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Review

Malpractice in head and neck cancer: a comprehensive medico-legal review

Emanuele Capasso[1], Claudia Casella[1], Mariagrazia Marisei[1], Marco Macculi[1], Ilenia Bianchi[2], Pierpaolo Di Lorenzo[1]

[1] Department of Advanced Biomedical Sciences, School of Medicine, University of Naples Federico II, Naples, Italy; [2] Laboratory of Personal Identification and Forensic Morphology, Department of Health Sciences, University of Florence, Florence, Italy

Summary

Head and neck (H&N) malignancies include a broad spectrum of clinical presentations and outcomes. Sources of risks, errors and mistakes are intrinsic to every therapeutical-diagnostic step leading to potential burden of malpractice allegations and threaten delivery of healthcare. The purpose of this review is to report key factors of malpractice litigation H&N neoplasms, analyzing its ethical-deontological and medico-legal aspects with a focus on Italian law. PubMed and Scopus databases were accessed to assess existing cases of oncological H&N malpractice. Twelve articles were identified according to search criteria in the selected period (2000-2024). Inclusion criteria lead to 6 articles pertaining to analysis of allegations of malpractice in H&N tumors. Diagnostic delay and informed consent issues are the most represented allegations. Poor access and lack of standardization in legal databases is commonly seen as a factor that holds back a thorough litigation analysis. This review adds evidence about common features of medical malpractice allegations through a medico-legal perspective that may help in adopting preventive strategies to mitigate risks and enhance patient safety. Combining data deriving from different studies, the paper contributes to understand the evolution of the trajectory of malpractice in this field.

Key words: medical malpractice, medico-legal issues, head and neck cancer

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Correspondence
Mariagrazia Marisei
E-mail: mariagrazia.marisei@unina.it

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Introduction

The head and neck (H&N) region includes the upper aerodigestive tract (oral cavity, nose, paranasal sinuses, pharynx, larynx, cervical esophagus), thyroid, associated lymph nodes, ears, soft tissues, and odontogenic and maxillofacial bone. The different tissues in this anatomic region give rise to a broad spectrum of neoplasms with differing morphologies, molecular alterations, risk factors, and treatment options[1,2]. The most common malignancy of the H&N (over 90%) is squamous cell carcinoma (SCC), which is the sixth most common neoplasm worldwide [3].

Typically diagnosed in older patients in association with heavy use of tobacco and alcohol, H&N cancers are slowly declining globally, in part because of decreased use of tobacco [4,5]. Conversely, cases of HPV-associated oropharyngeal cancer, induced primarily by HPV type 16, are increasing, predominantly among younger people in North America and northern Europe, reflecting a latency of 10 to 30 years after oral-sex exposure [6,7]. Patients with potentially suspicious mucosal changes should undergo specialistic evaluation with imaging analysis and diagnostic biopsy. Fine-needle aspiration biopsy is highly sensitive, specific, and accurate for the initial histologic diagnosis [8]. The signs and symptoms of the disease are related to the primary area involved and the extent of the neoplasm.

