

MEASURES OF PROTECTION AGAINST EXPOSURE TO CYTOSTATICS IN THE SURGICAL AREA.

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Cytostatics are substances capable of inhibiting or blocking the evolution of the neoplasia, performing in the different phases of the cellular cycle.

This mechanism makes them carcinogenic, mutagenic and/or teratogenic.

Although cytostatics treatments are beneficial to patients' health, the effects on the sanitary staff could be damaging.

Chemical therapies are highly developed, and at the same time have been combined in many different ways with other alternative treatments.

I'd like to begin with a few words of history .

Cytostatics treatments started in 1943, after the detection of medullary aplasias in soldiers exposed to mustard gas in the Second World War.

This fact unchained the use of nitrogenous mustards for the treatment of Hodgkins disease.

To start with the present situation, the use of cytostatics in the operating room is increasing and they've been used for different surgical specialities.

However, increasing therapeutic assistance means increasing health risks for the staff who administer it.

Nowadays,

it is difficult to establish the adverse effects on the staff in a longer exposure even in a low concentration of cytostatics.

Secondly I'd like to analyze our Juridic context, these laws are:

Ley General de Sanidad (Law 14 of 1986); It says the obligation of protecting workers' health

Ley de Prevención de Riesgos Laborales (Law 21 of 1995) : It collects the specific proceedings of the public administrations to protect workers' health

Royal Decree 665 of 1997 : for the prevention of the staff against the risk of the exposure to a carcinogenic substance or mutagenic substances in the work.

The publications from The National Institute of Security and Hygiene in the Work, environment limit values haven't been established.

It makes it more difficult to evaluate the risks of exposure, so that, the utilization of measures of individual protection is necessary.

Well, I think that's all before describing our goals, which are:

- To minimize the exposure to cytostatics in the surgical area.
- To minimize the risk of exposure of the staff to cytostatics.

As I mentioned earlier,

CYTOSTATICS substances are Mutagenic, teratogenic and carcinogenic, so I think that it is important to describe these concepts

MUTAGENIC substances are capable of inducing a genetic mutation or increasing the mutation rate, producing a change in the characteristics of its geno or phenotype.

TERATOGENIC substances have the capacity to interfere in the period of organogenesis and consequently produce congenital defects

Finally, **CARCINOGENIC** substances that by inhalation, ingestion or skin penetration can produce cancer or increase its frequency.

Let's now show you a diagram according to the classification of the International Agency for Research on Cancer evaluating the carcinogenic risk in chemical substance on humans.

Group 1	" Agent is carcinogenic to humans "
Group 2A	"Agent is <i>probably</i> carcinogenic to humans"
Group 2B	"Agent is <i>possibly</i> carcinogenic to humans"

There are no clear criteria how to classify cytostatic substances:

- Depending on the mechanism of action and chemical structure,
- Depending on the action level in the cellular cycle,
- According to their action during the cellular reproduction...

Bearing in mind the extensive nature of these classifications, I do not time to explain now.

The most important classification for this essay is How cytostatics can penetrate the body.

- **INHALATION:** aerosols and micro drops that become separated during the preparation and/or the administration.
- **DIRECT CONTACT:** Penetration of the medicine through open or mucous wounds.
- **ORAL:** Ingestion of foods, drinks and polluted cigarettes.
- **PARENTERAL ADMINISTRATION:** direct introduction of the drug by puncture or an accidental cut.

Awareness of the ways cytostatics can penetrate the body will result in personnel using both individual and collective measures of protection while manipulating cytostatic agents.

The main goals of the application of collective protection in the surgical area are, on one hand, to reduce the risk of dispersal of the cytostatic agents out of the restricted area, and on the other hand, to establish a circuit for the correct manipulation of these agents.

Before initializing the surgical technique the restricted area must be prepared. It is necessary to take into account the characteristics of the facilities.

The technique will take place in a controlled environment equipped with an air treatment system, and that has refrigeration endowed with filters H.E.P.A. (High Efficiency Particulate Air), also called absolute filters, which filter particles of air to a size of 0.3 microns with an efficiency of the 99.7%.

The correct signalling of the restricted area is "chemotherapy in course." This is useful to notify other health workers that they must protect themselves and adopt the appropriate safety measures before entering the restricted area. It is also important to limit the access and exit of the restricted area.

The cytostatic agent is prepared in the central pharmacy service of the hospital. The container has to guarantee mechanical resistance in order to avoid spills. The agent will be correctly labelled with the information that identifies the patient (name, surname, clinical history number, location, service), the type of drug being used (doses, final volume, type of serum, time, administration method and the date of the preparation, expiry date of administration) and lastly the conditions of conservation.

The transportation to the area of the administration will be held through an independent circuit using waterproof, resistant and easy cleaning containers. They must also be rigid in order to prevent accidental breaks. The containers will have to be clearly labelled indicating that they contain cytostatics.

During the process of administration it is necessary to adopt measures for the protection of the environment as well as for the manipulator and the security of the patient.

Even though extreme measures of precaution are taken the staff must be prepared in case of an accidental spill. The spills must be cleaned immediately. The protective team that must clothe the person in charge of cleaning, in case the spill is produced outside the restricted area, consists of : two specific pairs of gloves, a single use low permeability coat, security glasses, respiratory protection mask, and also booties and cap.

If there are glass fragments these will be removed with the help of a palette never with the hands.

It is very important to avoid the formation of aerosols, Liquids have to be cleaned up by cloths that are high density absorbent, and of double pre-cut.

Regarding the elimination of waste residues these will be thrown away in specific containers level IV.

