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Dutch evidence-based guidelines for amputation and prosthetics of the lower extremity: Amputation surgery and postoperative management. Part 1

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Abstract

Background: Surgeons still use a range of criteria to determine whether amputation is indicated. In addition, there is considerable debate regarding immediate postoperative management, especially concerning the use of 'immediate/delayed fitting' versus conservative elastic bandaging.
Objectives: To produce an evidence-based guideline for the amputation and prosthetics of the lower extremities. This guideline provides recommendations in support of daily practice and is based on the results of scientific research and further discussions focussed on establishing good medical practice. Part 1 focuses on amputation surgery and postoperative management.
Study design: Systematic literature design.
Methods: Literature search in five databases. Quality assessment on the basis of evidence-based guideline development.
Results: An evidence-based multidisciplinary guideline on amputation and prosthetics of the lower extremity.
Conclusion: The best care (in general) for patients undergoing amputation of a lower extremity is presented and discussed. This part of the guideline provides recommendations for diagnosis, referral, assessment, and undergoing amputation of a lower extremity and can be used to provide patient information.

Clinical relevance

This guideline provides recommendations in support of daily practice and is based on the results of scientific research and further discussions focussed on establishing good medical practice.

Keywords

Orthopaedic surgery, rehabilitation, pain research

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Background

An amputation of a lower extremity is a major event for the patient and his or her family. The incidence of amputation of a lower extremity is about 20 per 100,000, 60% of whom are male and 80% are older than 65 years. Every year, about 3300 cases of major amputation of a lower extremity occur in the Netherlands. In around 90%–95% of the cases, amputation is the result of vascular complications.[1]

Surgeons still use a range of criteria to determine whether amputation is indicated. In addition, there is considerable debate regarding immediate postoperative management, especially concerning the use of 'immediate/delayed fitting' versus conservative elastic bandaging. There is also a considerable variation in prosthetic prescription concerning the moment of initial prosthesis fitting and the use of replacement parts.[2] There is a considerable ambiguity with regard to the surgical techniques, the time of amputation and the subsequent rehabilitation programme. The existing variety of approaches in these areas can lead to over- or under-treatment. With increases in vascular disease, diabetes mellitus and an ageing population, but also with better vascular surgery techniques, improving the quality-of-care for patients undergoing leg amputation is still of major importance.

A structured, multidisciplinary approach is needed that includes a greater focus on the involvement of both (para) medics and prosthetists. The information available to patients can also be significantly improved.

These considerations prompted the Netherlands Society of Physical and Rehabilitation Medicine (VRA) to take the lead in the development of a multidisciplinary, evidence-based guideline for the amputation and prosthetics of the lower extremities. This guideline provides recommendations in support of daily practice and is based on the results of scientific research and further discussions focussed on establishing good medical practice. The best care (in general) for patients undergoing amputation of a lower extremity is presented and discussed. The guideline provides recommendations for diagnosis, referral, assessment, treatment and reintegration of patients undergoing amputation of a lower extremity and can be used to provide patient information. It also provides a starting point for local transmural agreements or protocols to promote implementation.

The specific objectives of this guideline are preventing injury to patient health by providing concrete recommendations regarding improved diagnostic and therapeutic possibilities, and the provision of clear statements on diagnosis and treatment and on the reintegration process to be followed by the patient. The goal is to achieve uniformity regarding the diagnosis, treatment and support in the various centres and to define the framework within which the multidisciplinary care of patients who undergo amputation of a lower extremity should take place. This guideline will also contribute to improved communication between clinicians and patients and between practitioners themselves, with special emphasis on the somatic, psychological, technical and care aspects.

The reader should consider that many of the treatment procedures we use in daily practice are common sense and in the absence of evidence certainly established. There are some treatments where level 1 or 2 evidence will never be available, and strict supporters of evidence-based practice should not become dogmatic and absence of evidence.

This guideline provides recommendations for the process of assessment of amputation up to and including the first definitive delivery of the prosthesis but limits itself to adult patients and makes no recommendations regarding amputation and prosthetics in children.

Because 90%–95% of amputations occur in patients with vascular disease, this guideline focuses primarily on this patient group. Oncological amputations and amputations due to trauma are only briefly discussed in this guideline.

