Practical Palliative Sedation Guidelines

Guia Pràctica de Sedació Pal.liativa

Guía Práctica de Sedación Paliativa

Societat Catalanobalear de Cures Pal·liatives

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Foreword

With great pleasure we present the *Practical Sedation Guidelines*, prepared by renowned professionals of the Catalan-Balearic Society of Palliative Care (SCBCP). It intends being a clear and useful instrument for the daily practice of all professionals who devote their efforts to improving the quality of the patients' lives. We present a practical guide which includes many examples in order to illustrate its use and it also includes specific sections, such as sedation at home or in the emergency department. We wished the edition to be published not only in Catalan, but also in Spanish and English, and its distribution to be as widespread as possible (for example, on the SCBCP website) as an expression of the will of the SCBCP to make its voice heard and show its expertise in the care of patients. Our aim is to continue along this path, and thus other clinical guidelines, which are already being developed and which will surely reflect the rigour and knowledge of the authors, will shortly be published. We hope, on behalf of the SCBCP, that these guidelines will be of great use in your daily work.

Miquel Domènech Mestre
President of the Societat Catalano Balear de Cures Pal·liatives

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Presentation

The Baix Llobregat is a region located to the south of the metropolitan area of Barcelona city; it includes several towns, and has a population of 1.500.000 inhabitants. The Baix Llobregat is also a Health Region where several palliative care teams work, some providing palliative home care whilst others are situated in social-health care centres, district hospitals, and in the third level university hospital of the region.

The health care professionals involved have a long history of cooperation sharing the care of patients with advanced diseases. As a mile-stone of their cooperation, it was decided at the beginning of 2011 to set up a cooperative group integrating as many of the palliative care teams working in the region as possible. The group was denominated The Baix Llobregat Palliative Care Group.

The aim of the Group was to produce guidelines, protocols, standard operating procedures or other appropriate materials to offer the best and equitable treatment for the population under the care of the Baix Llobregat Palliative Care Group. It was agreed from the beginning that improving and sharing strategies would be related exclusively with pharmacological and specific procedural techniques, but not with organizational or health policies.

The first subject agreed upon to work at was Palliative Sedation, as it was considered a common procedure that every team in the group faces at some time or other in their day-to-day tasks, taking into account our socio-cultural environment. Our aim was also to offer the guidelines as an aid to other teams and groups. For this reason it was decided to make three versions: Catalan, Spanish and English.

We would like to thank all collaborators for their dedication, effort and commitment, as well as their generosity in sharing their knowledge and experience to the benefit of all patients.

We are also very grateful for the support given by Grünenthal Pharma in divulging the guidelines and allowing it to reach the healthcare professionals and therefore the patients.

L'Hospitalet de Llobregat, December 2012

1.- Definition and Classification

1.1.- Definition.

Many definitions of Palliative Sedation have been launched over the last decades (*see end of this section (or see below*)).

On 26th January 2002, the Steering Committee of the Spanish Society of Palliative Care (SECPAL) gathered together in the Hospital Sta. Creu i St. Pau, in Barcelona, and endorsed the following definition:

"Palliative Sedation is the deliberate administration of drugs, at the required dose and combinations, to reduce the level of consciousness of a patient with advanced or terminal disease, as far as is needed to relieve one or more refractory symptoms, and with the patient's explicit, implicit or surrogate consent." (1.1) *

This definition encompasses:

A.- The deliberate administration of drugs…

It includes the following concepts:

a) The existence of a previous discussion within the team that sedation is indicated, so at the very end it is the doctor who indicates and prescribes the sedative drugs, with the agreement of the rest of the team. The indication should be distinguished from the claim for sedation, which could come from the patient, his/her family or a team member. The claim for sedation should be interpreted as an indicator of high distress, and can be followed by an indication of sedation or not, according to overall assessment.

b) The drug or drugs administered are given purposely to decrease patient's awareness.
Not all patients experiencing somnolence should be considered sedated, as all dying patients at the very end experience some degree of unawareness. The way to differentiate between a purposely sedated patient and non-pharmacologically induced sleepiness is the decline of patient's arousal over the previous days without modifying the drugs and their doses.

B.- …to reduce the consciousness of a patient …, as far as needed to relieve…

This implies the cornerstone concept of proportionality of drug administration against the patient's suffering.

Direct assessment of patient suffering is not always possible, but as in other specialities, an indirect way of assessment can be carried out by using sedation scales (please see section 3).

C.- …of a patient with advanced or terminal disease,…

This implies that a patient has a short life expectancy, usually from a few weeks to several hours.

Palliative Sedation, properly speaking, is not indicated in patients with a long life expectancy, which does not mean that patients with a survival expectancy of **several months do not deserve anxiolytic or hypnotic therapy according to their** condition.

D.-…to relieve one or more refractory symptoms…

This implies that patients can experience diverse symptoms which may be physical or emotional or both at the same time.

Even though psycho-emotional distress has been considered difficult to diagnose, its existence is apparent for most authors where palliative sedation is considered one of the therapeutic choices at the end of life (1.2).

Refractoriness is linked with the ability to relieve a symptom, from the patient's perspective, in a reasonable period of time. A formal definition of refractory symptom endorsed by the SECPAL* is:

> "Symptom refractoriness can be considered the symptom which cannot adequately be relieved even after intense efforts to find a tolerable treatment within a reasonable period of time without affecting the patient's consciousness" (1.1)

Refractoriness can be related to the clinical problem itself, to the knowledge available, the place where the patient is being cared for, or a combination of all three.

* **"El término refractario puede aplicarse a un síntoma cuando éste no puede ser adecuadamente controlado a pesar de los intensos esfuerzos para hallar un tratamiento tolerable en un plazo razonable sin que comprometa la consciencia del paciente."**

Traditionally, a difference is made between "refractory symptom" and "difficult symptom". A difficult symptom could be defined as:

> A symptom with realistic choices to be alleviated considering the current medical knowledge and patient circumstances, and which needs intensive multimodal treatment. [Definition modified from (1.1)]

E.- ...with the patient´s explicit, implicit or surrogate consent."

Consent is important as sedation invades the person's greatest intimacy, reducing or abolishing the patient's ability to interact and relate with other people, and communicate his/her preferences and wishes.

Team members should thoroughly search for the patients' preferences, values and wishes governing their lives and care, mainly at the end of life, through an advanced care planning. Including the family in this process is strongly advisable in our social context.

In the circumstances described above and with a competent patient, obtaining explicit or implicit consent should not be difficult.

In the case of a non-competent patient, the team decision can only rely on the family (next of kin) and their knowledge of the values and wishes governing the patient's life, or the wishes previously expressed by the patient when he or she was competent.

In any case, and in a non-competent patient, sedation is a medical procedure indicated in a patient experiencing extreme suffering and sedation must not be put off in search of consent.

Other definitions of Palliative Sedation

> 1-'*Terminal sedation' is defined as the intention of deliberately inducing and maintaining deep sleep, but not deliberately causing death in very specific circumstances. These are: (i) for the relief of one or more intractable symptoms when all other possible interventions have failed and the patient is perceived to be close to death.(ii) for the relief of profound anguish (possibly spiritual) that is not amenable to spiritual, psychological or other interventions and the patient is perceived to be close to death.* (1.3)
>
> 2-*The use of sedative medications to relieve intolerable and refractory distress by the reduction in patient consciousness* (1.4)
>
> 3-*The intentional administration of sedative drugs in dosages and combinations required to reduce the consciousness of a terminal patient as much as necessary to adequately relieve one or more refractory symptoms.* (1.5)
>
> 4- *Therapeutic (or palliative) sedation in the context of palliative medicine is the monitored use of medications intended to induce a state of decreased or absent awareness (unconsciousness) in order to relieve the burden of otherwise intractable suffering in a manner that is ethically acceptable to the patient, family and health-care providers.* (1.6)

1.2.- Classification.

Palliative Sedation can be classified according to: (1.7)

A) Aim:

- **Primary:** reduction of consciousness as a desired effect of the medication.
- **Secondary**: reduction of consciousness as a side-effect (somnolence) of a given drug for the control of an underlying symptom.

B) Duration:

- **Intermittent:** combines periods of alertness with others in which consciousness is reduced.
- **Continuous:** there is a steady reduction of consciousness.

C) Degree:

- **Mild:** allows some degree of communication (verbal or non-verbal)
- **Deep:** unconsciousness, no communication is possible (pharmacological coma)

1.3.- What is not Palliative Sedation.

- The non-intended somnolence (as a side-effect) experienced by some patients when taking certain medications such as antihistaminics, anticonvulsants, neuroleptics, benzodiazepines or analgesics.

- The arousal impairment due to neurological damage or metabolic injury, or other causes of brain dysfunction.

- The administration of a lethal dose of a drug (or combination), after the patient's repeated request, and for compassionate reasons (suffering) with the aim of causing the patient's quick and painless death. This is called euthanasia**.

- The administration of a lethal dose of a drug (or combination) with the aim of causing the patient's quick, painless death, without the patient's request, and for compassionate reasons (suffering). This is called murder.

- To prescribe drugs and give advice to a patient on how to use them, in order to commit suicide. When this is done by a doctor it is called Medically Assisted Suicide. When it is carried out without medical advice, it is called Assisted Suicide.

