

Guidelines for clinical use of local anaesthetics in minor ambulatory surgery with no anaesthetist's care

G. Bettelli *, E. Dall'Olmi, A. Buttazzi, E. Cantoni, G.M. Cavallini, A. Cimitan, G. Cristiani, S. Dallari, A. Marchetti, L. Morselli, M. Monteleone, A. Segre, E. Silingardi, R. Simonazzi, F. Tavoni, E. Torcia, A. Volpe

Working Group for Day Surgery, Policlinico di Modena, Modena, Italy

1. Introduction

For doctors operating in public or private health structures, and sometimes in the patient's home, it is everyday practice to perform local anaesthesia by infiltration or troncular block when painful therapeutic manoeuvres are involved (suture of small wounds, dental care, episiotomy, removal of small surface growths, biopsies, etc.). In such practices there is generally no reservation about operating in the absence of a specialist in anaesthesiology and resuscitation.

Occasionally, however, instances are reported of serious complications or even deaths during surgery with local anaesthesia, and this is frequently the case in private ambulatory surgery. In these cases it is not always possible to document the lines of demarcation of professional responsibility (in terms of error of evaluation by the operator regarding the general conditions of the patient, or errors in the dosage of drugs or performance of techniques); but it is often possible to demonstrate, with hindsight, that the presence of a physician expert in anaesthesiology and resuscitation would reasonably have enabled such effects to be obviated.

It is worth noting that the literature contains no clear-cut and reliable indications regarding the margins of acceptability of the practice in question, nor any clear lines of demarcation to identify the situations in which it is possible to operate according to such criteria and those where further assessment is necessary or this type of intervention should not be performed. All the more so, since not all physicians carrying out local anaesthesia have had the opportunity, during their training, to examine thoroughly not only the pharmacology of local anaesthetics and the techniques of local anaesthesia, but

also the essential manoeuvres of cardiopulmonary resuscitation, which may often be needed in cases of accidents.

It is important to recall that for local hospitals an Anaesthesia and Resuscitation Service is not obligatory, whereas it is so for regional and provincial hospitals. Hence, in the local hospitals, interventions with local or loco-regional anaesthesia may be performed without the assistance of the anaesthetist and a resuscitation service. Moreover, there is no regulation prescribing limits to the utilisation of these techniques for any graduate in medicine and surgery who is licensed to exercise the profession and duly enrolled on the professional register.

Within the hospital structures, and especially the larger ones, accidents from local anaesthetics are probably less frequent than elsewhere, and certainly of a less serious nature. In spite of this, anaesthetists are not infrequently called to the operating table for consultation, for treatment of vago-vagal syndromes, episodes of arrhythmia, lipothymic crises or, more rarely, symptoms of genuine overdose, absolute or relative, of local anaesthetics.

It should anyway be emphasised that, even where local anaesthesia in the absence of an anaesthetist is warranted and dosages are correctly established, the employment of local anaesthetics, like any other medical act, is subject to a series of possible complications or side-effects.

In any case, the use of local anaesthetics is subsumed into the broader context of pharmacological therapy and hence, like it, must be subject to the general principles of drug therapy, according to which the interaction between patient and substance administered gives rise to a number of phenomena that can be defined, described and quantified with a reasonable margin of precision [6]. The aim of the Guidelines pro-

* Corresponding author.

posed herein is to optimise the possibility of defining, describing and quantifying these phenomena in advance for operators having to administer local anaesthetics to patients who require them, in the absence of specialists in anaesthetics and resuscitation. Also it would seem neither reasonable nor realistic to assume the presence of the specialist anaesthetist in all cases of surgery under local anaesthesia. Concerning the doctrine of quality, they stand as both a reference document and a device to enable conformity with procedures, having been drawn up with precise regard for the standard UNI EN ISO 9002 [13].