This article is divided into part 1 and part 2. In part 1, the indication criteria for amputation, surgical techniques, patient information, postoperative management, pain management and complications are discussed. In part 2, the focus will be on the rehabilitation process including, psychosocial aspects, rehabilitation factors and training goals, return to work, prosthetic provision and components and other considerations.

Methods

The recommendations in this guideline are, for as far as possible, based on evidence from published scientific research. Relevant articles were identified by performing systematic searches in the Cochrane Library, MEDLINE, Embase, PsycINFO and CINAHL. Languages were limited to Dutch, English, German and French. Manual searches were also conducted. Search dates were between 1966 (MEDLINE) and 1980 (Embase) and no later than January 2011. The main keywords used to identify the patient population in MEDLINE were as follows: Medical Subject Heading (MeSH) terms – Amputation/or Disarticulation/or Amputation Stumps/or Amputation, Traumatic. Important selection criteria were as follows: comparative studies with robust evidence such as meta-analyses, systematic reviews, randomised controlled trials (RCTs) and controlled trials (CTs). Where these were unavailable, further comparative cohort studies, comparative case-control studies or non-comparative studies were sought. Case reports were also used to aid opinion-forming regarding certain key questions. The quality of these articles was assessed by epidemiologists from the Dutch Institute for Healthcare Improvement (CBO) on the basis of evidence-based guideline development

Table 1. Classification of methodological quality of individual studies.

	Intervention	Diagnostic accuracy of research	Injury or side effects, aetiology, prognosis[a]
A1	Systematic review of at least two independent studies of level A2		
A2	Randomised double-blind comparative clinical studies of good quality and sufficient scope	A study in comparison with a reference test ('gold standard') with predefined limitations and independent assessment of the results of test and gold standard values, on a sufficiently large series of consecutive patients, with all having undergone both the index and reference test	Prospective cohort study of sufficient size and follow-up, which is adequately controlled for confounding and in which selective follow-up is sufficiently excluded
B	Comparative study, but not including all the features listed under level A2 (this also includes case-control studies, cohort studies)	Study compared with a reference test, but not with all features described under level A2	Prospective cohort study, but not with all features described under level A2 or retrospective cohort study or case-control study
C	Non-comparative study		
D	Expert opinion		

[a]This classification applies only in situations where controlled trials are not possible for ethical or other reasons. When controlled trials are possible, the classification for interventions is valid.

Table 2. Level of conclusions.

	Conclusion based on
1	Study of level A1 or at least two independently conducted studies of level A2, with consistent results
2	One study of level A2 or at least two independently conducted studies of level B
3	One study of level B or C
4	Expert opinion

(EBRO) assessment forms. Articles of mediocre or poor quality were excluded. After this selection, the remaining articles formed the basis for the various conclusions set out in the guideline. The selected articles were then graded according to the degree of proof, using the following format (Table 1). The degree and level of evidence are described in Table 2.

In order to arrive at a recommendation, in addition to the scientific evidence, other aspects are often of importance, including patient preferences, availability of special techniques or expertise, organisational aspects, social consequences and costs. The definitive recommendation is based on the available evidence in conjunction with these considerations (in text in italics).

Results

Indication criteria for amputation

Database and cited reference search revealed 28 relevant studies after selection. Also, the results were largely based on the international Trans-Atlantic Inter-Society Consensus for the Management of Peripheral Arterial Disease,[3] the VA/DoD Clinical Practice Guideline For Rehabilitation of Lower Limb Amputation[4] and the *Guideline of Diagnostics and Treatment of Vascular Disorders of the Lower Extremity* by the Dutch Society for Surgery and the Radiological Society of the Netherlands.[5]

The working group recommends that all diabetic patients with ulcers be assessed for peripheral vascular disease using objective tests such as duplex in combination with ankle–brachial index.

To avoid possible amputation, it is recommended that patients with critical ischaemia and patients who develop foot ulcers be treated using a multidisciplinary approach (including a surgeon, interventional radiologist, vascular internist and rehabilitation physician).