**** Differences between Palliative Sedation and Euthanasia (1.1, 1.8, 1.9)**

	Palliative Sedation	Euthanasia
Intention	Relieve a refractory symptom	Cause death to alleviate suffering
Procedure	Proportional drug administration against patient's suffering	Administration of a lethal dose of a drug or combination of drugs
Outcome	Alleviation of suffering	Cause a quick and painless death

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2.- Ethical and legal aspects

2.1.- How can Palliative Sedation be considered good practice? (2.1)

- Make sure that all decision-making procedures are accurately followed, and recorded in the medical records.

- The information to be recorded must be the following :

- Summary of the patient's overall clinical situation and survival prognostication
- Which refractory symptom requires Palliative Sedation?
- Why has the symptom become refractory? (treatment attempts failed or are not indicated due to patient's condition or impending death)
- Consent given by (if patient cannot give the consent explain the reason)
- Drugs given, titration and sedation assessment

Case Nº 1

Patient diagnosed with non-small cell lung cancer with liver and bone secondaries, beyond antitumoral treatment. Admitted 5 days ago for increased dyspnoea, currently at rest, and which becomes refractory after steroids, oxygen and morphine have been given with little clinical benefit being found by the patient, who is complaining of increased chest discomfort and suffering. PaP Score C, PPS 10, Albumin 21g/L, total lymphocytes 600/mm^3.
Current situation and treatment options have been explained to the patient and his family, and they agree and consent to increase medication in search of comfort accepting an eventual decrease of awareness.

Case Nº 2

- **Background:** *Patient diagnosed of breast cancer 7 years ago, with bone, liver and brain secondaries.*
- **Place of Care:** *home for the last month.*
- **Clinical situation***: progressive PPS decline and bed bound for the last week. Yesterday evening, she started a hyperactive delirium episode.*
- **Refractory symptom:** *Hyperactive delirium.*
- **Prognosis:** *Short life expectancy (days)*
- **Therapeutic attempts:** *Delirium due to brain damage ± opioids) and the unrealistic aetiological treatment options.*
- **Consent:** *Patient not able to consent. Her husband and son agree with the indication of palliative sedation and to remain at home.*

2.2.- The concept of double effect related to Palliative Sedation

- The doctrine holds (2.2, 2.3, 2.4, 2.5) that, in the context of actions that have both good and bad effects, an action that has a bad effect is morally permissible if:

  (a) The action itself is good or at least neutral.
  (b) Its perpetrator's intention is solely to produce the good effect; the bad effect could be foreseen but not intended.
  (c) The good effect is not achieved through the bad, and
  (d) There is sufficient reason (proportionality) to permit the bad effect.

- The principle of double effect has usually been invoked in the case of Palliative Sedation arguing as a good effect the alleviation of suffering and the bad effect to hasten death, as follows:

  (a) The administration of sedatives is good or at least neutral.
  (b) The intention is to reduce suffering even though hastening death could be foreseen (intention is made evident through the clinical notes).
  (c) The alleviation of suffering is not achieved through producing the patient's death.
  (d) Alleviation of suffering in a dying patient is sufficient reason to allow life to be shortened.

- Some authors (2.6, 2.7) understand that the principle of double effect does not apply fully in the case of Palliative Sedation, since the conflict is not between suffering, alleviation and death, but rather between alleviation and loss of conscience. So affirming that the Palliative Sedation can cause the death of a dying patient is seen as a tautology (redundancy).

- The use of Palliative Sedation relies on the same principles reasoned for symptom control, in terms of non-maleficence (allow suffering, sedation not indicated) and autonomy (consent) (2.7).

2.3.- Truth telling (2.8)

- Truth is of value in itself, and patients should be told as much of the truth as they want to know.

- The patient's right to know the truth is based on the following aspects:

  1) Our societal life is sustained and depends on honest communication.
  2) Patient-carer relationships depend on trust.
  3) True information enables patients to make appropriate treatment decisions according to their values and wishes.

- Professional carers are ethically responsible for the use of appropriate communication skills to communicate the truth to the patient and family.

- The practical skills include the ability to give the information that the patient can understand, believe, interpret and assimilate in the context of his/her life and current situation.

- Patient's appropriate truth should be understood as a spectrum that allows the patients to understand, believe, interpret and assimilate the information given. The information given must always be true but can range from providing high suspicion to detailed information; this is chosen by the patient, with a skilful professional approach.

- In the case of palliative sedation, the competent patient should be able to understand and retrieve information on the benefit of sedation (relieve unbearable suffering) and consequences[†] (decline of conscience, communication and oral intake).

- Most patients in whom palliative sedation is indicated are cachectic, lethargic, exhausted and emotionally collapsed, in which case it is ethically defensible to give less than the bare truth based on a harm/benefit calculation. But it is unjustifiable to tell lies.

2.4.- Competence

- Competence is a concept derived from autonomy addressed to the specific problem of patient decision making.

- Competence requires the ability to make a rational decision (that means it is to be made on the basis of reasoning, although it could be imperfect).

- Criteria used to judge a competent patient are (2.8) (2.9):

  (a) Informed of the facts and probabilities.
  (b) Able to understand and believe the facts and probabilities.
  (c) Able to make a voluntary choice (absence of coercion).
  (d) Able to make a reasoned choice.
  (e) Able to communicate that choice.

- In the case of Palliative Sedation it is as follows:

  (a) The evolution of the disease and the refractory symptom is reviewed with the patient (family in the case of non-autonomous patients). It is explained how the symptom is now and that treatment failed and that Palliative Sedation is an ultimate and

[†] Not all patients see the decline of conscience as harmful, in fact most of them consider it alleviation.

recommended/indicated approach (facts and probabilities of treatment).

(b) Validate with the patient (family in case of non-autonomous patients), the understanding of the information previously given.

(c) Validate with the patient (family in case of non-autonomous patients), that it is the option He/She really wants.

(d) Validate with the patient (family in case of non-autonomous patients), that options are well understood.

(e) Ask the patient (family in case of non-autonomous patients), to put into words His/Her decision.

For a practical approach, please see section 3.3.- How to obtain consent.

2.5.- Nutrition and Hydration

- It is usually understood and accepted that slowing and eventual cessation of oral intake is a normal part of a natural dying process.
- In any circumstances when Palliative sedation is indicated the palliative care team must address the patient and/or the family, according to the clinical situation.
- In the sedated patient, nutrition and hydration must be offered or given on the patient's request while the oral route is available.
- In patients on parenteral hydration prior to starting Palliative Sedation, it is recommended to check this issue, in advance, with the patient and in due course with the family.
- Parenteral hydration could be seen by the patient (family) as an important issue (2.10), in which case it would be advisable to keep it to a minimum (eg. 500 mL/day), but an individualized approach is always recommended.

2.6.- Deontological and legal aspects

- Currently, in Catalonia or Spain there is no specific legislation concerning Palliative Sedation or end-of-life care.
- In article 20 of the Statute of Autonomy of Catalonia, the right of each Catalonian citizen to receive appropriate treatment of pain and integral palliative care and live with dignity his/her dying process, is stipulated.

article 20. **Dret a viure amb dignitat el procés de la mort**

1. Totes les persones tenen dret a rebre un tractament adequat del dolor i cures pal·liatives integrals i a viure amb dignitat el procés de llur mort.‡

- The Deontologic Code of The Catalonian Medical Association Council (2.11), when dealing with the dying process, states that the physician has the obligation to help the patient to live with dignity until the end according to his/her values. The physician must treat the dying patient avoiding his/her physical and mental distress.

De la mort VII §

68.- Tota persona té dret a viure amb dignitat fins al moment de la mort i el metge ha de vetllar perquè aquest dret sigui respectat. El metge ha de tenir en compte que el malalt té el dret de rebutjar el tractament per prolongar la vida. És deure mèdic fonamental d'ajudar el pacient a assumir la mort d'acord amb les seves creences i allò que hagi donat sentit a la seva vida. Quan l'estat del malalt no li permeti prendre decisions, el metge acceptarà la de les persones vinculades responsables del pacient, però els assenyalarà el deure de respectar el que es creu que hauria estat el parer del malalt.

69.- El metge haurà de respectar i atendre les recomanacions del pacient reflectides en el document de voluntats anticipades quan n'hi hagi.

70.- L'objectiu de l'atenció a les persones en situació de malaltia terminal no és d'escurçar ni allargar la seva vida, si no el de promoure la seva màxima qualitat possible. El tractament de la situació d'agonia ha de pretendre evitar el patiment i l'angoixa. En els casos de mort cerebral, el metge haurà de suprimir els mitjans que mantenen una aparença de vida si no és que són necessaris per a un trasplantament previst.

‡ Article 20. Right to live with dignity during the dying process
1. All persons are entitled to receive appropriate treatment for pain, integral palliative care and live with dignity during their dying process.