Even though many H&N tumours are symptomatic and relatively visible or palpable, a significant proportion are still diagnosed at advanced stages (stage III and IV) [9], with consequent delay in treatment. The evaluation of the patient with H&N cancer must be multidisciplinary and the choice of treatment depends on the location of the primary tumor, its staging, general health conditions, aesthetic and functional results secondary to the proposed treatment and patient preferences. Although the improvement in treatment techniques in recent years has contributed to determining both greater chances of recovery and the containment of adverse events related to treatment, the management of H&N diseases are still sources of medical malpractice. Four important risks for malpractice litigation in H&N surgery were identified: young patient age, perioperative complications, delay of or missed diagnosis, and persistence or recurrence of disease [10]. The management of patients suffering from H&N pathologies also has different ethical-deontological and medico-legal aspects, such as protection of personal data, respect for the patient's decision-making autonomy and the responsible exercise of professional activity, which are essential for a correct diagnostic-therapeutic framework. In Italy, the protection of patient' privacy is achieved through compliance with the European Regulation for the protection of personal data (Reg. 2016/679/UE) [11], a behavior of healthcare workers inspired by professional secrecy, and based on the informed consent for the processing of patient's personal data. The patient's decision-making autonomy is based on a shared decision-making process, which includes both an expression of a valid and informed consent regarding medical treatment, and respect for any refusal of the proposed treatment and desistance from therapeutic obstinacy. If the patient refuses healthcare treatments necessary for his survival, the physician suggests to the patient and, if he/she agrees, to their family, the consequences of this decision and the possible alternatives, promoting each action of support to the patient himself. Summarizing, a responsible exercise of medical activity presupposes the acquisition of valid informed consent to the proposed healthcare treatment, the provision of complete and correct healthcare activities, as well as the duty to assist the patient in every phase of his illness. The aim of the study is to analyze the ethical-deontological and medico-legal aspects of malpractice in H&N oncological pathology throughout the diagnostic and treatment processes, with a focus on Italian regulation.

Materials and methods

A systematic literature search was carried out to identify the main features of medical malpractice in H&N cancer. To this purpose, we searched in "all fields" of the PubMed (https://pubmed.ncbi.nlm.nih.gov) and Scopus databases (https://www.scopus.com) using the combination of the following search terms: "Head and neck" AND "malpractice". To widen the research also "litigation", "informed consent" and "cancer" were terms used in the search strategy. The search period ranged from January 2000 to December 2024, and only articles published in English were selected. The search produced a different number of results in PubMed (n = 100) and Scopus (n = 1922). The data were further screened by including only reviews and systematic reviews and limiting the subject area to Medicine and Dentistry. This search methodology produced 424 articles, which were manually screened, and if potentially eligible, their full text was reviewed. The screening phase included a first selection which excluded papers with a lack of clear malpractice allegation in H&N pathology. Furthermore, papers not related to oncological pathology were excluded. Two reviewers conducted the search separately, achieving the same results. An overview of the search methodology is shown in Figure 1.

Results

Four hundred and twenty-four articles were identified according to search criteria in the selected period and 12 were assessed for eligibility. Inclusion criteria lead to 6 articles pertaining to analysis of allegations of malpractice in H&N tumors. One of the most common aspects was the scarce accessibility to databases [12]. Availability of data is a common feature outlined also to have a proper litigation analysis [13,14], therefore the intrinsic generalized risk of bias concerns potentially limited data on which analyzed review have been developed through the years. Not only accessibility to databases seems to be a desirable achievement but also standardization of databases is crucial to compare data [15]. One of the most represented allegations regards consent issues[13,15,16], as well as delay in diagnosis that is of utmost importance in young patients whose symptoms are hardly reconducted to malignant conditions[10,13,14]. Diagnostic-therapeutic pathways include several professional figures, whereby multidisciplinarity is a factor identified as an explanation for the fact that in malpractice proceedings against physicians, other specialist figures, such as anaesthetists and radiologists, typically appear alongside the otorhinolaryngologists [15,16].

Most of the cases resulting in the conviction of the health professional involved the otorhinolaryngolo-