When the condition of the patient is too poor to allow a planned revascularisation procedure or when it is unlikely that restoration of circulation will lead to a functional extremity, primary amputation must be considered.

Multidisciplinary treatment (surgeon, anaesthesiologist/pain specialist, rehabilitation physician and possibly internist) is also necessary for the treatment of pain, cardiovascular risks, co-morbidity and the co-determination of the amputation level.

A secondary amputation should be performed when a subsequent vascular reconstruction is no longer possible or whether, despite successful vascular reconstruction, a progressive distal deterioration has occurred.

An amputation is necessary and/or indicated when there is a severe (life-threatening) infection, a foot lost to extensive necrosis or intractable pain due to vascular disease.

Critical ischaemia may be an indication for amputation in patients with arterial obstructive vascular disease.

Immediate amputation should be considered in cases of acute ischaemia and sepsis.

Clinical criteria are used to assess the amputation level. It may be helpful to take transcutaneous oxygen or toe pressure measurements. Arterial disease can be demonstrated with non-invasive or with invasive vascular examination. The vascular laboratory plays an important role in non-invasive studies.

It is advisable to assign a vascular surgeon as the chief clinician for a patient with critical ischaemia.

Before deciding to proceed with amputation, the vascularisation of the extremity should be assessed by means of physical examination and assessment of the level and quality of arterial pulsations, the degree of ischaemia and co-morbidity.

In addition to the clinical assessment, additional tests such as transcutaneous oxygen measurements or toe pressure measurements can be carried out. Initial localisation of vascular anomalies can take place with the help of haemodynamic measurements such as segmental blood pressure measurement or pulse volume recording.

In the case of a discrepancy between clinical and pressure measurements, vascular imaging can be definitive.

Where imaging of arterial abnormalities is necessary for treatment decisions, the following techniques are recommended: (1) duplex examination, (2) digital subtraction angiography (DSA), (3) magnetic resonance angiography (MRA) and (4) computed tomography angiography (CTA). If the vascular status of the extremity is not yet established or if demarcation of the region for amputation has not yet taken place, it is advisable to postpone amputation.

Deferred amputation should not take place within the first 3 weeks after revascularisation because blood flow to the leg can still improve within the 3 weeks following revascularisation.

The decision to amputate should be taken by an experienced surgeon, familiar with the multiple treatment methods at the various amputation levels, muscle balance and wound closure. Experience with amputation techniques is of importance. The amputation should preferably be performed by an experienced surgeon or supervised by an experienced surgeon.

It is recommended that treatment takes place within a multidisciplinary amputation team (consisting of a surgeon, rehabilitation physician, anaesthesiologist/pain specialist, physiotherapist and possibly an orthopaedic technician or prosthetist).

When determining the level of amputation, the preoperative mobility and prospects for postoperative patient mobility should be considered.

In patients with an indication for amputation and limited mobility, aged over 70 years, with dementia, end-stage renal disease and/or severe coronary artery disease, a transfemoral amputation (TFA) or knee-disarticulation (KD) should be considered.

If the above considerations rule out a transtibial amputation (TTA), a KD may be considered due to its relative advantages over a TFA (all level 4).

Surgical techniques

A systematic search of MEDLINE and Embase was conducted, which included searching for systematic reviews, RCTs and cohort studies. The search yielded 276 abstracts. A 'full text' assessment was eventually performed in 48 articles, after screening for content and study design (RCT). Following evaluation, the remaining six articles are all related to TTAs.[6–10] No items of sufficient academic quality were found on TFA or KD. This finding has been described earlier in the 'ISPO consensus conference (1990) report on amputation surgery', published in 1992.[11] No new items have appeared since.

In a Cochrane review by Tisi and Callam of the scientific literature up to July 2008, the authors searched for RCTs that evaluated the effect of different surgical techniques in patients with ischaemia of a lower extremity.[12] They only found three RCTs. Although the review was of high quality, the included trials were of limited size with the exception of that of Ruckley et al. There was also no possibility of blinding in these studies. Therefore, the evidence from this review can be classified as level A2, once[6] and level B, twice. A comparison of 'two-stage below knee amputations (BKA)' (guillotine amputation at the ankle followed by a long posterior flap BKA with delayed primary skin closure) with 'one-stage BKA' in a small RCT of 30 patients showed a better stump healing after 6 months in the 'two-stage' group (odds ratio (OR) = 0.08; 95% confidence interval (CI) = 0.01–0.89). However, there was no difference in the postoperative infection rate or the re-amputation rate.[7] The mobility rate did not differ significantly (47% in the 'two-stage' group and 54% in the 'one-stage' group).