§ VII's death
68. - Everyone has the right to live with dignity until the moment of death: the physician should ensure that this right is respected. The physician should consider that the patient has the right to refuse treatment to prolong life. Medical fundamental duty is to help the patient to accept death according to their beliefs and what has given meaning to their life. When the patient's condition does not allow him/her to make decisions, the doctor will accept the decisions of those involved and responsible for the care of the patient, but indicate the duty to respect what is believed to have been the patient's opinion.
69. - The physician must respect and respond to the recommendations reflected in the patient's advance directive document where this exists.
70. - The goal of care for terminally ill persons is not to shorten or lengthen their lives, but to promote the highest possible quality of life. The aim of the treatment of death agony is to avoid suffering and anguish. In cases of brain death, the doctor will withdraw the measures maintaining a semblance of life unless this is needed for a scheduled organ transplant.

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3. - Procedure

3.1. - When should a symptom be considered refractory?

▪ We will consider as refractory any physical or emotional symptom after assessing the patient's general condition and prognosis.

▪ No further attempts of treatment are considered adequate due to their low efficiency or excessive burden on the patient (side effects, invasive techniques, added emotional distress, among others).

▪ No further therapeutic options are available, based on current medical knowledge.

▪ No more therapeutic options are available where the patient and the transfer is perceived as undergoing a risk or being a burden to, or is unwanted by the patient (or the patient's family if he/she is incompetent).

▪ The expectation of survival is so short that any treatment is considered futile.

▪ The patient does not wish to undergo other treatments.

▪ In the case of an incompetent patient, the family does not see fit to submit the patient to further treatments.

Case Nº.3

A 67 year-old patient diagnosed of colon cancer with liver metastasis and peritoneal carcinomatosis now complains of abdominal pain that has not improved with analgesics increased over the last 2 days, has frank jaundice, confusion, edema and rectal bleeding. He has been bedbound over the last week with only occasional fluid intake.
Given the physical and cognitive decline, non-response to treatment and few options to improve the patient's condition, the symptoms (pain, confusion and rectal bleeding) are considered refractory.
The team and the family discuss possible wishes expressed by the patient and the location for palliative sedation.

3.2 -. How long could the patient live?

▪ The two most important independent prognostic factors are the gradual loss of function and malnutrition (3.1).

▪ Doctors and nurses tend to systematically overestimate patient survival (3.2), which improves when considering other prognostic factors:

• **PaP Score** (3.3)

▪ Addressing Palliative Sedation to a patient (and family) living through such a stressful moment is always an uncomfortable situation.

▪ Always keep in mind that each patient and family are different (personalize).

Before starting

▪ Review the medical history of the patient; refresh disease progression and treatments given.

▪ Before initiating any conversation about sedation, make the patient aware of your wish to begin an important new subject and ask them if they wish any other person, (usually family), to be present.

Case Nº 5

A) ...
- (Doctor) Mr. M., in the last four days I have had the impression that your breathlessness has not improved as much as we expected.
If you don't object, I think we should talk about what could be the next step. Do you agree?
- (Patient) Yes
- (Doctor)Do you wish anybody from your family to be present during this conversation?
- (Patient) Yes
- (Doctor) Who would you like to be present during the conversation?

(B) ...
- (Doctor) Mr. M., in the last four days I have had the impression that your breathlessness has not improved as much as we expected.
If you have no objection, I think we should talk about what could be the next step. Do you agree?
- (Patient) No
- (Doctor) Would you prefer that we talked to your family about this ...
- (Patient) Yes / No ...

Conversation

▪ Sedation and its consent must be put in a logical place in the progress and failure of treatment of a particular symptom. This must be done in a way that sedation would be seen the next logical step after failure of previous treatments.

▪ The consequences of sedation should be explained in a gentle way, both desirable effects (improvement of suffering), and those unwanted (decreased intake of food and drink, and loss of communication).

Case Nº 6.

....
- (Doctor) Mr. M. Do you remember how your breathlessness was four days ago?
- (Patient) Dr. Yes, it was terrible, and it still is!
- (Doctor) As you probably remember, we increased the dose of morphine, and oxygen. Do you believe it has helped?
- (Patient) Well, at first it seemed to work, but worsened again. I feel desperate.
- (Doctor) In circumstances like yours, we normally give drugs to make the patient more comfortable, making him/her less conscious of the difficulty with breathing. We do give some tranquilizers. Do you think this would help you at the moment?
- (Patient) Yes, Doctor, I ... I feel so bad that your proposal is a good idea.
- (Doctor) Mr. M. if you agree with this new approach, you should be aware that in one way, it will improve shortness of breath, but in another, you will have greater difficulty in eating, drinking and talking as you are doing now. Do you agree?
- (Patient) Yes (or not)
...

When the patient hesitates before making the decision, it is useful to provide a therapeutic trial to determine its effectiveness (transient sedation).
...
- (Patient) I really do not know. I'm afraid it could fail, as happened with the morphine.
- (Doctor) Well, if you are not sure of the benefits, or afraid of how you will feel, we propose a test to see how it goes, and then we can discuss treatment.
...

▪ Obtain explicit consent (the patient should verbalize). This is important to avoid any misunderstanding, because such discussions usually take place in an emotionally tense atmosphere.

▪ To speak explicitly of impending death to a patient experiencing intense distress to indicate sedation, is clinically useless, unnecessary and unjustifiable.

Case Nº 7

...
- (Doctor) Just to be sure I understand what you said: you accept the fact that you can feel more sleepy in order to improve your breathlessness.
- (Patient) Yes doctor, you understand me correctly.
...

3.3.2 -. How to obtain the consent of an incompetent patient

▪ When the patient is not competent, the team should direct their inquiries to relatives or legal representatives.

▪ Review with the family, with kindness and clarity, the present situation, what is causing discomfort, failed treatments and the indication of sedation.

▪ In all cases it is very important to explain to the family how the symptoms are affecting the patient. For example, the difference between tachypnea and dyspnoea. In the case of delirium a more thorough and detailed explanation is recommended as patient behaviour changes and can easily be interpreted as pain or suffering.

▪ Make clear that Sedation is the approach indicated in the patient's clinical situation and ask for their acceptance.

▪ Specifically ask the family if they have any doubts about the patient's nutrition and hydration, communication and predicted survival.

▪ Explain to the family that they can continue caring for the patient, especially by offering specific types of care (eg. care of mouth, skin, etc.) and notifying the team of any sign of patient discomfort (eg. spasms, grimacing, etc.).

▪ Always provide updated information on the status of the patient, offer availability, privacy and support.

3.3.3 - What to do when no one can give consent

▪ As with any other situation, the decision-making procedure should be clearly recorded in the medical record, but more detailed.

▪ Do not delay sedation (3.6)

3.4.- Starting sedation

3. 4.1. - What to do with drugs the patient was taking beforehand

▪ Given the fact that the main objective is comfort, the steps to follow are:

• Inform the family.

• Withdraw drugs that are currently not useful: laxatives, heparin, hypoglycemic agents, antibiotics, steroids, etc..

• Remember that you do NOT have to withdraw 3rd step analgesic drugs. In the case of use of transdermal patches, the same treatment can be continued.

3.4.2. – Protocol for pharmacological action

a) Route of administration, starting dose and adjustments.

• The choice of the route of administration will depend on:

- the clinical situation (eg. we should try to avoid the subcutaneous route in patients with anasarca and those with blood dyscrasia, the intravenous route being preferable).

- the drug to be administered (eg. Propofol can only be administered intravenously).

- the speed needed to treat symptoms (eg. when faced with a massive haemorrhage, we should seek to ensure the fastest action).

- the expected time of sedation (eg. given a mixture of various drugs we evaluate the possibility of local intolerance: phlebitis, dermatitis)

- the location of the patient (home/hospital).

• The intravenous route provides faster onset of action and sometimes we can achieve the level of sedation required for refractory symptom control with an initial induction bolus. Then treatment con be continued, especially at home, via the subcutaneous route.

• The doses of drugs must be individualized in each case, taking into account a number of factors:

- Prior exposure to opioids
- Development of tolerance to medication used
- Age of the patient
- Previous history of alcohol or drug abuse
- Stage of disease
- State of the renal and hepatic function
- Level of sedation to be achieved

Concepts to consider:

• **Rescue Dose:** This is an"Extra" dose that is used in cases of emergency or exacerbation of the symptom. It is recommended that the rescue dose be the same as the dose of induction, or 1/6 of the total daily dose.

• **Adjustment** is performed at least every 24 hours, by adding the total rescue doses that were necessary during the previous day, to the regular doses administered.

* **In hospitalized patients**, it is recommended to adjust the dosage during the first 4 hours after onset of sedation and then every 8 hours for at least the first day.

