Oral Cancer and Treatment Information Involved in Therapeutic Decision-Making

Maria Sofia Rini¹, Stefania Zerbo S.² and Antonina Argo²

¹Private Practice of Dentistry, University of Bologna, Bologna, Italy and ²Department of Health Promotion, Maternal and Child Care, “G.D’Alessandro”, Legal Medicine Section, University of Palermo, Palermo, Italy

Abstract: Early detection of oral cancer improves survival after treatment and the quality of life. The adoption of standardized methodological protocols of screening has increased the possibilities for early identification and for appropriate treatment. The informed consent must be obtained by patients before any treatment and/or surgical procedure. The clinical and surgical details must be discussed with the patient. The patient must know potential risks and benefits. Consent must be documented in the medical record and consent forms may serve to document the physician’s discussion with the patient. All dentists are trained to detect the early signs of oral cancer. The health professional have a key role in identify the early signs of oral cancer in order to plan the treatment and management of the disease. The work aims to provide simple practical information to collect the patient’s consent and encouraging him to improve healthy behaviors. In this work the critical issues of clinical practice in order to improve the management of oral cancer are analyzed. The information must include an exhaustive discussion of objectives, risks, and benefits of each option including the option of not choosing the treatment/procedure of care. The authors identify three different situations: information and consent to a generic prevention, information and consent in case of suspected diagnosis or early diagnosis and information and consent the case of advanced cancer.

The authors sought to identify effective information approaches. Approaches that need to be documented in the medical records, that become communication instrument between the patient and the physician. The folder is also a historical memory of what happened. The patient’s refusal must be informed also. The patient must know the possible risks of not proceeding with therapies or with proposed treatment.

Keywords: Oral cancer, Diagnosis, Informed consent, Consent form, Information approaches.

1. INTRODUCTION


Oral squamous cell carcinoma (OSCC) is the most common cancer of oral cavity that represents more than 90% of the malignancies [12-16].

However, standardized methodological protocols of screening has increased the possibilities for early identification. Unfortunately in most cases of patients with OSCC the diagnosis is made at advanced stages.

A complete oral cavity exploration is effective way for early diagnosis [17-23]. Diagnostic delay may be ascribable to patient and/or professional delay [24-26].

Civil litigations may occur due to alleged delay or misdiagnosis. The adoption of current guidelines for the early diagnosis of cancer and for the management of the treatment may reduce the risk of damages claimed [27]. It is necessary to develop systematically a more effective approach in communicating with patients. The information must include a complete discussion of objectives, risks, and benefits of each option, the potential late and long-term complications of treatment including the consequences of not choosing the treatment/procedure.

Consent must be documented in the medical record and consent forms may serve to document the physician’s discussion with the patient.

The most common risk factors of oral cancer including smoking [28-31], alcohol abuse [32,33] a diet poor in fruit and fresh vegetables [34], trauma of oral mucosa [35-38], Candida infections, Epstein Barr virus, HCV, Papillomavirus [39-44], poor oral hygiene, precancerous [45,46].

The patient must be informed that avoiding risk factors does not necessarily reduce the risk of cancer, but it can help, a later diagnosis may involve and implies a more invasive and multidisciplinary treatments consisting of surgery, radiotherapy and chemotherapy [47-49].

In Italy are treated 9 thousand cases already advanced, you could save many lives as well as improve the quality of life and save with a timely intervention at least 35 million euro a year. [50]
In Italy on average there are 10 new cases per year per 100,000 inhabitants and the incidence in men is more than 50% compared to women. Increasing incidence of oral cancer, particularly amongst younger persons is observed in the recent years. [50]

Oral cancer prevention and early diagnosis are the most effective way to contrast the disease and require full patient collaboration who must necessarily be well informed. Health promotion is critical, particularly regarding sexual behavior, tobacco cessation and dental care.

In cases of advanced oral cancer the patient must be informed regarding common complications due to surgical, chemotherapy and radiation treatment.

The authors believe it is possible to identify three different situations that require three different types of information:

1. Information and consent to a generic prevention;
2. Information and consent in case of suspected diagnosis or early diagnosis;
3. Information and consent in the case of advanced cancer.

2. MATERIALS AND METHODS

Oral exploration is the gold standard for oral cancer screening while biopsy and histopathological examination are necessary to detect identified lesions. Imaging techniques (DPT, CT, and MRI) are frequently used to supplement the clinical evaluation and staging of the primary tumor.

For example ulcerate lesions must be carefully examined. In presence of irritants (such us a mobile dental prosthesis) it is necessary to remove them and recognize the tissues after some days (about 15). Consequently, if the ulcer disappears it is advisable to re-evaluate the prosthesis and correct any defects. On the other hand if the lesion persists further clinical investigation are required. The oral cavity is easily inspectable and it is necessary to identify the lesions at risk of malignant evolution. Some suspected lesions must be observed and monitored over time. Patient’s collaboration and awareness are essential in these cases. Some lesions are at greater clinical risk, such as leukoplasic or erythematous areas, swelling or persistent ulcers.

We tried to understand how to effectively communicate these concepts to patients in order to achieve maximum collaboration, without frightening it unnecessarily. However even simplifying or trivializing risks can lead to negative results.