There are indications that 'two-stage' TTA stump results in better healing than the 'one-stage' technique with 'long posterior flap', but it does not lead to improved long-term outcomes (level 4).

In a trial by the Joint Vascular Research Group (n = 191), 'skew flap' BKA was compared with 'long posterior flap' BKA.[6] After almost 12 months, no difference in stump healing, infection or re-amputation rate was found. Mobility (60% for 'skew flaps' and 49% for 'long posterior flap') was also not significantly different (relative risk (RR) = 1.22; 95% CI = 0.94–1.58). The reviewers note, however, that the surgeons participating in the RCT probably had little experience with the 'skew flap' procedure. This may have played a role in the absence of an effect.

There is no evidence that the 'skew flap' procedure gives better results than 'long posterior flap' procedure (level 2).

Finally, a small RCT with 41 patients showed that stump healing in patients treated with 'sagittal flap' (58%) did not differ from that of patients treated with 'long posterior flap' (55%) (OR = 1:04; 95% CI = 0:45 to 2:43). There was no difference in the re-amputation rate, the percentage with a suitable prosthesis or mortality between the two groups. Mobility was also equivalent.[8]

Evidence suggests that a TTA with a 'sagittal flap' does not give superior results compared with 'long posterior flap' (level 3).

A rule of thumb is that an osseous length of 10–15 cm below the medial knee joint gap is optimal in a TTA. An alternative is that the length of the amputated tibia is equal to the width of the tibial plateau. However, contraindications are when an infection is present at less than 3 cm from the tibial tuberosity. This is because knee extension cannot be performed with a very short stump. The fibula should be cut at least 1 cm more proximally than the tibia. The distal bone structures are dissected at an angle of 40°–60° and rasped to prevent damage to the myocutaneous flap. If the bone is cut with the aid of a mechanically driven saw, cooling with physiological saline can prevent thermal injury to the bone; an ischaemic leg has no heat regulatory mechanisms. Irrigating the wound also prevents contamination with bone meal.

In a TTA, an osseous length of 10–15 cm below the medial knee joint gap is optimal (level 4).

The evidence on surgical techniques in TFAs and KD lacks a truly firm foundation. When a KD is possible, it is preferable to a TFA. There is no favoured site for the height of a TFA. The assessment should be based on whether or not the knee joint can be saved. The skin is cut using the fish mouth approach. A priority should be to preserve as much length as possible. However, in the case of a very short thigh stump, a hip disarticulation may offer a better solution for the subsequent provision of a prosthesis. Fixation of the amputated muscles through a myodesis results in an improved and more stable stump, through the preservation of muscle volume and opportunities for improved revalidation. It is also important to avoid flexion contracture of the hip. The hip adductor muscles, in particular the adductor magnus, are important in countering lateral movements of the femur. The bonding of the adductors to the stump will, therefore, be a priority. If a stump is too short, an abduction contracture may occur, and a stump that is too long may pose a problem when installing a prosthetic knee. The contralateral side should be taken as a benchmark, with a length of at least 10 cm above the medial knee joint gap. The patellar tendon should be fixed to the cruciate ligaments in a KD, but the patella should not to be fixed by K wires and should not be removed. Nerves should be cut under traction. The members of the working group have therefore formulated their own recommendations (based on expert opinion).

The goal of a TFA is to obtain, by means of a myodesis, a dynamic stump with good motor control and sensitivity.

The fish mouth incision should preferably be used during TFA.

In a TFA, the aim should be to maintain the maximum length possible. However, in order to install a knee prosthesis and to maintain a thigh of equal length to the contralateral side, amputation should occur at least 10 cm proximal to the medial knee joint space.

If possible, a KD is preferable to a TFA. The patella should not be fixed and should not be removed. A strong preference was expressed for a myodesis, in this case, the securing of the patellar tendon.