***In patients at home**, the adjustment can be performed every 24 hours.

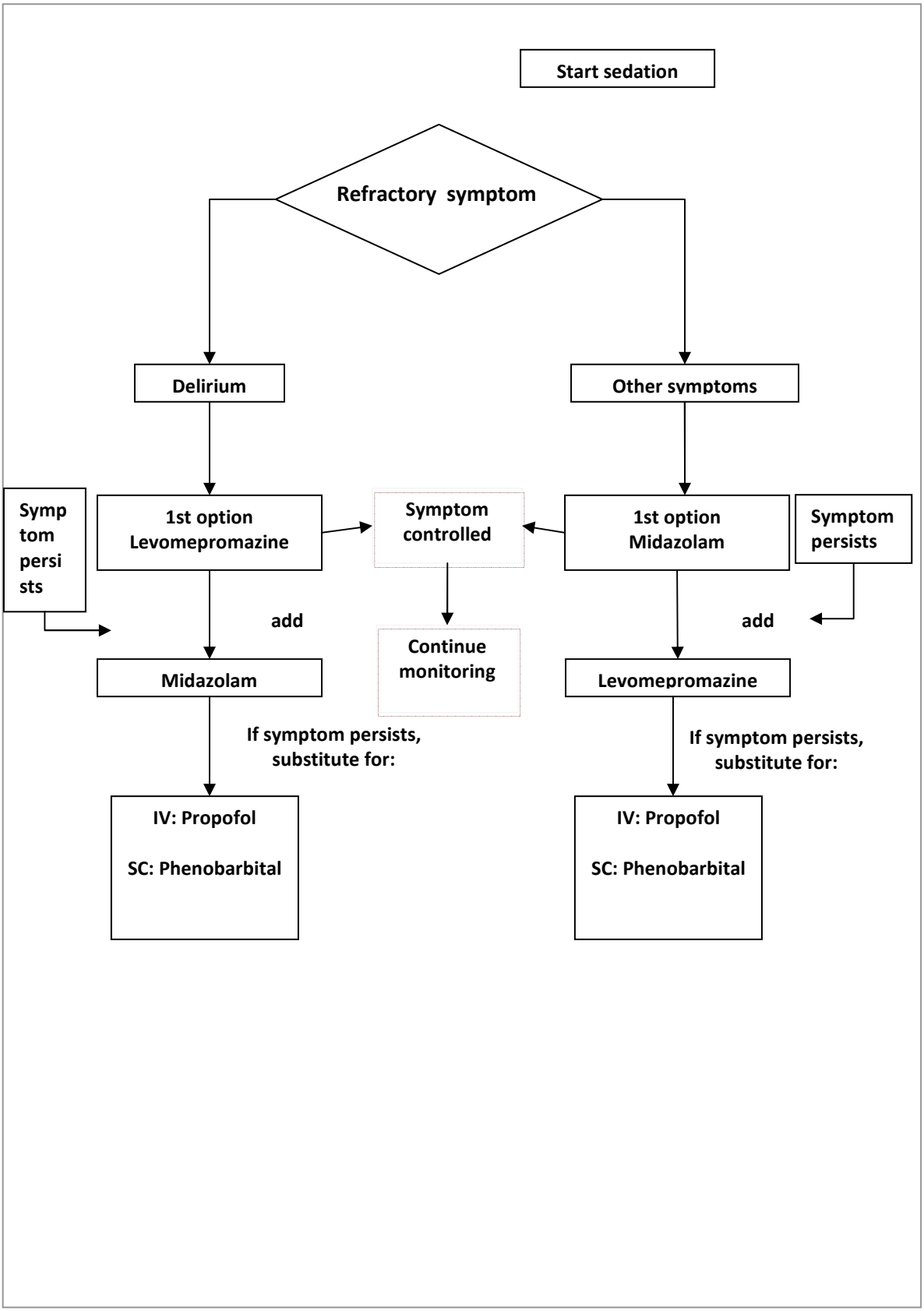
• **Midazolam** is the drug recommended as first choice except for delirium.

• If the refractory symptom is delirium, or midazolam fails, **levomepromazine** should be used alone or, if necessary, in combination with midazolam.

• If this does not achieve the required level of sedation, we switch to **phenobarbital or propofol.**

• If the drug of choice fails, always check possible **causes of sedation failure**: e.g. obstruction of hollow viscera (urinary retention or fecal obstruction, etc.).

Algorhythm for pharmacological treatment of palliative sedation



b) Drugs

b.1. - Levomepromazine (ampoules 25mg / 1 mL)

Indication
Delirium refractory to haloperidol (or neuroleptics) where palliative sedation is required. Its potent anticholinergic action may be useful to reduce intestinal secretions in the patient with intestinal obstruction.

Caution: risk of urinary retention in patients with Prostatic Syndrome.

Contraindications:
Severe hepatic insufficiency (patient with jaundice)

Procedure:
Start:
(depending on the "fragility" of the patient)
- Patients > 80 years of age, cachectic and not too agitated, start with a bolus of 12.5 mg t.d.s SC or IV.
- Patients <80 years of age and very agitated, treat with 25 mg bolus t.d.s. SC or IV.
- With a continuous infusion pump, start with 50-100mg SC or IV / 24 hours. It is recommended to dilute drugs with saline or glucosaline solution as this causes fewer problems of instability of the mixture.

▪ If the patient was being treated with Midazolam for other reasons (convulsions, anxiety) and has delirium, it is recommended to reduce the dose of midazolam by 50% in the initial treatment with Levomepromazine.

Dose adjustment:
- Rescue dose equivalent to initial dose (12.5 mg to 25 mg)
- Prescribe a rescue dose every 30 '.
- If after 3 consecutive rescue doses the patient has not become stabilized, increase the dose by 50% of the daily dose, and so on until the episode of agitation is controlled with a maximum dose of 300mg / day.

▪ However, if there is no response to the increased dose, we should add midazolam.

b.2. - Midazolam (ampoules 15mg/3mL, 5mg/5mL)

Indication
- Refractory Dyspnoea
- Massive hemorrhage

- Refractory Delirium (second choice after Levomepromazine)

Contraindications:
Allergy / Hypersensitivity to midazolam

Antidote: Flumazenil

Procedure:
Start:

- SC route
  - Induction (bolus) 10 mg
  - Rescue (bolus) 10 mg
  - CSCI initial dose 60 mg / 24 hours

- IV route
  - Induction (bolus) 5 mg
  - Rescue (bolus) 5 mg
  - CIVI initial dose 60 mg / 24 hours

▪ In massive bleeding which requires a rapid and profound sedation, double the recommended dose.

▪ In patients over 80 years of age, cachectic (<40 kg) and who have not previously been taking benzodiazepines, it is advisable to reduce the dose by 50%.

Dose adjustment:
We propose two strategies, choose the most appropriate one depending on the situation:
• **Rapid adjustment:** after initiating sedation, if the patient requires more than 3 rescue doses in the first 4 hours, increase the infusion for the next 4 hours according to needs. Increase the rescue dose between 33 - 50% according to previous efficacy.
Such adjustments are performed during the first 8 hours after the onset of sedation and then one should proceed according to standard adjustment.

Case Nº 8.

E.g. A patient on 60 mg midazolam delivered by CIVI/24h, needs 7 rescue doses of 5 mg, with a variable effect every 15-30 minutes, during the first 4 hours.
By adding all rescue doses (5mg x 7), the new infusion dose will be 95mg/24 hours that can be rounded up to 105 mg (7ampoules) and the rescue dose should be increased to 7.5mg due to limited effect with the previous dose.
Usually adjustments are made by modifying infusion speed if midazolam is the only drug in the infusion pump. In this case:

Midazolam 60 mg + 500 mL saline (21mL / h), so if we wish to administer 105 mg it will be = 36 mL / h.

When there is a mixture of more than one drug being infused, a possible solution is to calculate the IV infusion for just 4 hours, until the patient is stabilized and then adjust according to needs.

E.g: Midazolam 60mg + Morphine 120 mg/CIVI/24 h.
For 4 hours: 100mL saline solution + Midazolam 10mg + Morphine 20mg / IV (25mL / h)
In the previous case, after increasing the dose of Midazolam:
100mL saline solution + Midazolam 15mg + Morphine 20 mg / IV (25mL / h) and midazolam 7.5 mg rescue dose.

• **Standard Adjustment:** Add the total rescue dose administered during the last 24 hours to the previous daily dose.
The new rescue dose is 1/6 of the new total daily dose.

Case Nº 9.

E.g. Patient at home treated with SC bolus. He/she is on midazolam 5 mg every 4 hours (5mg x 6=30mg per day). In the last 24 hours he/she has needed 4 rescue doses (5mg x 4=20mg) to settle. The next dose of midazolam will be 30+20 = 50mg; we round up to 60 mg for administration convenience, and prescribe midazolam 10 mg every 4 hours and midazolam 10mg/SC prn.

Maximum daily dose: 240 mg / day (equivalent to 10mg / h)

▪ Failure to obtain the appropriate level of sedation with 240 mg / day midazolam: add levomepromazine (see paragraph on levomepromazine).

b.3. - Phenobarbital (ampoules 200 mg/1mL)

Indication
Refractory symptoms with midazolam / levomepromazine sedation.
Consider its use especially in patients with a history of epilepsy and difficulty in obtaining an IV access.

Contraindications:
Allergy / Hypersensitivity

Procedure:

- Withdraw benzodiazepines and neuroleptics, and halve the dose of opiates, before starting.
- Do not mix with other drugs.

Start:

- Induction (bolus) 200 mg / IM
- Rescue dose (bolus) 100 mg / IM
- Initial dose 800mg in 24 hr (continuous subcutaneous infusion (CSCI))

Dose adjustment:

Adjust according to response and requirements of rescue doses up to 1200 mg/24h CSCI.

