy was found, at the cervical region, the presence of a large necrotic area mixed to a collection of purulent material diffusely infiltrating the cervical muscles up to extend inferiorly to the soft tissues of the mediastinum. At this level, moreover, there was the presence of copious amounts of purulent material that covered the pleura and pericardium, as part of an anatomo-pathologic framework altogether compatible with the necrotizing fasciitis and mediastinitis. A general clinical presentation of multi-visceral congestion coexisted, particularly at brain and lung parenchyma; this was further confirmed by the histopathological observations.

Case 2

A 50-year-old female with positive pathological anamnesis for diabetes mellitus and hypertension, both under effective therapeutic control, arrived to the medical attention because of the presence of an abscess in the third upper of the right labium majus with cutaneous fistulisation and the presence of pain in external genitalia. During the hospitalization, the vital parameters of the patient showed the presence of fever (37,8 °C) with increased concentration of neutrophils in the blood test, an hyperglycemia and a sinus tachycardia. Fever, hyperglycemia and elevated blood pressure were present during next days of hospitalization, in addition to increased creatinine values (1,6 mg/dL) four days after entering in the department. Physical examination, on this date, showed the presence of swelling on the root of the right thigh with skin flush, indicating the presence of a subcutaneous phlegmon. After an episode of paroxysmal atrial fibrillation, and a subsequent decline in the general conditions of the patient, was placed indication for a change in antibiotic therapy as persisted the clinical features of strong neutrophilia and the increase of indices of renal dysfunction.
Five days after the entrance to the ward, the patient was subjected to surgical curettage and drainage of abscess extended until the root of the thigh, pointing to the subsequent transfer of the subject to another hospital in order to submit her to an hyperbaric treatment. This therapeutic option, however, did not find any success, and the patient died in the same day for a multi-organ failure due to a septic shock.

Discussion

NF is a quite rare infection, with a thousand new cases reported in the USA [9]. Although the epidemiology of NF suggests no predilection of age or sex [6], some authors reported a male predominance. The age of onset of NF is 28 – 44 years, while it is extremely rare in children, prevailing in this last case in countries with poor hygienic prevention. The average age of the patients that exceed

this pathology is 35 years, while the average age of patients do not survive to NF is 49 years. However, the overall mortality rate vary between 9 and 29 % [10].

The exact pathogenesis of the NF has not been conclusively established; it was found, however, that after microbial invasion of subcutaneous tissues, bacterial toxins cause tissue damaging with an uncontrolled release of proteolytic enzymes from the membranes of the cells with consequently massive necrosis [11]. Moreover bacterial toxins stimulate cytokines production resulting in a systemic inflammatory syndrome progressing to a septic shock, multisystem organ dysfunction and death [12]. The most cases of NF occurs in the abdominal wall, in the perineum and in the limbs; it is an uncommon observation a NF of the head and neck [8]. From an etiological point of view, it has been documented as sources of NF every damage of the skin, like cuts, abrasions, ulcers and surgical incisions. Although the skin is the most common way of access of the bacteria, possible portal of entry could be mucosal lacerations, dental or salivary gland diseases.

The clinical presentation of the first stages of NF is not specific because it is characterized only by an area of inflamed soft tissue, therefore in the early stages of the disease the diagnosis can be difficult. Typically the development of symptoms is sudden with pain and local swelling; after a few hours, the pain gradually leaves the place to a state of anesthesia. First signs and symptoms that should rise the suspicion of NF are swelling, erythema and pain disproportionate to the injury seen [7]. The infection develops as an area of erythema which rapidly spreads to the surrounding normal skin in the following hours, until the appearance of evident tissues necrosis [13]. The most important objective signs, ultimately, are the tissue necrosis, the emission of putrid material, blisters, severe pain, production of gas and the rapid fistulisation within deep tissue. In this stage the local signs are usually associated to systemic symptoms, as fever, hypotension and tachycardia, up to a critical stage of the disease [14].

Timely diagnosis, not easy for the peculiar appearance of the disease, is important as the NF typically spreads rapidly and can lead to multiorgan failure, ARDS and death. Blood cultures should be taken in addition to clinical monitoring and routine laboratory evaluations to obtain pathologic diagnosis. Although the group A *Streptococcus* is the most common germ isolated, more frequently the infection is caused by a set of aerobic and anaerobic Gram-positive and Gram-negative bacteria. Timely diagnosis, the immediate administration of broad-spectrum antibiotics and early and aggressive debridement of all tissue affected are the key steps to reduce the morbidity and mortality of these quickly progressive infections.

Although a diagnosis of NF is important to set up adequate therapy, it is crucial to begin the empiric treatment as soon as possible, which consists in quick correction of hypovolemia and electrolyte balance; administration of broad-spectrum antibiotics to cover all microorganism which may be involved, later, when the pathogen is identified, it is necessary to switch to a targeted therapy; early extended surgical excision of necrotic tissue; supporting therapy consisting in enteral or parenteral nutrition and anti-thrombotic prophylaxis.