The preferred incision in the case of a KD extends from the attachment of the patellae ligament to both sides and produces two symmetrical skin flaps (all level 4).

Choksy et al.[9] published the results of a well-conducted RCT (n = 64) on the effect of a tourniquet in TTA. Use of a tourniquet resulted in less blood loss and lower transfusion requirements. In an observational pilot study in 89 patients who underwent a TTA, Wolthuis et al.[10] looked at the effect of a tourniquet on the same and several additional outcome parameters. Similar reductions in blood loss and transfusion requirements were seen, but they also reported a significant reduction in the number of stump revisions.

It is likely that the use of a tourniquet in TTA results in less blood loss and a reduced need for transfusion (level 2).

There are indications that the use of a tourniquet in TTA leads to fewer stump revisions (level 3).

The use of a tourniquet in TTA is recommended because tourniquet use results in less blood loss and may also result in fewer stump revisions (level 4).

Patient information

No literature was found on the subject of information for patients with an amputation of a lower extremity. Instead, interviews with a total of 32 patients were used.

Information is a vital part of any medical treatment, and this is also confirmed in the Dutch Law on the Medical Treatment Agreement (WGBO) (1995). Any information must be tailored to the specific needs of the individual patient and included in patient records. It is useful to prepare a checklist detailing the minimum information that should be provided to the patient. This can be completed and supplemented by every practitioner involved in the treatment. As in the specific case of an amputation, the patient comes into contact with a relatively large number of disciplines, the development of a single information dossier should be considered so that each discipline can see which items have already been discussed and what may still need attention.

Treatment should be consistent and consistently implemented and should ideally follow a set framework or care plan. Therefore, when the treatment plan has changed in the course of the treatment for any reason, this must be explained and discussed with the patient. In the case of transfer to another healthcare institution, a satisfactory transfer of information must take place and the treatment should ideally be seamlessly continued.

It should be made clear that treatment is carried out by a team, with an emphasis on the influence of the patient on the treatment plan as a whole and with objectives suited to the future needs of the patient. It makes sense to ensure that recurring discussions take place not only in the presence of the patient but also with the involvement of family members and other involved parties. A patient should be in the best possible condition when deciding for amputation (in particular, pain-free). The treating disciplines, depending on local circumstances are: Rehabilitation physician, Specialist in geriatric medicine or elderly care, Anaesthesiologist (pain specialist), Physiotherapist, Nurse, Prosthetist, Orthopaedic shoemaker, Occupational therapist, Healthcare psychologist, Activity coordinator, Social worker, Dietician, Pastoral carers and Movement therapist.

Points to consider when providing information to patients undergoing leg amputation, including an aspect of self-management (the order is not intended to suggest any particular sequence in time), are as follows:

- Causes of amputation and complicating factors: diabetes mellitus, vascular problems in general, tumours, trauma, smoking and nutritional status;
- Time schedule of the entire treatment;
- Amputation level: practical consequences and future (im)possibilities;
- Functional prognosis, dependent on amputation level, age and health status (co-morbidity) and also the psychological condition of the patient;
- Complications: wound problems (infection, wound dehiscence, poor stump shape), chances of re-amputation, phantom pain (sensations) and stump pain;
- Importance of wound healing, stump healing and stump dressing, aspects related to oedema;
- Practicing with the stump in terms of agility, co-ordination, muscle strength and contracture prevention;
- Stump and skin care;
- Physical consequences for the rest of the body (e.g. increased energy consumption when walking);
- Coming to terms with the amputation (anxiety, depression but also teaching of coping strategies), reaction of the social environment;
- Consequences for the social environment and social contacts;
- Practice by the patient with and without a prosthesis in various everyday situations (gait training, balance training, transfers, fall training, sports and games, etc.) but also in terms of activities of daily living (ADL) such as dressing, washing and household tasks;
- Types of prostheses and their components;
- Measuring and fitting of the prosthesis, including the maintenance and care of the prosthesis;
- Sexuality;
- Adjustments in the home and in assistive devices;
- Social adjustments, help with dealing with government bodies, reintegration into society and the workplace;
- Dismissal and any follow-up arrangements;
- Patient information and peer support;

Information for patients (electronic, oral or written) and for those directly involved in patient care is an essential component in the treatment of patients undergoing amputation of a lower extremity.