Comment:

Barbiturates quickly produce cardiorespiratory instability with rapid onset of type II rattling, so it is advisable to start concomitant scopolamine / hyoscine.

b.4. - Propofol (10mg/mL ampoules)

Indications

- Symptoms refractory to midazolam/ levomepromazine sedation.
- Intermittent sedation requiring quick recovery.
- In particular consider its use in patients with contraindications or difficulty in using the SC route.
- Allergy to benzodiazepines and barbiturates.

Contraindications:

Allergy / hypersensitivity to the drug or excipient (soybean)

Procedure:

- Withdraw benzodiazepines and neuroleptics, and halve the dose of opiates.
- Do not mix with other drugs.
- Exclusive use via the IV route
- If you wish to dilute, use only 5% dextrose solution.

Start:

- Induction (bolus) 1 - 1.5 mg / kg in 1 to 3 '/ IV
- Continuous intravenous infusion 3 mg / kg / hour
- Rescue dose= 50% of induction dose. Subsequent to the rescue dose, increase infusion speed 33%.

Dose adjustment:

According to response and rescue dose consumption.

Comment:
Risk of seizures in patients with a history of primary or secondary epilepsy.
Tolerance should be expected due to high liposolubility and thus the need for rapid dose adjustment.
Potent antiemetic.

3.5. - Which instruments are used to measure the level of sedation?

▪ To monitor the level of patient comfort, the level of sedation is evaluated indirectly by using sedation scales.

▪ We recommend the modified Ramsay Scale (Ramsay-ICO) based on our daily practice .

Ramsay Scale-ICO
1-Agitated, anxious
2- Quiet, oriented and collaborative
3a - Agitated response to verbal stimuli
3b - Quiet response to verbal stimuli
4a - Quick and agitated response to painful stimuli
4b - Quick and quiet response to painful stimuli
5-Slow response to painful stimuli
6-No response

▪ We strongly recommend avoiding aggressive actions to assess the response to pain, like:
- Pressure on sternum
-Pressure on mastoid
-Puncture

▪ It is recommended to evaluate pain response with strong pressure applied to the interdigital space between the thumb and forefinger.

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4. - Treatment of accompanying symptoms during sedation

• During sedation, symptoms like rattling and myoclonus may appear which can add more stress to the family and the feeling that the patient is uncomfortable. A proactive and early intervention helps to avoid unpleasant memories and prevent potential complications during grieving.

• During sedation, as the consciousness of the patient decreases and death approaches any of the following symptoms may occur:

4.1-. Death Rattle

▪ Excessive secretions in the respiratory tract, usually in the unconscious patient during the last days of life.

▪ The best treatment is early detection by palpation or auscultation of the chest, and treatment before rattling becomes audible at the bedside of the patient.

▪**Non-pharmacological measures**:

• Avoid the patient having his neck in extension (this avoids noisy breathing)
• Encourage the patient to be placed in the lateral position with the neck slightly flexed.
•Turn the patient
• Explain the origin of the accompanying secretions and the lack of impact / discomfort for the patient.

▪ **Pharmacological treatment**

• **Scopolamine hydrochloride**
Dose: 0.5 mg to a maximum of 4 mg per day.

Dose: 0.5-1 mg every 4-6h. SC / IV or 3 mg in 24 hours as SC / IV infusion.
-It is recommended before starting the infusion to administer an induction bolus of 0.5-1 mg SC / IV.
-Warn the family that a transient red face and mydriasis may appear after bolus administration of scopolamine.
-The sedative effect, well known with the use of scopolamine hydrochloride, is seen as adjuvant in this situation.

- **N-butyl hyoscine bromide**

  Dose: 20 mg up to 120 mg daily.

  Dosage: 20 mg every 4-6h SC / IV, or 60-120 mg in 24 hours by continuous SC or IV infusion.

4.2. - Fever

▪ Treat fever in cases of distress (diaforesis, chills) or history/risk of seizures in the previous days.

▪ Once initiated, antipyretic treatment should be administered regularly.

▪ **Non-pharmacological measures**

- Consider physical measures, cool clothes.

▪ **Pharmacological treatment**

- **Acetaminophen** 650 mg per rectum, or 1g IV every 6-8 hours.
- **Ketorolac** 30 mg SC / IV t.d.s. (90 mg per day by CSCI /CIVI)
- **Metamizol** 2gr t.d.s IV or IM

4.3. - Myoclonus and seizures

▪ If the patient is in hospital, leave an intravenous line inserted if he has previously had seizures or a risk for them.

▪ If the patient is at home, the route of choice is subcutaneous, or per rectum if the former involves difficulties in handling.

▪ **Pharmacological treatment**

- **Midazolam:** We start with a 10mg bolus and continue with a continuous sc /iv infusion 15 to 30 mg/24h. (4.1)

Other pharmacological options:

- **Rectal Diazepam** 10mg every 15 minutes until seizures stop.

• **Clonazepam**. Start with a 1 mg bolus and proceed with a continuous SC or IV infusion of 1.5 to 3 mg/24h

• **Phenobarbital.** We start with an intramuscular bolus of 200 mg and continue subcutaneously or with a continuous iv infusion of 600mg/24h.

▪ The patient should be in the lateral position, protected by bedrails and pillows to reduce the risk of injury.

4.4. - Regurgitation of gastric contents.

• This situation can occur mainly with upper intestinal occlusion.

• In the patient who already has a nasogastric (NG) tube inserted, we recommend maintaining it in order to facilitate emptying of the stomach contents, leaving the tube connected to a urine collection bag for drainage. If the family demands the withdrawal of the tube, empty the stomach before removal.

• If the patient has no NG tube, warn the family about the possibility of regurgitation some time before death. Reassure them, informing them that it is gastric content but we avoid the patient suffering with the medication administered. (4.2, 4.3)

•We always recommend that the patient be kept in the lateral position to reduce the risk of aspiration and it will also facilitate hygiene.

4.5. – Bleeding

▪ If the patient is in hospital, leave an intravenous line in for patients who have previously bled or are at risk of doing so (4.1)

▪ If the patient is at home, the route of choice will be subcutaneous, or per rectum if the former leads to problems in handling.

▪ **Recommendations:**

- Prepare dark towels to reduce the visual impact of a massive hemorrhage.
- Have the medication ready for rapid administration when needed.
- Ask relatives to leave the room.

▪ **Pharmacological treatment**

Midazolam in doses of 15mg sc or iv every 5 minutes until deep sedation is accomplished. Alternatively we can use diazepam per rectum.

4.6. - Acute urinary retention

▪ Suspect this possibility in a patient who presents:

- Restlessness
- Hypogastric pain on palpation
- Occasional incontinence
- And especially if you are dealing with drugs with anticholinergic effects (scopolamine, hyoscine butylbromide or levomepromazine).

▪ The recommendation will be urethral catheterization and if that is not possible, control by increasing drug sedation.

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5. Family Care

•Palliative sedation is a situation of great emotional impact on the family. This malaise should be addressed by professionals otherwise it can lead to the family not having a clear awareness of the patient's situation and / or having doubts about whether or not it is functioning correctly.

• When a patient is sedated, the process of family care involves the participation of the entire interdisciplinary team, both in the hospital and at home, as well as the patients and their families.

• We will have more opportunities to obtain the cooperation of the family if we try to understand and respond to their personal and/or relational difficulties.

• Our actions with regard to care of the family must boost their participation in decision making and educate them in the giving of care. This operation requires previous work to identify the main caregiver, resilience and vulnerability factors.

• Keys to improving satisfaction and reducing family stress:

• Frequent, regular and comprehensive information should be given, especially for the sedation process, before, during and afterwards, if necessary.

• Provide arguments to differentiate sedation from euthanasia. Note that motivation, nature and outcome of sedation is not death but a relief from intolerable suffering. Imminent death is therefore an expected but not an intended result.

• Share responsibility for decision making.

• Give intense emotional support from the start, to encourage the expression of emotions, feelings, worries, fears, doubts and positive reinforcement of the caregiver's task.

• Periodic monitoring of symptoms.

• We do proactive work to prevent complications. Give oral and written explanations. Leave guidelines at home (Appendix 2) and on the computer medical record if it exists.

• Make them part of the care, basically **comfort measures**:

- **Re-position the patient:** avoid unnecessary mobilizations, respect natural position of the patient. When turning the patient avoid applying pressure and stretching. Use pillows in different ways to support the body. Place the patient on a special air-filled mattress to avoid or alleviate bedsores. Encourage the family to

be close to the patient, approaching without fear, and promote gratifying contact such as a gentle massage, for example.

- **Mouth Care:** In order to prevent dryness, odor and build up of debris, instruct the caregiver to perform the following measures:
  - Removal of non-fixed dentures.
  - Spray inside the mouth using a solution of chamomile with lemon juice.
  - Clean and drag debris from the mouth with a swab using Vaseline to soften the built up residues.
  - Lubricate the lips with lipsalve or Vaseline.

- **Eye Care:** Wash eyes with saline solution or artificial tears to avoid a film or rheum forming.

- **Skin care:**
  - In this situation the skin is fragile and sensitive, so regular hygiene should be contemplated for skin care.
  - Promote hydration of the skin by applying a moisturizer with a gentle massage to avoid discomfort.
  - The aim of treating ulcers is not to cure them, but to prevent odor, pain and progression.