2. Origin and aim of the work [9–10]

The Guidelines that follow are the fruit of reflection by physicians belonging to the 'Working Group for One-day Surgery' of Modena Hospital, regarding the subject of common orientation on the use of local anaesthetics, to be applied in circumstances where the presence and collaboration of anaesthetists is not envisaged. In particular, it is felt necessary to provide guidelines that, while respecting the various requirements of the different surgical specialities, envisage—in line with criteria shared by all operators involved—the performance of local anaesthesia through all stages, from evaluation of the patient and identification of the possible risk factors, to the choice of the most appropriate anaesthetic, the patient's informed consent, the techniques of optimisation and enhancement of the drugs used, the clinical supervision during local anaesthesia and the surgical manoeuvre entailed, to the documentation of the activity performed, the management of failure and the treatment of possible complications.

Currently, the literature offers none of the data needed to define the real frequency of accidents from local anaesthetics in public or private structures, nor to distinguish between small accidents and serious ones. The principal difficulty in making even an approximate estimate stems from the fact that, hitherto, it has not been deemed necessary, systematically and in all cases, to adopt any specific procedure so that possible side-effects in the performance of local anaesthesia can be properly recorded and periodically analysed, with the aim, among other things, of ongoing technical improvement.

The present work has its origin in these reflections. It is in line with the themes and operating methodology belonging to a quality system, understood as a management philosophy aimed at defining the standards that characterise a particular performance or product, at establishing a precise path of the work performed, and at checking and correcting possible errors, evaluated as 'non-conformity'.

The field of operation of this first edition is restricted to superficial, non-invasive surgery, not requiring administration of sedative or analgesic drugs, performed on patients free of risk factors and belonging to ASA Classes I–IIa. The goals do not include here the definition of criteria according to which dedicated anaesthetic assistance should be held necessary during an operation carried out under local anaesthesia.

Lastly, these Guidelines were devised with the aim of contributing to the definition of operative standards by which minor surgery can be performed, in a purely ambulatory regime, in public or private structures, and, if necessary, outside the circuits and provision of assistance reserved for one-day surgery.

3. Guidelines for clinical use of local anaesthetics

3.1. General remarks (see UNI EN ISO 9002—4.3: Contract review) [1,2,5,12]

The safe use and correct choice of local anaesthetic requires that the operator performing the local anaesthesia has:

- a precise knowledge of the characteristics of these drugs, their possible toxic effects, the doses that can be used safely and the factors that may influence the expected plasma concentration following administration of a given amount of the drug;
- a precise knowledge of the patient and his/her clinical history, with special attention to such elements as may appear risk factors vis-à-vis the administration of local anaesthetics;
- The availability of equipment needed for clinical supervision of the patient and/or monitoring of vital functions, plus any equipment that may become necessary in case of complications or adverse reactions.

3.2. Criteria of choice for local anaesthesia (see UNI EN ISO 9002—4.3: Contract review) [4,5,7]

In every case, the decision to operate with local anaesthesia must take account of the following premises:

- the surgery must be feasible, with dosages of LA not exceeding the maximum permitted for the drug used, making allowance for appropriate adjustments with reference to age, body weight, site and times of administration and simultaneous use of vasoconstrictors;
- sufficient comfort for the patient must be guaranteed (absence of pain, duration of operation predictably limited to 40–60 min); prior to intervention, the patient must be informed as to the type of anaesthesia to be performed and the risks associated therewith;

- the criteria inherent in the technique of performance and safety must be followed (monitoring of vital functions, possibility of venous access and fluid replacement, of administration of vagolytic, cortisone, antihypertensive and minor sedative drugs; availability of equipment and drugs for cardiopulmonary resuscitation; availability of material for documentation and recording all stages of the operation performed);
- for troncular block, use of electrostimulators and thorough study and analysis of evoked muscular response is recommended.

3.3. Evaluation of the patient (see UNI EN ISO 9002—4.3: Contract review) [1–2]

Even where low doses of local anaesthetics are involved, pre-assessment of the patient is always essential, in order to identify the ASA class and the presence of possible pathologies, risk factors or contra-indications to use of local anaesthetics. The following are deemed to be risk factors:

- hypovolaemia and shock
- epilepsy
- assumption of MAOI drugs and tricyclic antidepressives
- hypertension
- coronary impairment
- serious arterial disease
- insulin-dependent diabetes
- porphyria
- previous allergic symptoms following LA administration.