Treatment should be consistent and consistently implemented, ideally in the form of a care plan.

As treatment involves multiple disciplines, it is advisable that any items discussed are recorded and defined in a manner that is clear to all disciplines.

Information resources should be developed at the local level (all level 4).

Postoperative management

The main objectives in the immediate postoperative phase relate to wound healing, pain control, forming of the amputation stump and early mobilisation.[1] A specific focus is the treatment of oedema, which is intrinsic to TTA and negatively affects wound healing. Oedema causes increased pressure in the stump and thereby increased tension on the suture, which may result in skin necrosis due to insufficient microcirculation.[13] Both in clinical practice as well as in the scientific literature, the discussion surrounding the choice of postoperative dressing focuses on the TTA patient group. In general, light elastic bandages or stump stockings are recommended for TFA stumps.[1]

A systematic search was conducted in MEDLINE and Embase for systematic reviews, RCTs and cohort studies. The search yielded 218 abstracts. After screening for content and study design (RCT), 28 articles were reviewed in full text. Following this evaluation, six articles remained: three studies in which a 'rigid dressing' (RD) was compared with a soft dressing (SD),[14–16] a study in which a 'plaster cast socket' was compared with an elastic bandage,[17] a study comparing the effect of a vacuum fabricated removable rigid dressing (RRD) and that of a conventionally manufactured RD[18] and a study[19] in which the effect

of a RRD on reduction of the stump volume was examined in comparison with an SD.

The methodological quality of three studies[14–16] was poor to moderate and included an inadequate description of co-interventions, compliance, drop-out rates and blinding. Blinding of the patient and practitioner in this type of research is difficult, but blinding of the assessor is possible in some cases. The moderate methodological quality leads to a substantial risk of bias. In most of the studies, there was no or only a summary description of inclusion criteria, and some studies also lacked clear initial criteria regarding primary or secondary outcome measures, thus resulting in a possibility of selective reporting. The only outcome measure in these studies[14–16] was 'time (days) to fitting of a prosthesis'. The studies by Deutsch and Woodburn found no significant difference in number of days to fitting of a prosthesis, while the study by Wong did report a significant difference. Given the different approaches to data presentation, it is difficult to compare these studies.

The study by Vigier et al.[17] (n = 56) compared the effect of a RD, which had to be worn for 5 h a day, with that of a SD. The study was of poor methodological quality (e.g. poorly described randomisation, lack of blinding). Large and significant effects were found in favour of the RD with respect to wound healing (71.2 ± 31.7 vs 96.8 ± 54.9 days; p = 0.04) and hospital stay (99.8 ± 22.4 vs 129.9 ± 48.3 days; p = 0.04).

In a study by Johannesson et al.[18] (n = 27), a 'vacuum-manufactured RRD' was compared with a conventional RRD. The study was of sufficient methodological quality, and similar results were found for the vacuum-manufactured RRD compared with the conventional RRD with respect to time to prosthetic fitting, wound healing and function at 3 months.

There is a small difference in favour of the (semi-)RD in comparison with the SD in terms of a reduction in the number of days to prosthesis fitting (level 2).

There is a difference in favour of the RD in comparison with the SD in the time required for wound healing (level 3).

There appears to be no difference between the manufactured vacuum RRD and conventional RRD with respect to time to prosthesis fitting, wound healing and function at 3 months (level 3).

In comparison with the SD, the RD seems to result in fewer contractures (level 4).

In relation to the objectives of postoperative management and the evidence in the literature, a number of additional factors may need consideration such as knee flexion contracture, wound healing of the amputation stump, volume of the amputation stump, stump pain management, stump protection, time to prosthetic fitting, performance with a prosthesis, clinical practice and organisational considerations. The working group considers that

In patients with TTA or KD, a RD is the treatment of choice during the early postoperative phase.

Before switching to treatment with a RD, all logistical obstacles should have been overcome.

The RRD may be considered when one wishes to apply a RD in patients with TTA and regular wound monitoring is indicated.