This work aims to identify clinical effective and useful medico-legal information patterns to support verbal information: simple and summary patterns

3. RESULT AND CONCLUSION

3.1. Legal and Ethical Basis of Informed Consent

The Convention on human rights and Biomedicine (Oviedo, 1997) and the European Charter of fundamental Rights (Nizza 2000) states that free and informed consent is a human fundamental right to safeguard individual’s dignity. The Article 5 of Oviedo Convention declare that “an intervention in the health field may only be carried out after the person concerned has given free and informed consent to it. This person shall beforehand be given appropriate information as to the purpose an nature of the intervention as well as on its consequences and risks. The person concerned may freely withdraw consent at any time”. The Article 3 of European Charter of fundamental Rights states “everyone has the right to respect for his or her physical and mental integrity. in the fields of medicine and biology, the following must be respected in particular the free and informed consent of the person concerned according to the procedures laid down by law”. Both articles protect the principle of self-determination in medical cure as, also, highlighted by Italian Constitution in article 32 "... no one may be obliged to undergo any health treatment except under the provisions of the law ...". Recently the Italian Act of Adavanced treatment directives n 2801/2017 (approved on 16 December 2017) states that patient’s consent to a treatment procedure must be informed.

The current version of May, 2014 of Italian Code of Medical Deontology, in the last edition, for the first time expressly planned the informed dissent to clinical practice in article 35.

If the patient is unable to provide consent, the patient’s legal representative or, in the case of a minor, the patient’s parent(s), represents the patient in the consent process. The patient or legal representative must have every opportunity to understand the risks, benefits, and alternatives of the proposed treatment or procedure [51-53].
4. INFORMATION AND CONSENT

Italian dentists must be aware that information and consent are two distinct, closely processes that should be treated separately and specifically [54-55].

The information must include an exhaustive discussion of objectives, risks, and benefits of each option including the option of not choosing the treatment/procedure of care. The awareness refuse to undertake clinical treatment/procedure exempt the professional from liability, but the patient is informed about the possible risks of not proceeding with the proposed treatment.

Consent must be transcribed in the medical record, and consent forms may serve to document the physician’s discussion with the patient. A useful method of documentation is a physician note in the medical record indicating that the discussion took place and that the consent of the patient was obtained. The note should also include the date and time of the discussion, the content of the discussion, an evaluation of the patient’s understanding and a signature of patient.

The informed consent process requires face-to-face discussion of the procedure between the dentist and the patient. In the case of a minor, consent should be obtained from the patient’s parent(s) or legal representative. The consent process must include a comprehensive discussion of the benefits and potential risks of the procedure as well as reasonable alternatives to the procedure. The patient or legal representative should have the opportunity to ask questions and clarify all doubts.

The set of information that dentists must given to patient with oral cancer and suspected lesion includes various issues.

The survival rate depend on the tumor stage: the patients at stage I and II can be successfully treated with therapeutic approach consisting in surgery or radiation therapy with less morbidity than patients with advanced cancers.

The dentist must inform all patients of the need to prevent oral cancer by means of periodic clinical examination and control of flawed habits [56-57].

The dentist will discuss with the patient the best options to treat a disease. The treatment depends on several factors, including the type and stage of the cancer. The surgery is the most frequent treatment for oral cancer. The type of surgery depends on the extension and stage of the tumor.

Surgical techniques may consist on removal of the tumor and/or a larger area surrounding healthy tissue, (glossectomy, maxillectomy, removal of lymph nodes), plastic surgery to re-establish tissues removed, dental surgery to remove teeth. Chemotherapy may be used to reduce the neoplasia mass before surgery or radiation, or it may be combined with radiation to increase the effectiveness of both treatments. In the later stage when it is impossible a surgery approach the treatment include the chemotherapy and radiotherapy.

The patient must be informed about the potential acute and long-term complications of the surgery, radio and chemotherapy. The most common complications include mucositis, dysgeusia, xerostomia, infectious diseases, pain, cranial nerves lesions, mastication and swallowing damage.

The dentist must inform the patient to observe an optimal oral hygiene during treatment, adequate nutrition, and avoiding tobacco and alcohol in order to prevent or minimize oral complications. To ensure that the patient fully understands what is required, provide detailed instructions on specific oral care practices, such as how and when to brush and floss, how to recognize signs of complications, and respect the appointments established by the dentist.

In cases of evident suspicion lesion of malignancy the biopsy in essential in order to make the diagnosis and the management of therapeutic treatment.

4.1. Paperwork

The paperwork integrates and summarizes the content of the verbal information process. For this reason it should be simple and schematic considering the patient's condition and the possible/probable pathological evolutions. The information must be personalized and presented in a manner which is compatible with the individual patient's educational level, comprehension skills, and psychological and emotional status in order to accept or refuse the proposed treatment.

In absence of injuries or suspected diagnoses of oral cancer, but in presence of situations at risk it is sufficient that the paperwork certifies the information and attests the need for frequent checks and reduction of risk factors. In case of suspected diagnosis, the
paperwork must clearly indicate the need for diagnostic investigations, possible therapies and complication.