In Spain, the residues are classified depending on the type of substance and the final process to eliminate them.

The specific containers to eliminate residues that have been in contact with cytostatics are called "Type IV". Their final treatment is incineration.

The transport of the surgical instruments used during the technique, will follow the same circuit as the rest they must be clearly identified and inside of hermetical containers. Once it arrives at the sterilization service it will be put in a high disinfection washer.

When the technique has finished, the restricted area must be cleaned exhaustively. The process of cleaning will be done by dragging an alkaline soapy solution. During the cleaning of the restricted zone the staff will dress according to the procedure of individual protection measures.

All the material used during the cleaning is considered contaminated waste.

On first account, it is necessary to take into consideration that in view of the risks there exists a valuation criteria for the staff who will work with this technique. All those workers who do not suffer any pathology will be suitable for the manipulation of cytostatics.

Excluded in a permanent way:

- Allergic to the cytostatic substance and/or with important dermatological pathology.
- Women with antecedents of miscarriage, in fertile age and/or wanting to reproduce.
- People who work with ionizing, due to the synergic effect between both agents.
- People that previously have received treatment with cytostatics or immunosuppressors.
- People who are immunodepressed.

Excluded in a temporary way:

- Pregnant women and mothers in lactation period.
- Any worker, of either sex, attempting to have children.

- Worker who has suffered an accident with cytostatics and is in medical study.
- Workers with a transitory pathology susceptible to worsen if in contact with cytostatics.

Let me start with the measures of individual protection.

Mask: The respiratory mask that will be used is the FFP3 type, without exhalatory valve, offering protection in front of non volatile solid and liquid particles. The mask will adapt to the form of the face and be moulded by a metallic ribbon found on the part of the nose, and clamped by two elastic ribbons found on the superior and inferior part of the head. It will be used by all staff in the operating room, it must be worn from the beginning of the procedure with chemotherapy administration, until the staff exit the restricted area.

Cap: Double cap will be used in order to go in and out of the restricted area. It has to be one use only, made of interwoven fabric, nonporous, and that does not detach particles.

Glasses: The glasses will be manufactured in PVC (polyvinyl chloride), with a lateral protection and must be easy to clean. Staff workers who already wear corrective glasses must adapt the protection glasses to their eyesight.

Gown: The staff who manipulate cytostatics will have to use a gown with the following characteristics:

- One use only, with an opening in the back, knee long length and elastic fists.
- Waterproof, and reinforced in the front and sleeves.
- The members of the team that come in touch with the surgical field will wear the sterile gown, the rest will not.
- In case of exposure it must be changed immediately.
- The staff must not go out of the restricted area wearing the gown.

Gloves: Hands must be washed with water and soap before and after the use of the gloves. Latex Sterile gloves of latex must be of thickness inferior to 0,3mm. The use of talc gloves is advised against since the particles of the talc can attract the cytostatic. Gloves of polyvinyl chloride must not be used since in certain preparations they are permeable. Materials indicated are nitrile, polyurethane and neoprene. ALL THE STAFF INSIDE the restricted area HAVE TO USE DOUBLE gloves.

You will first put on powder free gloves low in proteins and on top another glove with a superior thickness. When in direct contact with a patient that is receiving chemotherapy and until leaving the restricted area when cleaning spills of the cytostatic. No glove is completely waterproof to all cytostatics. The permeability of the glove depends on the type of drug, contact time, thickness of the material and integrity of the glove.

Gloves must be changed approximately every half hour

- when working with the cytostatics and immediately when they become contaminated with the cytostatic
- when they break or after the procedure is finished.
- In the manipulation of excretions of a patient
- that is receiving cytostatic treatment.
- In the manipulation of contaminated surgical instruments

Shoes: shoes must be closed, waterproof, and made of plastic material that can be washed at the end of the procedure. - the use of booties on top of the shoes, is indispensable so that they can be taken off when leaving the restricted area. Moving on now to the first example we would explain,

In the 80's, Paul Sugarbaker in USA, was the first surgeon who use intraperitoneal chemotherapy during an abdominal surgery.

He performed an extensive extirpation of the tissues affected by peritoneal carcinomatosis with the immediate application and in situ of the appropriate cytostatic drug.

It was called "Coliseum technique" The cytostatics are administered at high temperature, through a peristaltic perfusion pump. In this case, to avoid the dispersion of the agent while it remains in the abdominal cavity, which is open, The Surgical field will be isolated with a non transpiring material, Connected to an extraction bell. This device has to have a system of high efficiency filters and a minimum of speed capture of 30 l/min

I shall present another case when cytostatics are present in the surgical area. It is in the Trabeculectomy technique for the glaucoma treatment.

The cytostatics that modulate healing such as the antimetabolites 5-fluorouracil (5FU) and Mitomycin-C (MMC) have revolutioned glaucoma surgery in patients with high risk of surgical failure.

Cytostatic agent is applied in a scleral flap with sponges.

To sum up,

some long-term toxic effects of the exposure to cytostatics have not been able to be established yet. Since there are no limit values that indicate pathology The absence of datum epidemiologic to a chronic exposure of the sanitary staff in the cytostatics is unknown.

It is indispensable to adopt measures that help to reduce this risk.

The guidelines of the laws of workers risks prevention establish that whenever it is possible the collective measures of prevention are preferable to the individual ones.

Existing bibliography: makes evident that the risks of the administration of cytostatics in this type of techniques can not be controlled using only collective safety measures. The best way to inform and to manage these measures is to do a standard nurse procedure.

They have to be up to date and easy to consult.

In our hospital all the special surgical nurses procedures can be consulted through internet.

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