▪ It is important to care for and devote time and space to the family by listening to and understanding them; ensure that the information we provide is understood.

▪ Once it is verified that the family has understood and accepted the situation, it should be demonstrated that their participation helps to reduce pain and subsequently assists in the preparation of the grieving process.

Recommended reading:

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6. – Sedation at home

▪ Palliative sedation involves a complex situation due to its specific characteristics, so the participation of a specialized palliative care team is recommended. This intervention may be shared with the primary care team whenever possible.

6.1. - Description of the scenario and specific issues

Home environment.

We know that a significant period of palliative care takes place at home and also the patient's preferences for care at the end of his life could include dying at home. It will be important, therefore, to know what the distinguishing characteristics of palliative sedation at home are.

▪ What are the requirements for sedation at home?

- Patient and family wish to remain at home
- Acceptance of domiciliary intervention.
- External factors that make follow up possible: conditions of housing and environment, availability, financial resources, time, etc..
- Support from a specialized palliative care team coordinated with the primary care team, and all the resources involved in the procedure.
- Consensus by the patient / family that the patient dies at home. In some cases emotionally traumatic past experiences discourage this.

▪ The care of a patient with impending death, who requires palliative sedation, creates a situation of crisis. Such crises cause people who experience them to lose emotional control for management and therefore the ability to propose and generate solutions. Our intervention will vary according to whether the patient was already being monitored by a home care or not:

a. Patient monitoring by the home care team.

- Evaluate clinical situation.

  Inform the patient and / or caregiver of the clinical situation and agree on the treatment plan.
- Record informed consent in medical records.
- Initiate palliative sedation.

b. Patient not under care by Palliative Home care team

- We introduce all members of the team, and explain that it was the primary care physician who indicated our intervention. We provide oral and written

information about the service: target our intervention, program of visits, schedule, telephone numbers, etc..
• Information gathering and integral assessment
• Inform the patient and / or caregiver of the clinical situation and agree on the treatment plan (in this case it is particularly important given the time required for patient and / or caregiver to clarify their doubts).
• Record informed consent in the medical records.
• Initiate palliative sedation.

In both cases we will consider the following aspects.

▪ The patient has the right to know that the symptoms cannot be controlled any other way and that once sedation is initiated, the level of consciousness will decrease. Time for reflection should be provided and preparations made to ensure there is an appropriate environment for it to be carried out.

▪ When given continuous deep sedation, it is very important to explain to the family that the patient may be unconscious and will gradually become calmer in the hours following the onset of sedation, and it is the right time to say goodbye.

6.2. - Practical aspects

6.2.1 Guidelines for intervention.

• **Identifying the referent caregiver.** This person will be responsible for the plan of care and post-mortem management that includes: calling the Primary Care Center, funeral services and the Home Care Team.

• **Review of plan of care tailored to the situation of palliative sedation.**
• Inform that once sedation has been initiated care must be taken with the administration of food and fluids orally as they face the risk of aspiration and the patient suffering. Give recommendations on care of the mouth. Evaluate the withdrawal of all oral medication and others (insulin, heparin, inhalers, etc.)
• Assess the withdrawal of subcutaneous hydration if being used. In cases in which it will be maintained, change to 500ml/24h SC and place it in a different area from where the continuous infusion pump with medication is placed.
• Consider the use of opioids for good control of pain. Continue those administered by the transdermal route and rotate others with an equivalent dose to the subcutaneous route (usually morphine).

- **Initiate subcutaneous treatment.**

  - Palliative sedation involves a decreased level of consciousness, and therefore difficulty in oral intake. At home, the route of choice will be subcutaneous.
  - Before applying this technique, patients and families often need a clarifying explanation that reassures them and inspires security to achieve objectives.
  - To facilitate good adherence leave a treatment sheet with the prescribed therapeutic regimen and rescue doses, that we will be updated as time progresses. This sheet will also be useful for other professionals involved in monitoring. (Appendix 2)
  - We provide information about the basic operation of the infusion pump and the proper handling of bolus if the patient needs extra doses.

- **Provide comfort care. (Appendix 3)**
  - Care of mouth
  - Turning the patient
  - Hygiene
  - Care of ulcers

- **Monitoring after sedation is started.**

We will make telephone contact every 12 hours and home visits every 24 hours for:

- Control of symptoms.
- Level of sedation using the Ramsay scale.
- Emotional state of the family.

6.2.2. - Management of Subcutaneous route.

- **What are the advantages of the subcutaneous route at home?**
  - Less aggressive, less painful, has no risk of phlebitis or extravasation.
  - Hospitalization is not required.
  - Maintains patient autonomy
  - Easy to use for family caregivers and the patient.
  - Fewer complications than intravenously.
  - Provides peace of mind for the family.

- **Complications of subcutaneous route (always inform the caregiver)**

  - Local reaction with erythema and itching (less than 10% of cases) that ceases after changing the puncture site.

- Adverse reaction to the material.
- Accidental loss of butterfly.
- Fluid leakage from site of puncture.
- Bruising or bleeding at the puncture site.
- Crystallization of drugs with swelling and pain.

• Subcutaneous technique

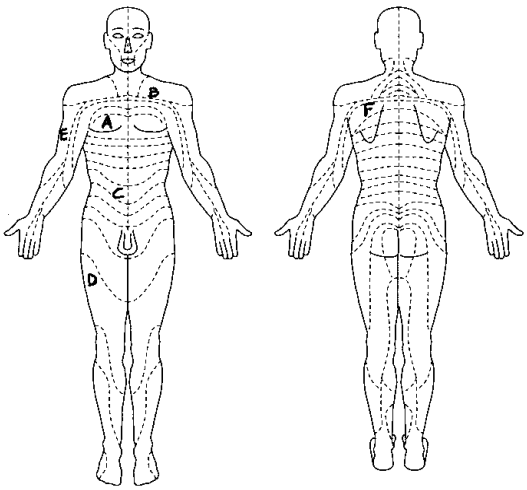
a)Rules for subcutaneous administration of medication:

• Intermittent Infusion: for administering treatment periodically. The effect of the medication comes in the form of peaks by repeated subcutaneous injections. We use a winged needle (butterfly) fixed to the skin, through which the medication is administered to prevent repeated punctures. The dose of each drug can be prepared in the syringe. If there are difficulties with handling by caregivers, we may leave as many syringes prepared with medication as daily bolus' are needed.

• Continuous infusion: to administer medication in a continuous manner to control the symptoms of a patient by using an infusion pump. The rate of release of the medication is uniform and the effect of the medication is sustained over time.

b)Puncture site

A subcutaneous puncture can theoretically be performed anywhere on the body where there is subcutaneous tissue. Areas are used interchangeably; the anterior chest (infraclavicular area), anterior and outer arms (deltoid). The upper abdominal quadrants and thighs are not recommended as they are more uncomfortable for the patient and more difficult to access and control for nurses.



PUNCTURE ZONES

A. Pectoral area
B. Infraclavicular area
C. Abdomen (avoid periumbilical region)
D. Thigh (not to be used if incontinent)
E. Anterior and Outer arm
F. Scapula region (for agitated patients with a risk of self-manipulation)

Please choose areas with no redness, swelling, oedema or wounds and that are not within the field of radiation therapy.

c) Puncture Technique

• Use 23g or 25g butterflies, and fix with transparent adhesive dressings which are preferred for better control of the injection point.

d)Duration of the injection site

•We recommend not to change the butterfly until there are signs or symptoms of local intolerance. The duration varies from 1 day to 3 weeks.

e) Nursing care.

• Replenish the reservoir of the infusion pump, if being used, whenever necessary.
• Inspect the infusion site frequently for signs of local irritation that may alter the absorption capacity of the skin.
• Change the injection site each time one suspects reduced absorption or complications.

• Management of continuous infusion pumps

a) Advantages of continuous infusion.

• It enables administration of multiple medications at the same time, if they are compatible.
• Allows control of several symptoms at once.
• Offers the possibility of sedation safely at home, with less manipulation of medication and errors by caregivers.
• It provides the opportunity to train family members and informal caregivers.
• Lowers the workload for professionals and carers.
• The correct, continuous drug regimen ensures comfort in an end-of-life situation.

b)Problems arising from continuous infusion.

• The infuser does not empty: usually due to the presence of an air bubble in the system output. Correct by purging the system and verifying that a drop of the drug flows continuously from the tip of the infusion set.
• Obstruction of the needle at the puncture site due to the presence of a blood clot.

c)To Charge the continuous elastomeric infusion pump (EIP). Dose-Fuser Model.

▪ When you load the infusion pump you should consider the following variables:
-The out-flow measured in ml / h (0.5 ml / h and 1.2 ml / h) are the most widely used.
-The time range: 24h, 5 days or 7 days (preferably 1 to 3 days).

-The total load measured in ml, which is related to the two parameters above.

• With these variables as a reference, calculate the total volume of drug to be administered according to the type of elastomeric pump (see Table 1), completing the total capacity of the device with saline solution (up to 12ml if the rate of flow is 0, 5ml/h, and up to 28ml if the flow rate is 1.2 ml / h).

•Add 5 ml to the total volume when filling the reservoir to purge the system.

▪ The reservoir is not rechargeable (disposable product).