The informative content of paperwork in the case of advanced cancer requires care and prudence, but must summarize all the information concerning the type of treatment, acute and long term complications related to cancer treatment, outcomes.

It is necessary to respect and document the patient’s right to refuse and not to be informed about the treatment. Each paperwork must contain spaces for customizing the form and for any note.

4.2. Form

4.2.1. Generic Prevention

Dear Sir / Madam

Oral carcinoma is a malignant neoplasm originating from the epithelial tissues lining the oral cavity. The incidence of oral oncological diseases is high. The early identification of the risk conditions is fundamental for the correct prevention and management of the disease.

Survival is better in case of limitation of the neoplasm to the site of onset. Initially the critical lesions are asymptomatic.

Today’s visit has highlighted some predisposing conditions for the onset of oral cancer. Following the informative report, in addition to the same it summarizes the necessity:

- to remove the risk factors in his case identified in:
  ◊ Cigarette smoke and tobacco chewing
  ◊ Consumption of alcohol
  ◊ Repeated traumatism
  ◊ Poor oral hygiene
  ◊ Sun exposure and use of the pipe
  ◊ Other….

- to carry out frequency checks, every……..
- to maintain correct oral hygiene
- to undergo professional hygiene every

We recommend that you quickly contact your dentist in case of suspected lesions

Attention before signing this form We invite you to read it carefully and mentally review what we have said and the information provided to you. Do not hesitate to ask us for additional information if something is not clear to you or to express your dissent.

Thank you

INFORMED CONSENT

◊ I consider myself adequately informed and I am obliged to follow the proposed therapeutic/preventative procedure

There, ......................... Signature .........................

INFORMED DISSENT

◊ I refuse to undertake proposed therapeutic/preventive procedure even though informed about the possible risks of not proceeding with the proposed treatment

There, ......................... Signature .........................

4.3. SUSPECTED DIAGNOSIS OR EARLY DIAGNOSIS

Dear Sir / Madam

Today’s visit highlighted some critical issues that need monitoring and therapy. Following the information provided, in addition we summarize the following:

1. Oral carcinoma is a malignant neoplasm originating from the epithelial tissues lining the oral cavity;
2. The incidence of oral oncological diseases is high;
3. The early identification of the risk conditions is fundamental for the correct prevention and management of the disease;
4. Survival is better in case of limitation of the neoplasm to the site of onset;
5. Delaying diagnosis leads to serious consequences.

In his case, the following were highlighted:

a) Risk conditions:
  ◊ Cigarette smoke and tobacco chewing
  ◊ Consumption of alcohol
Repeat traumatism
- Poor oral hygiene
- Sun exposure and use of the pipe (preferential seat the lip)
- Other

b) Injury

Other Are needed:
- Diagnostic investigations
- Biopsy
- Oncological visit
- Surgical removal
- Other

Attention before signing this form We invite you to read it carefully and mentally review what we have said and the information provided to you. Do not hesitate to ask us for additional information if something is not clear to you or to express your dissent.

Thank you

INFORMED CONSENT
- I consider myself adequately informed and I am obliged to follow the proposed therapeutic / preventative procedure

There, ....................... Signature ......................

INFORMED DISSENT
- I refuse to undergo diagnostic investigation and/or proposed procedure even though informed about the possible risks of not proceeding with the proposed treatment

There, ....................... Signature ......................

4.4. Advanced Neoplasia

Dear Sir / Madam

Today's visit highlighted some critical lesions that are used to diagnose cancer pathology and which require specialized treatment in the nature of
- urgency
- deferred urgency.

Following the information provided, in addition to the same we summarize the following:
- Oral carcinoma is a malignant neoplasm originating from the epithelial tissues lining the oral cavity
- The disease was diagnosed in advanced stages

You need oncological evaluations and specific therapies (surgery and / or radiotherapy)
- Survival is better in case of limitation of the neoplasm to the site of onset
- Subsequently frequent checks and removal of all risk factors will be required:
  - Cigarette smoke and tobacco chewing
  - Consumption of alcohol
  - Repeated traumatism
  - Poor oral hygiene
  - Sun exposure and use of the pipe
  - Other
- Next check is ..... 
- Next professional hygiene is
- In case of further suspected injury, please contact us urgently

Attention before signing this form We invite you to read it carefully and mentally review what we have said and the information provided to you. Do not hesitate to ask us for additional information if something is not clear to you or to express your dissent.

Thank you

INFORMED CONSENT
- I consider myself adequately informed and I am obliged to follow the proposed therapeutic / preventative procedure

There, ....................... Signature ......................

INFORMED DISSENT
- I refuse to undergo diagnostic investigation and/or proposed procedure even though informed about the possible risks of not proceeding with the proposed treatment

There, ....................... Signature ......................
informed about the possible risks of not proceeding with the proposed treatment.

There, ........................................ Signature ............................

5. UNINFORMED CONSENT

I ask not to be informed about my oral health and the necessary therapies of which:

◊ I authorize the execution
◊ I do not authorize the execution
◊ I authorize you to inform __________________

There, ........................................ Signature ............................

REFERENCES


