Kennedy's terminal ulcer and pressure injury: two different aspects of medical liability related to the same injury

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ABSTRACT

Recent case law shows disadvantageous legal disputes with a major defeat due to negligence in treating pressure ulcers, even when they are wrongly-diagnosed terminal lesions, such as Kennedy's terminal ulcer, and, therefore, untreatable illnesses that do not imply medical liability. The authors examine both the recent case law, based on deaths that occurred in the last 15 years, and linked, even partially, to pressure injury, and medical records, underlining the differences between these two injuries and focusing on the possible forms of medical liability and current judicial trends.

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Introduction

A skin lesion in a terminal patient is often diagnosed as a pressure injury, so-called bedsore, leading the patient's heirs to potentially file a lawsuit for medical liability, because these types of lesions are usually caused by insufficient assistance. From the examination of the medical records and of specialist literature,[1-4] it turns out that a good number of these lesions can be easily classified as Kennedy's terminal ulcers (some of them even as 3:30 syndrome,[5] with a life expectancy of few hours), typical end-of-life events that are inevitable, incurable and, therefore, lacking in any kind of medical liability, except for rough mistakes.

Pressure injuries

A pressure injury is a specific skin wound -subcutaneous, muscular, and/or osseous- caused by prolonged pressure and/or repeated friction (external factors) between the support surface and the bony prominence areas of the body of a patient in bed or immobilized because of elderly age or clinical conditions (internal factors).

When the compression exceeds capillary circulation's pressure value, often altered by edema or pathological conditions that affect the skin or the circulation system, oxygenated blood doesn't reach the tissues and this leads to ischemia; firstly, the body reacts to it with a vasodilation (erythema) that is followed by tissue necrosis (when it doesn't heal).

For this reason, pressure injuries due to forced posture mainly arise from the most superficial bony prominences, such as the sacrococcygeal junction, the ischium, heels and feet, shoulders and shoulder blades, elbows and, last but not least, the occipital bone.

To prevent similar complications, it is required not only to move the patient regularly on a particular mattress, as it has been maintained since 1948,[6] but also to reduce as much as possible any risk factor in high-risk patients (through accurate risk assessment and suitable nutrition, skin care, early mobilization even in critical patients in intensive cares,[7] right support surfaces such as inflatable automated mattresses that help unload the pressure from contact areas, procedures to move the patient - especially the unconscious ones, the use of specific materials to help sliding movements…).[8]

Stages of pressure injuries

To classify pressure injuries, the most accredited model is the one developed by EPUAP (European Pressure Ulcer Advisory Panel), NPUAP (National Pressure Ulcer Advisory Panel), and PPPIA (Pan Pacific Pressure Injury Alliance), which considers 4 different stages based on the involved tissues.

1º stage: lasting erythema, that doesn't turn white when pressure is applied (non-blanching erythema);
2º stage: emerging superficial lesion, that only involves epidermis and dermis;
3º stage: necrosis reaches the hypodermis (subcutaneous tissue);
4º stage: wound reaches muscles and underlying bones.
Unspecified stage: eschars or necrotic tissues don't allow to understand of the depth of the lesion (Figure 1)

End-of-life lesions and Kennedy's terminal ulcer

In 2003, the medical community started to talk about skin failure,[10] claiming that the skin, as other organs do, can undergo severe deficiencies and failures in the final stages of life; between 2008 and 2009, a team of American experts founded a working group and published a document, called S.C.A.L.E (Skin Changes At Life's End), that analyzed all end-of-life events related to the skin, enhancing the knowledge of similar lesions, previously only described in Kennedy's Terminal Ulcer (K.T.U.) studies.[12]

The panel of experts not only studied the mechanisms that bring about skin distress but also understood and affirmed that these lesions are incurable since they are part of terminal physiological processes; the panel also developed 10 "*statements*" related to the topic (to this day, still largely unknown to most): i) physiological changes that occur as a result of the dying process may affect the skin and soft tissues, can be unavoidable, and may occur with the application of appropriate interventions that meet or exceed the standard of care; ii) the plan of care and patient response should be documented and reflected in the entire medical record; iii) patient-centered concerns should be addressed including pain and activities of daily living; iv) skin changes at life's end are a reflection of compromised skin (and not related to external factors); v) expectations around the patient's end-of-life goals and concerns should be communicated among the members of the interprofessional team and the patient's circle of care; vi) risk factors, symptoms, and signs associated with SCALE have not been fully elucidated, but may include some factors, like progressive weakness, suboptimal nutrition, etc.; vii) a total skin assessment should be performed regularly and document all areas of concern consistent with the wishes and conditions of the patient. Pay special attention to bony prominences and skin areas with underlying cartilage; viii) consultation with a qualified healthcare professional is recommended for any skin changes associated with increased pain, signs of infection, and skin breakdown, and whenever the patient's circle of care expresses a significant concern; ix) the probable skin change etiology and goals of care should be determined; x) patients and concerned individuals should be educated regarding SCALE and the plan of care.