Table 1. – Volume of infusion pumps, speed and duration of administration.

Normal Capacity	65ml	100ml.	150ml.	250ml.
Maximum	80ml.	130ml.	180ml.	265ml.
5 days	0.5ml / h.	0.8ml / h.	1.2ml / h.	2ml. / h.
2 days	1.3ml / h.	2.0ml / h.	3.1ml / h.	5.2ml / h.
1 day	2.7ml / h.	4.1ml / h.	6.2ml / h.	10.4ml / h.

Case Nº 10

We begin palliative sedation with the following drugs in a continuous infusion pump:
Midazolam (5mg/mL) 30mg/24h + 2% Morphine (20mg/mL) 60mg/24h

Calculate the volume in mL to be placed in the infusor pump: 6mL Midazolam + 3mL 2% morphine = Total 9ml/24h

We use an EIP with a flow rate of 0.5 mL / h equivalent to 12ml/24h. (able to increase to 12mL/24h)

Charge the infusor pump with the drugs and fill to the desired capacity of the device (12mL for a duration of 24 hours at 0.5mL/h) by adding 3mL of saline to the 9 mL of medication (morphine and midazolam).

Add 5mL more saline for the initial purging of the line and filter.

The total volume of treatment for 24 hours would then be 17mL. If you wish to leave a charge for 2 or 3 days the same proportions are used. Table 2 shows the volumes for administration for 2 and for 3 days.

	1 day (12 mL)	2 days (24 mL)	3 days (36 mL)
Midazolam	6 mL	12 mL	18 mL
2% Morphine	3 mL	6 mL	9 mL
Saline	3+5 mL	6+5 mL	9+5 mL
Total	17 mL	29 mL	41 mL

Other types of elastomeric infusion pumps are available (Appendix 4)

- **Use of drugs and compatible mixtures**

a) Drugs that can be used for palliative sedation

- Sedation with midazolam is started at doses of 5-7.5mg subcutaneously every 4 hours or 30-45mg every 24 hours in continuous infusion.

- If not effective, increase the previous dose by 50% to a maximum of 200mg/day.

- If midazolam is ineffective, or when the refractory symptom is delirium, start with Levomepromazine. Starting doses of 12.5-25mg by subcutaneous injection q.d.s or 50-100 mg every 24 hour by continuous infusion are recommended. If not effective, increase the dose by 50% to a maximum of 300mg/dia.

- If the patient was receiving midazolam, we recommend reducing the dose of midazolam by 50% and then decrease progressively according to clinical response.

- If Levomepromazine is not effective consider transfer to hospital or start phenobarbital. We start with a bolus of 200 mg im followed by continuous sc infusion starting at 800 to 1200mg/24h or alternatively continue with subcutaneous bolus of 200 mg q.d.s

- If none of these drugs are effective we transfer the patient to the hospital.

b) Combinations of drugs without risk of precipitation

Midazolam + Morphine + hyoscine + Levomepromazine
Midazolam +Morphine + metoclopramide + hyoscine
Midazolam + Morphine + Haloperidol + hyoscine

Phenobarbital is not administered with other drugs

- The chance of precipitation increases, the higher the number of drugs mixed.

6.3. - Coordination of resources

Home monitoring necessarily implies adequate coordination between different levels of care and different professionals involved in patient care.

- Once the decision to initiate palliative sedation is taken and subcutaneous treatment begins, the support team provides a medical record, signed by the doctor in charge, with the patient's treatment and extra doses in case any other symptoms, not contemplated at the time of the visit, may appear. Thus, both the family / caregiver as well as the primary care team have a record as to the patient's treatment with information regarding other therapeutic possibilities, therefore avoiding unnecessary visits to the Emergency Department.
- We will also provide the family with information as to coverage at the weekends and during holidays, and contact telephone numbers to ensure proper coverage 24 hours a day, 7 days a week.
- We will telephone the referent professional at the Primary Care Center to report the start of palliative sedation.

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7.-Sedation in the Emergency Department.

The use of palliative sedation in the context of the emergency department is controversial and poorly studied. In fact in a review published on the subject, only one study in France has been found (7.1), which concluded that half of the patients who died in the emergency department were receiving palliative care but it was considered insufficient, since most patients died after the decision to withdraw life supporting measures was taken, and that management of end-of-life care should be improved in the emergency department.

7.1. What situations can arise?

• **Patients known to have advanced and terminal diseases** with new onset of severe symptoms which require urgent evaluation in a medical center, **even if they are only on palliative treatment.** This includes regularly monitored patients cared for by palliative care teams both at home and in hospital, as well as those in whom the medical records show evidence of this approach.

• Patients with serious symptoms who require urgent evaluation in a medical center, who are **known to suffer from advanced chronic organic failure but in whom the situation of terminality has not yet been determined and no palliative treatment has been started.** This includes patients with chronic disease usually other than cancer (CHF, COPD, CKD, Alzheimer's disease, cirrhosis, etc.), or cancer patients whose current approach is not known.

• **Patients in acute and life-threatening clinical situations** (massive gastrointestinal bleeding, intracranial hemorrhage, massive pulmonary embolism, rupture of aneurysm, etc.) with or without chronic diseases.

In such situations, we have a patient with a probable life expectancy of hours or days, who may possibly enter into death agony during their time in the Emergency Department.

In those circumstances where a patient can die in the emergency department, **when would palliative sedation be recommended?**

By referring to the definition, one would contemplate sedation when the presence of refractory symptoms produces unbearable suffering, and not only the high probability of death being close.

7.2. Process and decision making in emergencies:

- Evaluate background and current clinical status of the patient.

- Start etiological (if possible) and / or symptomatic treatment.

- Reassess every hour:

  - Response to treatment
  -Presence of refractory symptoms
  -Presence of suffering

- If, within a reasonable period of time, no adequate response to treatment and onset of refractory symptom / s is present with severe physical and / or psychological suffering for the patient, answer the following questions:

- 1. The patient has advanced disease? (Yes / No)

- 2. The treatment of the underlying pathology prior to arrival in the emergency department was essentially palliative? (Yes / No)

-3. Has any etiological or replacement therapy of their underlying disease been ruled out? (Yes / No)

-4. Is there any record of the poor prognosis of the disease and / or is it known that any life-threatening situations should be managed in a palliative way? (Yes / No)

-5. Is the prognosis of this complication, in the current clinical context of the patient, fatal in the short term? (Yes / No)

In case all the answers to the above questions are <u>YES</u> consider the indication of palliative sedation.

Case Nº 11

An 85 year-old male patient with COPD Gold IV, Congestive heart failure, FE 35%, domiciliary oxygen on opioid treatment for dyspnoea. He is admitted to the emergency room with paroxysmal nocturnal dyspnoea and increased resting dyspnoea, fever and hyperactive delirium. Intensive diuretic treatment, bronchodilators, corticosteroids and antibiotics are started. In addition opioids and neuroleptics are administered. Non-invasive ventilation is also administered but not tolerated by the patient.
After 6 hours of this treatment no clinical improvement is objectified, respiratory distress persisting with hypoxia and metabolic acidosis, oliguria and hypotension continuing.
The family conveys the wish that the patient should not suffer.
In this case you might consider palliative sedation.

Case Nº 12

A 78 year-old male patient with a history of hypertension, COPD Gold IV, and an inoperable, 6cm diameter Abdominal Aortic Aneurysm due to comorbidity, arrives at the Emergency Room with a sharp stabbing pain in the epigastrium and mesogastrium irradiated to the back with a VAS intensity of 10/10, which appears after defecation effort. On physical examination, the patient is diaphoretic, hypothermic, with a rictus due to abdominal pain, no clear peritoneal irritation, no distal pulses. CT scan informs of Aortic Abdominal dissection from celiac trunk to iliac arteries.
The patient is in severe pain and requires 10mg Morphine to reduce the pain to VAS 5/10. Patient and family are informed that no surgical procedure could be performed due to comorbidity. The patient requests pain control and accepts the possibility of decreasing level of consciousness if the pain is refractory.
After a further dose of Morphine the patient remained relaxed and slept peacefully. An hour later he died free of pain.

In the case that palliative sedation is indicated, share and agree with the team the decision to initiate the process for obtaining consent (see section 3.3).

7.3. - Obtaining consent

- To obtain consent of the **competent patient:**

(We recommend that one informs the family beforehand and, if possible, for them to go accompanied by a member of the team).

- Explain to the patient that we would like to talk about something important and ask him if he wishes his family to be present.

- Explain the cause of his arrival at the emergency department and the course of his illness so far.
- Assess the degree of physical discomfort and emotional suffering.
- Recommend decreasing the level of consciousness as appropiate treatment.
- Validate the understanding of the information supplied and proposed treatment (sedation).
- Obtain explicit consent or refusal.

• To obtain the consent of the family (**incompetent patient**).

- Explain the cause of arrival at the emergency department and the course of the illness so far.
- Explain the degree of physical and emotional discomfort that the patient suffers.
- Propose decreasing the patient's level of consciousness as appropriate treatment.
- Validate the understanding of the information supplied and proposed treatment (sedation).
- Obtain explicit consent or refusal.