It must also be specified that:

- epilepsy is a classic contra-indication for local anaesthetics [3]; with lidocaine, the contra-indication is relative, but it must be recalled that even minimum overdose may produce convulsions; in such cases, therefore, local anaesthesia will be performed only after venous access has been made available;
- hypertension and coronary impairment are risk factors mainly as regards the use of anaesthetic solutions containing adrenalin;
- since mepivacaine and bupivacaine may accentuate vasospasm in presence of serious arterial disease, in such cases the drug of choice is lidocaine without vasoconstrictor.

3.4. Choice of local anaesthetic and modality of administration (see UNI EN ISO 9002—4.9: Process control)

- Since the safest drug, from the point of view of allergy and intrinsic toxicity, is lidocaine, this must be deemed the first-choice drug [1,2].
- Thereafter, the choice falls on mepivacaine.

- Bupivacaine will be used only if effectively indicated in view of its long-lasting action and in cases where analgesia of the required duration cannot be obtained by addition of vasoconstrictors or alkalising agents to less toxic substances, or in case of ascertained contra-indication to use of lidocaine and mepivacaine.
- In every case, bupivacaine will be used with continuous ECG monitoring, bearing in mind its potential cardiotoxicity and after ensuring that the patient presents no heart disease and is not taking calcium antagonists, beta-blockers [8] or benzodiazepines.
- Every injection or re-injection must be preceded by aspiration, in order to detect possible vascular ruptures.
- The aspiration must be moderate and not involve any change of position of the needle.
- The injection of local anaesthetic should not be rapid, especially in richly vascularised tissues.
- Whenever it becomes necessary to administer large amounts of LA and where this is not contra-indicated, it is preferable to employ the form associated with the vasoconstrictor [12].

3.5. Use of adjuvants (see UNI EN ISO 9002—4.9: Process control)

- Adrenalin is the most efficient of the vasoconstrictors; it can be used when no contra-indications are present [1,2].
- The recommended concentration in adults is 1/100 000; in children the preferred concentration is 1/200 000, and 1/400 000 in unweaned babies.
- Adrenalin-containing solution must not be used for blocks in regions where the arterial vascularisation is of terminal type (digital, penis and periorbital blocks).
- In order to halve the LA concentration, with the result (though there is not complete agreement on this point) of increasing its duration of action and reducing its time of latency, 10% sodium bicarbonate may be temporarily added, at volume equal to the LA [1].

3.6. Clinical supervision (see UNI EN ISO 9002—4.9: Process control) [4]

- During the operation, the patient's general condition must be supervised by a member of the team, who will be assigned this explicit task in advance.
- The patient must be supervised in order to identify possible reactions to the drugs used and physiological or behavioural alterations. By means of observation or monitoring of the variables indicated by the member of the team responsible, the supervision will regard the condition of the circulation (e.g. arterial

pressure, cardiac frequency and rhythm), oxygenation (e.g. skin colour, respiratory frequency, saturimetry) and mental state (e.g. through ongoing verbal contact).

- The person entrusted with this supervision must be sufficiently familiar with the working of any monitoring equipment that may be necessary and capable of interpreting the information collected.
- The documentation recorded on the local anaesthesia form must state exactly the type of assistance and intra-operative supervision performed.

3.7. Management of failure (see UNI EN ISO 9002—4.13: Control of nonconforming product)

If the type of anaesthesia performed should be insufficient to ensure analgesia, the situation may present problems for both patient and operator, so that not only is the necessary comfort for patient and operator not guaranteed, but even the safety of the patient and of the operation may be placed in jeopardy.

- In such cases, steps must be taken to respect the dignity of the person and the safety of the operation.
- The critical point is the operator's ability to discern whether further administrations of LA may or may not produce toxic reactions.
- In case of doubt or failure, or if it becomes necessary to administer sedatives and/or analgesics, the cooperation of an anaesthetist must be urgently requested.