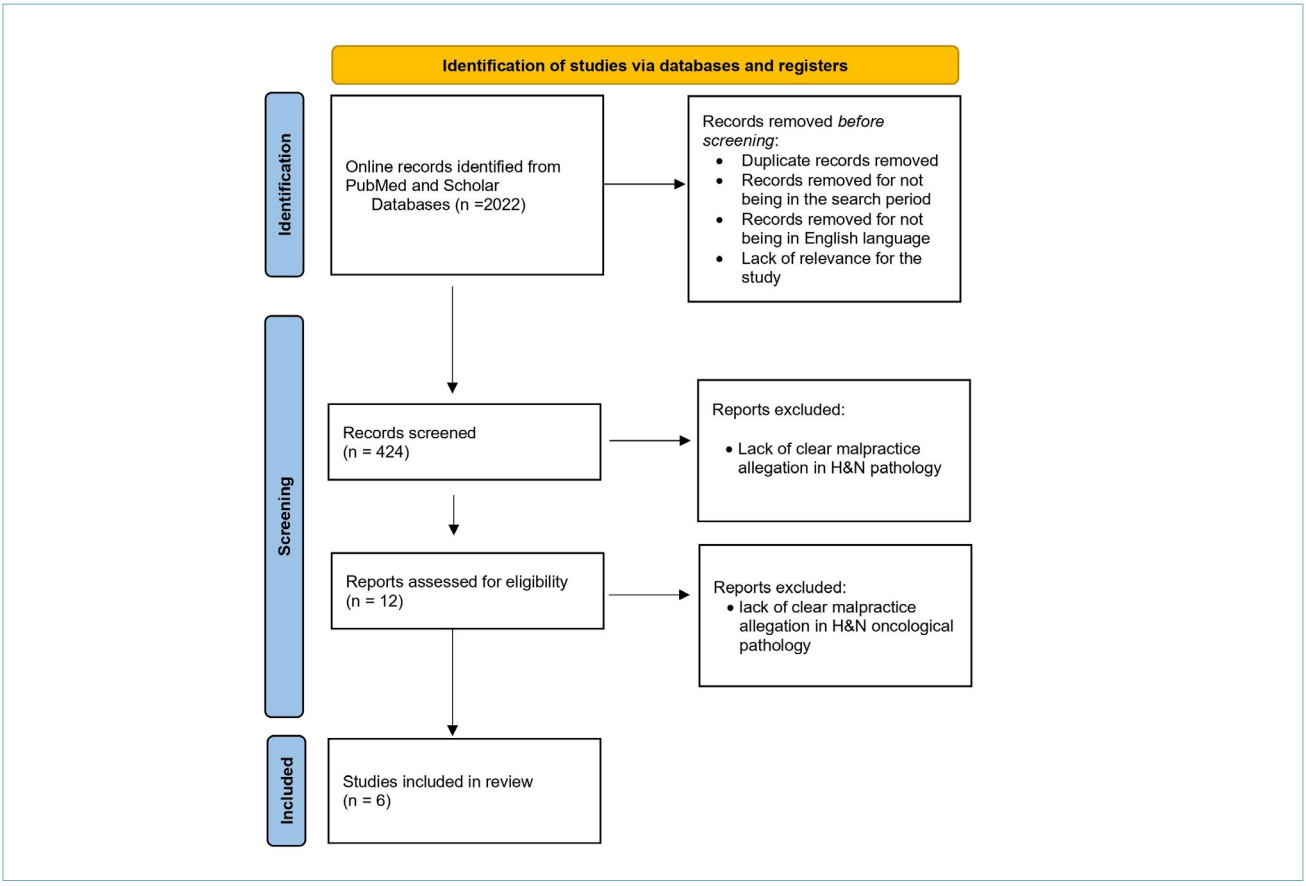

Figure 1. PRISMA Flowchart. Search methodology for identifying features of malpractice in H&N oncological pathology for the period 2000 to 2024

gist and no other professionals such as pathologists and radiologists, demonstrating how proof of a causal link is more difficult in cases of omissive liability [15]. The eradicating scope of cancer surgery may lead to abrupt functional loss and the patient's self-perception of postoperative changes may increase allegations of malpractice [14]. The completeness and proper maintenance of health records can play a decisive role in malpractice cases in the field of H&N oncology, where, however, negative outcomes are more often due to the stage and biology of the tumor than to deviation from a required professional behavior [12]. Table I outlines basic characteristics of each review, whereas the most relevant features are reported in Table II.

Table I. Study characteristics included in review.

First author (year)	Primary diagnosis	Allegations	Judicial outcome of cases	Amount awarded
Lydiatt (2004)	✓	✓	✓	-
Simonsen (2012)	✓	✓	✓	✓
Harréus (2013)	✓	✓	-	-
Epstein (2015)	✓	✓	✓	✓
Ceremsak (2021)	✓	✓	✓	-
Fritz (2023)	✓	✓	✓	✓

Table II. Relevant features in H&N malpractice litigations.