▪ If refusal for Palliative sedation, maintain treatment, minimize suffering, maintain continuous assessment.

• After starting palliative sedation it is IMPORTANT to:

- Ensure privacy for patient and family.

- Devote a specific time and place to review with the family, the indication, expectations, potential practical support and immediate prognosis.

7.4.- Drug to use:

This has been mentioned in previous sections. Adapt the dosage to the context of the emergency department.

It is recommended, especially if in doubt, to obtain the appraisal and assessment of a palliative care team.

7.5.- The clinical record:

Ensure proper registration of the patient's clinical situation, the refractory symptom under treatment and the consent obtained, as well as monitoring the process (level of consciousness, symptoms, drugs used, doses, etc.). (For more details see section 2.1)

Important:

Palliative sedation emphasizes the proportionality of the procedure and the fact that the symptoms under treatment are refractory in the context of a patient close to death. Therefore creating formulations (cocktails) for palliative sedation is considered therapeutically inappropriate.

References

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Appendix I

Palliative Prognostic Score (PaP Score)

PaP Score and Classification of Patients in Three Risk Groups

	Partial score
Dyspnea	
no	0
yes	1
Anorexia	
no	0
yes	1.5
KPS	
≥50	0
30–40	0
10–20	2.5
CPS (weeks)	
>12	0
11–12	2.0
9–10	2.5
7–8	2.5
5–6	4.5
3–4	6.0
1–2	8.5
Total WBC	
normal (4,800–8,500 cell/mm^3)	0
high (8,501–11,000 cell/mm^3)	0.5
very high (>11,000 cell/mm^3)	1.5
Lymphocyte percentage	
normal (20.0–40.0%)	0
low (12.0–19.9%)	1.0
very low (0–11.9%)	2.5
Risk groups	**Total Score**
A 30-day survival probability >70%	0–5.5
B 30-day survival probability 30–70%	5.6–11.0
C 30-day survival probability <30%	11.1–17.5

PaP Score = Dyspnea score + Anorexia score + KPS score + CPS score + Total WBC score + Lymphocyte percentage score.

Palliative Performance Score (PPSv2)

Palliative Performance Scale (PPSv2)
version 2

PPS Level	Ambulation	Activity & Evidence of Disease	Self-Care	Intake	Conscious Level
100%	Full	Normal activity & work No evidence of disease	Full	Normal	Full
90%	Full	Normal activity & work Some evidence of disease	Full	Normal	Full
80%	Full	Normal activity *with* Effort Some evidence of disease	Full	Normal or reduced	Full
70%	Reduced	Unable Normal Job/Work Significant disease	Full	Normal or reduced	Full
60%	Reduced	Unable hobby/house work Significant disease	Occasional assistance necessary	Normal or reduced	Full or Confusion
50%	Mainly Sit/Lie	Unable to do any work Extensive disease	Considerable assistance required	Normal or reduced	Full or Confusion
40%	Mainly in Bed	Unable to do most activity Extensive disease	Mainly assistance	Normal or reduced	Full or Drowsy +/- Confusion
30%	Totally Bed Bound	Unable to do any activity Extensive disease	Total Care	Normal or reduced	Full or Drowsy +/- Confusion
20%	Totally Bed Bound	Unable to do any activity Extensive disease	Total Care	Minimal to sips	Full or Drowsy +/- Confusion
10%	Totally Bed Bound	Unable to do any activity Extensive disease	Total Care	Mouth care only	Drowsy or Coma +/- Confusion
0%	Death	-	-	-	-

Palliative Performance Index

Factor	Partial score
PPS 10–20%	4
PPS 30–50%	2.5
PPS >50%	0
Delirium	4
Dyspnoea at rest	3.5
Oral intake mouthfuls or less	2.5
Oral intake reduced but more than mouthfuls	1
Oral intake normal	0
Oedema	1

Total score (sum of partial scores) and expected survival

- Group A (total score <2.0): greater than 6 weeks
- Group B (2.0–4): 3–6 weeks
- Group C (>4.0): less than 6 weeks

Appendix 2

Treatment sheet

MEDICAMENT	DOSIS	MOTIU								
MEDICAMENTO	**DOSIS**	**MOTIVO**	**4 h.**	**6h.**	**8 h.**	**12 h.**	**16h.**	**18 h.**	**20 h.**	**24 h.**

OPCIONAL

C/ERMITA, S/N

CAP BELLVITGE. TELF. 93 XXX.XXX.
HORARI : De 8 a 15 h

INFERMERA:
METGESSA:
TREBALLADORA SOCIAL:

URGÈNCIES: Trucar al 061

NOMBRE:

EDAD: **FECHA:**

MEDICAMENTOS MEDICAMENTS	MOTIVO MOTIU	DESAYUNO ESMORZAR	COMIDA DINAR	MERIENDA BERENAR	CENA SOPAR	DORMIR DORMIR

Appendix 3

1.- Care of the mouth.

a. Remove poorly fitting dentures.

b. Clean the mouth frequently and gently using a gauze moistened with water or tea. If the mouth is dirty or bloody, we can use hydrogen peroxide diluted 50% with saline.

C. Hydrate lips with cream bar or lipsalve.

2.- Patient turning (every 6 hours).

a. Providing the natural position for rest.

b. Place cushions to reposition and prevent pressure sores.

c. If rattling, lateral decubitus and mild neck flexion is recommended.

d. If fractures, look for antialgic position.

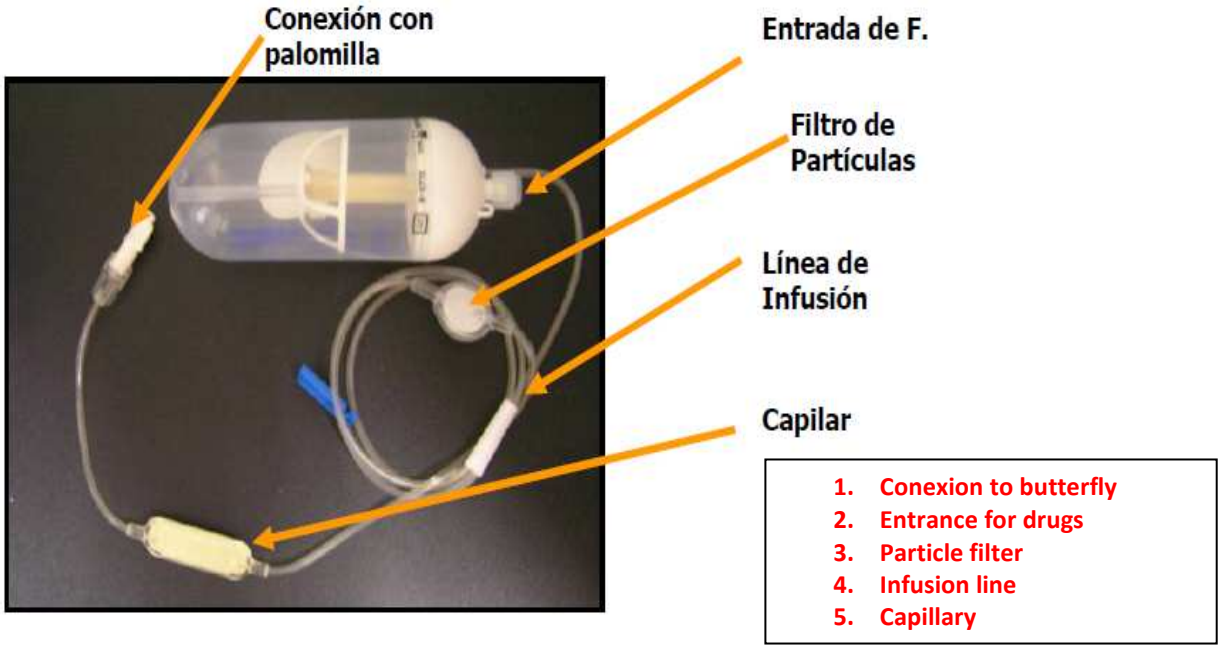
3.- Skin care.

a. Maintain hygiene and regular moisturizing of the body for comfort.

b. If care is needed for ulcers, use a topical anesthetic for pain and 2% metronidazole gel or dressings with activated carbon for odor. If bleeding, apply adrenaline to the ulcer and compression with a gauze.

Appendix 4
Elastomeric infusion pumps.

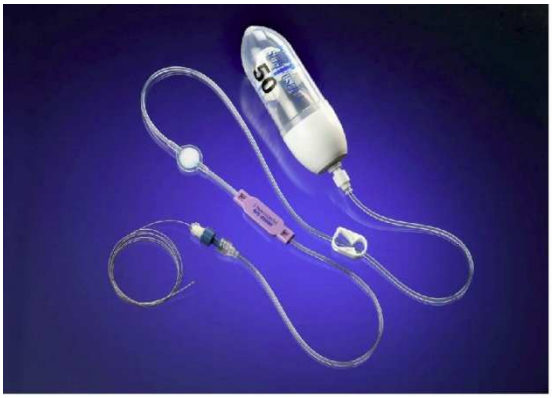
Elastomeric infusion dose FUSER



Elastomeric infusion Accufuser

Elastomeric infusion Easypump

Baxter elastomeric infusion pump



Elastomeric infusion Surefuser