This document, even if it has been reworked and expanded, remains a landmark in this sector, because not only it clearly states that not all lesions are treatable, but it also points out how to handle these incurable end-of-life injuries.[13]

Kennedy's terminal ulcer is the most known and observed lesion, and it requires specific attention, since it is constantly mistaken for a pressure injury and, for this reason, it often leads to lawsuits. Kennedy's ulcer incidence is higher than it is believed to be: Hanson *et al.*[14] found this kind of ulcer in 62.5% of hospitalized patients in their last two weeks of life. The ulcers were found almost exclusively in the sacrococcygeal area and the heels, but they have also been observed on calves, arms, and elbows.[15]

It is a full-thickness cutaneous lesion that appears and develops extremely rapidly: differently from normal pressure ulcers, that form progressively in a couple of days, this one emerges in a few hours, leading the specialists to call it an "*ah-ha ulcer*".[16] It is a typical example of skin failure: it's important to understand that the skin is an independent organ and it shows symptoms of the dying process in most patients.[12]

Figure 1. Pressure injury of indeterminate degree.

How to treat a KTU?

The therapy's highest priority is the assistance of the terminal patient while treating the local area is a secondary target: life expectancy and its quality come before anything else. In some cases, specialists might be able to start a healing process, but most of the time Kennedy's terminal ulcers tend to worsen, regardless of the chosen therapy.

Medical competence

Injury management only consists of the initial treatment and the monitoring of possible complications, focusing on palliative therapy for local and systemic pain.

Nursing competence

Nurses are the main professional figures in patient management, since it's their job to evaluate and adjust the medical care, choosing the best procedure to ensure relief in terminal stages. The most common question is: should I keep the patient still or mobilize him, causing him pain for an incurable injury?

Materials and Methods

We studied 24 clinical records of patients that, from 2 to 12 weeks before decease, presented with lesions classified as pressure injuries, as well as the latest sentences from "Corte di Cassazione" - Italian highest court of appeal - and we focused on those wounds that could be end-of-life lesions.

For this diagnosis, we applied the criteria used to identify Kennedy's terminal ulcer: i) sudden onset of the injury in the sacral area; ii) insufficient response to therapies and worsening of the wound; iii) a pear-shaped or butterfly-shaped lesion in the sacral area; iv) single lesion; v) purple/blue/red color.

Since the research was a retrospective study, we decided to recognize as KTUs only those injuries that met all 5 criteria.

As for the juridical analysis, we typed the words "lesion", "decubitus" and "ulcer" into two specific search engines (Leggi d'Italia and Top 24 Diritto), setting a 15-year timeframe and examining all those lawsuits in which the pressure injury was claimed or assessed to be the cause or concurrent cause of death.

Finally, we analyzed different sentences (both of first-instance trials and appeals) to understand the juridical trend.

This research guarantees anonymity.

Results

Among the 24 patients with sacral lesions, 16 (66,6%) of them meet Kennedy's terminal ulcer criteria. This percentage matches Hanson *et al*.[14]

The juridical research output hundreds of sentences, from which we had to take out all those lawsuits in which pressure injuries weren't declared cause or concurrent cause of death, as well as all those not pertinent to civil or penal lawsuits: the final result was a core of 24 civil lawsuits of first instance and 12 of second instance, 14 first instance penal suits (Corte d'assise) and 8 appeal cases.

Analyzing the Supreme Court case law, the study focused on 10 verdicts (6 penal suits and 4 civil cases), developed from previous convictions.

The results are: i) conviction of healthcare workers in civil lawsuits of the first instance: 18 out of 24 (75%); ii) conviction of healthcare workers in civil lawsuits of the second instance: 6 out of 12 (50%); iii) conviction of healthcare workers in penal lawsuits of the first instance: 8 out of 14 (57%); iv) conviction of healthcare workers in penal lawsuits of the second instance: 2 out of 8 (25%); v) conviction of healthcare workers in civil Supreme Court lawsuits: 4 out of 6 (66%); vi) conviction of healthcare workers in penal Supreme Court lawsuits: 0 out of 4 (0%).