3.8. Documentation of activity performed and back-up forms (see UNI EN ISO 9002—4.3.4: Records; 4.16: Control of quality records)

The performance of a small operation requiring a dose of LA of 100 mg or over (i.e. 20 ml of local anaesthetic at 0.5%, 10 ml at 1%, 5 ml at 2%) must be described on an appropriate form stating:

- summary of medical history and objective examination of the patient;
- type of drug used;
- dose administered in ml and concentration of the solution;
- site of injection;
- number of injections performed;
- times of administration;
- intra-operative assistance and monitoring effected and summary of significance of the data collected by means of said assistance and monitoring.

3.9. Discharge (see UNI EN ISO 9002—4.10.4: Final inspection and testing)

- Prior to discharge, it is indispensable for the patient to have regained a general condition compatible with leaving hospital and returning home.

- Following ambulatory surgery with local anaesthesia leading to transitory motor block of the muscles of a lower limb, it is essential to wait until the motor block has completely regressed [11].
- In every case, the patient must be completely informed on the duration and extension of a possible motor block, even partial and therefore expressed as a muscular weakness, that may remain after local anaesthesia.

3.10. Audit, corrective action and quality control (see UNI EN ISO 9002—4.17: Internal quality audit)

The use of local anaesthetics during ambulatory surgery without dedicated anaesthetic assistance should be consistent with the contents of these Guidelines.

At the start of each year, the surgical teams will check the availability of equipment and drugs for the treatment of LA complications in the places—other than the operating theatres—where they intend to perform minor surgery under local anaesthesia without the assistance of an anaesthetist, and will appoint one of their number to be responsible for the periodic maintenance and supply of said equipment.

In the presence of abnormal reactions or complications (anaphylactic reactions, overdose reactions, vago-vagal reactions, emotional reactions or other), a blood sample (5–10 ml in EDTA) will, if possible, be promptly obtained and sent to the pharmacological laboratory to determine plasma levels of local anaesthetic, after the patient has been informed. Complications (overdose reactions, vago-vagal reactions, emotional reactions, anaphylactic reactions, or other) arising during the use of local anaesthetics in conformity with these Guidelines will be described on the local anaesthesia form and notified in confidence to the Working Group.

At the start of each solar year, the descriptions of the said complications will be reviewed by all members of the team, with the aim, if necessary, of making revisions to these Guidelines.

References

- [1] D'Athis F. Pharmacologie des anesthésiques locaux—EMC (Paris, France). Anesthésie-Réanimation, 36320 A10, 1986; 11:20 pp.
- [2] Covino BG. Pharmacology of local anaesthetic agents. Br J Anaesth 1986; 58:701–716.
- [3] Scott DB. Toxic effects of local anaesthetic agents on central nervous system. Br J Anaesth 1986; 58:732–735.
- [4] Proposed recommended practices: monitoring the patient receiving local anesthesia. AORN J 1989; 49:623–628.
- [5] Scott DB. Maximum recommended doses of local anesthetic drugs (editorial). Br J Anaesth 1989; 63(4):373–374.

- [6] Nies AS. Principles of therapeutics. In: Goodman Gilman A. ed. *The Pharmacological Basis of Therapy*. New York: Pergamon Press, 1990, p. 62.
- [7] Butterworth IV JF, Strichartz GR. Molecular mechanism of local anesthetics: a review. *Anaesthesiology* 1990; 72:711–734.
- [8] De La Coussaye JE, Eledjan JE, Brugada J, Bassoul B, Gagno JP, Desh G, d'Athis F, Sassine A. Les betabloquants aggravent-ils la cardiotoxicité de la bupivacaine? Etude expérimentale. *Ann Fr Anesth Réanim* 1990; 9:132–136.
- [9] The Royal College of Surgeons of England, Commission on the Provision of Surgical Services: Guidelines for Day Case Surgery, revised edn., 1992.
- [10] Swales JD. Guidelines on guidelines. *J Hypertension* 1993; 11:899–903.
- [11] Kálmán Szell MB. Local anaesthesia and inguinal hernia repair; a cautionary tale. *Ann R Coll Surg Engl* 1994; 76:139–140.
- [12] Palve H, Kirvela O, Olin H, Syvalahti E, Kanto J. Maximum recommended doses of lignocaine are not toxic. *Br J Anaesth* 1995; 63:373–374.
- [13] Quality systems: model for quality assurance in production and installation. ISO 9002 1987.