Relevant features in H&N malpractice litigation
Delay in diagnosis/referral
Technical execution
Informed consent
Improper maintenance of health records
Difficulty in demonstrating omissive liability
Multidisciplinarity

Discussion

The main ethical-deontological and medico-legal aspects related to healthcare for patients with H&N lesions pertain to three specific areas classified as: protection of patient confidentiality, respect for the patient's decision-making autonomy, and responsible exercise of professional activity. Starting from the first point, in Europe, the discipline is regulated by the European Data Protection Regulation (GDPR). Consent for the processing of personal data falls under the authorization that the patient provides in response to comprehensive information regarding the purposes and conditions of processing, which is distinct from consent for medical acts. The information to be provided to the patient must be concise, transparent, intelligible, and easily accessible, using simple and clear language. It is no coincidence that more than informed consent the literature specifically mentions communication [16]. The methods for providing this information are determined by the data controller, considering all circumstances of processing and the context in which it occurs. Challenges of implementing GDPR in clinical practice specifically pertain to digitalization of healthcare records, telemedicine and the need to widen knowledge among healthcare workers of its provisions. Regarding consent for healthcare acts in Italy, Law n. 219/17 [17] stipulates, based on Article 32 of the Constitution, that "no healthcare treatment may be initiated or continued without the free and informed consent of the person concerned, except in cases expressly provided for by law".

Complete, updated, and understandable information must be provided concerning prevention, diagnostic pathway, diagnosis, prognosis, therapy, and any potential diagnostic-therapeutic alternatives, foreseeable risks and complications, as well as behaviors that the patient must observe during the care process, benefits and risks of not treating the diagnosed condition. The validity of consent expressed in written or video-recorded form by the patient is based on these premises. The qualitative and quantitative characteristics of the informational elements provided to the patient relate both to their potential understanding and to the appropriate time dedicated to the informational process. Moreover, in accordance with the code of medical ethics adopted since 2014 as well as Law 219/17, patients have the right to refuse all or part of this information; designate family members or a trusted person to receive information and express consent; refuse all or part of diagnostic assessments or indicated healthcare treatments; revoke/waive consent for healthcare acts at any time; physicians respect the patient's will (including negative will); obtain consent (or dissent) in written/video-recorded form/devices; transcribe the patient's will in their medical record or electronic health file. The completeness of consent includes addressing all foreseeable risks, including those statistically less likely, excluding only those absolutely exceptional and highly improbable. The most contentious issues in shared decision-making with patients suffering from oral and oropharyngeal cancer involve qualitative-quantitative characteristics of informational elements to be provided to patients, communication strategies to adopt, family involvement in decision-making processes, communication difficulties when addressing foreign patients' healthcare needs. In an area such as oncology-potentially devastating even to body image due to radical tumor removal in head and neck regions, the characteristic of comprehensive [18] information pertains to every single phase of intervention as well as potential burdens [19] in terms of suffering during postoperative rehabilitation. To overcome the dissonance between patients' expectations of their own body image and the eradicating scope of palliative or curative cancer surgery, the role of shared care planning is crucial. This tool is available to the patient suffering from a chronic, irreversible pathology with an inauspicious prognosis and allows them to agree with the healthcare team on the stages of their terminal course of treatment according to his very personal life priorities [17].

Physicians are required to continue their education regarding relationships with patients, communication skills, pain management, and palliative care. The ethical duty of informing and communicating with assisted individuals is established as stated in Article 33 of the Code of Medical Ethics [20]: "The physician adjusts communication according to the understanding capacity of the assisted person or their legal representative while responding to any request for clarification while considering their emotional sensitivity and reactivity, particularly in cases of severe or terminal prognosis, without excluding elements of hope. The physician respects necessary confidentiality regarding information and the will of the assisted person not to be informed or to delegate another person for information sharing while documenting this in medical records". The relationship between physician and patient is built on freedom of choice and identifying and sharing respective autonomies and responsibilities. In this relationship, physicians pursue a care alliance based on mutual trust and respect for values and rights alongside understandable and complete information while considering communication time as care time. Excluding cases of compulsory healthcare treatment ("T.S.O." for the Italian Law) or emergencies requiring immediate action, damages resulting

Table III. Schematic representation of types of compensable damage to patients.