The key words ("ulcer", "terminal" and "Kennedy") typed in the search engines didn't give any outcome, but it is worth mentioning that there is a nonsuit due to a consultancy of a wound specialist that diagnosed Kennedy's terminal ulcer.

Despite the high number of convictions for professional misconduct, the damage compensation was a variable, since it was determined on the bases of the patient's general conditions, the so-called loss of chance, and it only exceeded the 10% of legal disability in one clinical case (10%).

Discussion

Most cutaneous lesions in terminal patients might not be pressure injuries, but rather physiological end-of-life events that do not imply nursing or professional liability. However, most of the time this problem isn't solved properly either in wards, hospices or in courtrooms of first-instance lawsuits.

Does this mean that only professional liability lawsuits come before the judge or that there is a lack of knowledge in the field? Our study, even though it examined a limited sample, tends to support the second theory.

The analysis of judicial convictions shows a high rate in first-instance civil lawsuits, that decreases in appeal suits: this tendency might be caused by the fact that only heavy sentences are contested since only in similar circumstances it's worth the effort.

In penal lawsuits, the initial rate of convictions is lower, probably because the trial only begins after the prosecutor's inquiry, the verdict of the preliminary investigation judge (GIP), and the final decision of the pre-trial

hearing judge (GUP): for the case to be sent to trial, the responsibility has to be probable, if not almost proven.

Convictions in penal appeals are more than halved because medical liability is hard to prove beyond reasonable doubt and, personally, even harder to be believed.[13]

The Supreme Court, eventually, even without going into the matter, admitted a high percentage (33%) of civil actions, returning them to lower courts, which proves the complexity of the topic. Regarding penal lawsuits, however, the Supreme Court rejected all the appeals (100%).

These medically questionable decisions of judges are likely due to what the scientific community claimed in the past,[17,19] but those same theories have been proven wrong in the last twenty years:[3,4,20] thanks to scientific progress and to the lengthening of average lifespan (that, unfortunately, doesn't imply a better quality of life), it has been proved that the appearance of a pressure injury does not automatically entail medical negligence, but it can be a complication following the hospitalization, especially in patients with predisposed diseases.[21] The most renowned panels of experts agree on defining most of these injuries as unavoidable and only potentially preventable.[22-24]

Unfortunately, law firms and consumer associations promote similar lawsuits, assuming that nursing negligence is always the cause of the problem.[25,26]

In the judicial system, the trend is to convict for professional liability if there are omissions or intentional misbehaviors, without any presumption of guilt. On the other hand, the absence of pressure injuries in, patients doesn't prove the unconditional adequacy of the therapies.

Moreover, nowadays it's common to evaluate how the loss of chance decreased in percent during the diagnostic-therapeutic path, especially if it ended in death,[28] and how it determined the *exitus*.[29] Even our reduced number of clinical records proves what is being said, despite the extremely high percentage of civil convictions observed in the study.

To sum up, professional liability related to pressure injuries is not automatic, but it requires an individual study and a quantification of the eventual negligence, regarding the patient's disability and general conditions, considering how significantly it may have influenced the remaining quality of life and the development of the illness.

Kennedy's terminal ulcer, on the other hand, is an end-of-life lesion and, as a consequence, is inevitable (like many pressure injuries) and, most importantly, incurable. In such circumstances, healthcare workers can only reduce the pain and avoid it becoming a cause or concurrent cause of the inevitable death.

To determine the allocation of responsibility, in pressure injury management there is an increasingly important difference in the roles of doctors and nurses: the first ones may be responsible for setting the wrong therapeutic approach and for the unsuccessful (or lacking) diagnosis, while nurses might be responsible for the incorrect management of lesions and treatments, together with possible complications.

Conclusions

It is fundamental to distinguish an end-of-life lesion from a pressure injury to avoid convictions for professional liability. However, a correct diagnosis of a terminal lesion doesn't fully protect against convictions because in lawsuits (especially in civil suits) it is necessary to provide proper evidence for every single choice, even that of reducing the patient's mobilizations to avoid useless pain; otherwise, healthcare workers risk to be accused of negligence, if not even of abandonment. An informed consent to the therapy, possibly signed by the patient, is a necessary safeguard.

Last but not least, the choice of palliative therapies (instead of therapeutic ones) must be shared with the patient himself and with his relatives, involving (when possible) the care network and guaranteeing personal data protection.

By doing this, the patient will have a decent *exitus*, his relatives will be actively involved in the palliative process and the healthcare workers will have legal protection.

Eventually, the only thing left to do is to hope that even expert witnesses know the difference between Kennedy's terminal ulcers and common pressure injuries.

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