From the clinical cases described above we can be made important deductions both purely clinical and medico-legal regarding NF. Although these cases seem to have no statistical significance, not deviating substantially from literature data about this nosological entity, it is still interesting to note how both came to our attention after complaint to the Judicial Authority in order to detect possible medical malpractice hypothesis. Our particular experience leads us to conclude that the leading role, in order to make a medico-legal valuation about the appropriateness and adequacy of the administered treatment, lies in the timing of the surgery, when it is established the diagnosis of NF. In fact, in both cases desc [15] malpractice of the doctors involved in the care of the patient. The omission of an early surgical operation in a case reported by Bono et al, was the key factor that worsened the prognosis and caused the death of the patient [15].

Despite the rapid diagnostic classification and the early surgical treatment the two patients of our cases died for multi-organ failure by septic shock probably favored by coexisting diseases and negative prognostic factors. Indeed, the major complications related to mortality of larger series are septic shock and multi-organ failure [16]. Moreover, among predisposing causes of NF diabetes mellitus is of greater importance as is always present in larger retrospective analysis of NF along with liver cirrhosis hypertension, obesity and cardiac disease [17]. Recent studies, from a prognostic point of view, have shown, despite the contextual surgery and appropriate antibiotic therapy, a high mortality, around 30-50 %. In therapeutic management of the patient with NF, in addition to medical and surgical intervention, is important the interaction with the surgeon for the debridement, with the infectivologist, and with the microbiologist [18].

It should be specified in this point, how an ideal diagnostic algorithm of necrotizing fasciitis, the radiologic evaluation play a leading role; among these, ultrasound, computed tomography (CT) and magnetic resonance imaging (MRI). In particular, the CT appears to be the choice for its high sensitivity in the study of inflammatory or infectious processes and for staging the extension of NF, which very often does not have a direct correspondence with the severity of the signs and symptoms associated [7].

Another point of particular importance, as previously reported, concerns the timing of surgery. In fact, a delay in the surgical debridement procedure, which should carried out during the first day in hospital, is proven to be a poor prognostic factor. The medical therapy alone, although necessary, is insufficient in solving the prima-

ry outbreak of infection and, above all, in respect of its subsequent evolution in fasciitis. It can be considered, therefore, that the key elements to the achievement of the therapeutic success against the NF are represented by the early diagnosis combined with an aggressive surgical treatment [19]. In particular, the precocity of the surgical approach is aimed not only to limit the outbreak of infection but also to remove the necrotic tissue which appears to be the source of secondary infection with the toxin production by the responsible microorganism. About medical therapy, the empirical antibiotic therapy should be started without delay, intravenously. Indeed, given the progression of the disease, there is never enough time to wait for the results of cultures and therefore to undertake a targeted antibiotic therapy [20].

From a medico-legal point of view, each of these therapeutic steps is a possible factor valuable in terms of negligence and imprudence, and it could represent elements of professional liability. In particular, the timeliness of treatment more than the adequacy of the treatment itself, it is often the crucial element for the survival of the patient, because of the rapid and poor development of the primary infectious process of NF. However, in both cases reported there was no professional liability after forensic analysis of the events. In fact, in both cases the conduct of physicians were mainly faithful to what is suggested by the guide lines, as well as the diagnosis of NF and subsequent surgical approach of debridement were made as fast as possible, given the insidious onset of the clinical presentation and its subsequent rapid evolution.

An interesting aspect, to be further developed in the light of legislation in place in our country about the broader issue of the medical malpractice, could be to determine how much the events discussed in these two cases could have a different weight according to the different current present, past or future regulation [21]. In fact, at the time of this paper we are in a period of transition between the so-called "Decree *Balduzzi*" (Act 189/2012) and the "Decree *Gelli – Bianco*" (Act 24/2017), which further emphasizes the weight of the guide lines and the good clinical care practices as a criterion for judgment of the doctor work [22].

Riassunto

In questo lavoro abbiamo deciso di prendere in esame due casi: il primo riguarda un soggetto di sesso maschile, di 66 anni, deceduto a causa di una fatale fascite necrotizzante cervicale con associata mediastinite discendente, evolutesi da un primario ascesso peritonsillare; il secondo inerente una donna di 50 anni con un ascesso perineale, successivamente evoluto in fascite necrotizzante con associato shock settico fatale.

Dopo una considerazione sistematica della fascite necrotizzante come patologia ed un'analisi dei possibili rischi connessi ad un ritardo diagnostico o terapeutico, abbiamo analizzato la storia particolare dei due casi per evidenziare eventuali profili di criticabilità nell'operato professionale dei sanitari intervenuti.

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