	Absence of iatrogenic damage	Iatrogenic damage without culpable conduct by the physician (complication)	Iatrogenic damage due to culpable conduct by the physician
Presumed Consent (if correctly informed, patient would have given consent)	-	d	a
Presumed Dissent (if correctly informed, patient would have refused therapeutic act)	d	c, d	b, d

Legend. Types of recoverable damages

a. Damage to health (biological damage) resulting from incorrect execution of healthcare service (iatrogenic damage from medical error); b. Damage to health considered in its entirety (treatment outcome + iatrogenic damage from medical error); c. Biological damage differentiating between consequences of intervention and pre-existing disabling pathological state (complication); d. Harmful consequences not related to property, attached and proven (including by presumption), different from health damage (subjective suffering and contraction of freedom over oneself).

from failure to obtain a valid informed consent – due to incomplete, lacking or wrongful information – must be refunded even if the intervention performed was deemed necessary, correctly executed and proven effective against identified pathology. An omission or lack of information provided to patients constitutes dual harmful conduct: it infringes on health rights as well as violates self-determination rights resulting in damage that affects psychological-physical integrity along with a contraction of freedom over oneself. Table III [21] includes a representation of types of compensable damage to patients.

The specialist medical figures involved in care processes and possible profiles of professional healthcare responsibility include oncologists, general practitioners, otolaryngologists, dentists, radiologists, pathologists, surgeons, radiation therapists. These may involve professional responsibility due to omitted/delayed/incorrect diagnosis/treatment or even prevention as seen with healthcare practitioners. To avoid professional healthcare responsibility profiles while practicing any profession related to diagnostic-therapeutic pathways for H&N lesions it is necessary to ensure quality and comprehensibility of information provided to patients [22], including discomforts associated with treatments (e.g., postoperative suffering and self-perception) alongside potential worsening health conditions resulting from treatment execution itself as well as therapeutic alternatives; document expressed patient will; adhere strictly during healthcare service provision according to recommendations outlined in guidelines validated by the Minister of Health or good clinical-assistance practices where guidelines are absent; correctly integrate information about any software or algorithms based on artificial intelligence while identifying responsible parties for damages caused to third parties. An additional obligation is accurately drafting complete health certifications because negligent management may lead to medical liability profiles (defective completion or lack thereof allows presuming causal links between medical conduct and claimed unjust damages); demonstrate having taken all necessary precautions against "complications". A potential limitation of this study derives from cases not included in the review due to the partial accessibility of legal databases.

Conclusion

The theme of professional healthcare responsibility concerning H&N oncological pathology has been studied in the past resulting in numerous reviews. Common findings relate primarily to responsibility due to omitted diagnosis compared to errors in technical execution during interventions. Litigation analysis and access to legal databases also in countries different to US to conduct comprehensive medical legal assessment may help understand the evolution of the trajectory of malpractice in this field to adopt preventive strategies. A rigorous medico-legal approach and further research need to be conducted in the field of H&N pathology to mitigate risks and enhance patient safety. Medico-legal expertise, as part of an early multidisciplinary discussion in all complex and intricate clinical situations, may serve as a valid malpractice mitigation factor.

Conflict of interest statement

The authors have no relevant financial or non-financial interests to disclose.

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Ethical consideration

Authors ensure the integrity of the review process. Ethical committee approval is not applicable.

Authors contribution

Conceptualization, M.M. and P.D.L.; methodology, M.M. and M.Mac.; validation, C.C.; formal analysis, I.B.; investigation, M.M. and I.B.; data curation, E. C. and P.D.L.; writing—original draft preparation, M.M.; writing—review and editing, E.C. and M.Mac. All authors have read and agreed to the published version of the manuscript.

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