The working group is of the opinion that current postoperative management regarding stump dressing in TFA patients can be maintained. RDs are not recommended (all level 4).

Pain management

Amputation of a (part of) a lower extremity is a major mutilating procedure, with matching high postoperative pain scores. It is therefore important that appropriate postoperative pain management be applied in order to treat acute amputation stump pain. In addition to acute pain following amputation, a considerable number of patients develop chronic pain syndromes following treatment. Phantom pain, experienced as painful sensations in the amputated limb, is a neuropathic pain syndrome probably caused by central and peripheral neural mechanisms. There are also indications that neuroplastic changes play a role. Following the acute phase, some patients continue to experience pain in the stump, which is then described as chronic stump pain.[20] The source of pain in chronic stump pain is in the stump itself. Many patients experience pain even before amputation. During this phase, an anaesthesiologist (pain specialist) and a rehabilitation physician should be involved in the consultation. The literature was searched for evidence for a reduction in the incidence and severity of stump and phantom pain due to the use of certain anaesthetic techniques or the use of adjuvant pain medication, in addition to 'standard' postoperative pain management. A systematic search of MEDLINE, Embase and PsycINFO was conducted. The search yielded 204 abstracts. After screening for content and study design (RCT), seven relevant studies remained to address this question.[21–27] In general, the studies were of reasonable to good methodological quality, and almost all studies showed well-executed randomisation and blinding of patients, clinicians and assessors. The reporting of co-interventions and compliance (therapy adherence) were points on which some studies were inadequate. Most of the studies included a limited number of participants and four of the seven studies showed a high drop-out rate.[21,23–25]

Epidural or perineurial administration of bupivacaine, compared with placebo, has no significant effect on the intensity of stump and phantom pain in the short/medium–long (≤6 months) and long-term (12 months) (level 2).

Ketamine (epidural or intravenous), compared with placebo, has no significant effect on the incidence and

intensity of stump and phantom pain in the short/medium–long (≤6 months) and long-term (12 months) (level 2).

Compared with placebo, gabapentin has no effect on the incidence and intensity of stump and phantom pain in the short/medium–long-term (≤6 months) (level 3).

There is no difference between epidural and perineurial analgesia (bupivacaine) in the incidence of stump pain and phantom pain over the long term (12 months) (level 3).

Non-pharmacological therapies such as Transcutaneous Electrical Neurostimulation, Farabloc and psychological interventions such as mirror therapy, eye movement desensitisation and reprocessing (EMDR) and hypnosis are often used later in the rehabilitation process and therefore fall outside the scope of this guideline. Specialised techniques in the field of chronic pain management also fall outside the scope of this guideline.

Acute postoperative pain should be treated in accordance with the insights detailed in the Dutch guideline 'Postoperative pain treatment'.

Epidural treatment has a place in the perioperative management of pain.

Continuing pain treatment by epidural or perineurial catheters, despite having no significant effect on phantom pain over the medium–long term, has a place in the treatment of acute postoperative pain following amputation.

Due to neurotoxicity, epidural infusion of ketamine cannot be recommended.

Use of gabapentin can be considered for patients with phantom pain.

Use of amitriptyline can be considered for patients with phantom pain (all level 4).

Complications

Many complications can occur following an amputation of a lower extremity. They may be of a psychological nature (self-esteem, stress, etc.), the effects of pre-existing co-morbidities (heart failure), but may also be at the local level. Local complications may include (more at the transtibial level than the transfemoral level) wound healing disorders, skin problems, allergies (prosthetic materials), oedema, pain (phantom pain and stump pain) but also contractures of adjacent joints. These complications can occur at any level of amputation.

Amputations in the knee area result in common complications, the most important being wound healing disorders. These can be divided into disorders that lead to secondary wound healing after treatment (such as wound edge necrosis, dehiscence and infection) and disorders that are so severe that re-amputation is necessary (usually progressive ischaemia with extensive necrosis or wound infection with sepsis). In addition, factors related to the surgical technique can lead to amputation stumps that do not allow loading (and thus mobility). Finally, contractures may occur during the postoperative period, leading to the loss of a chance of mobility.

A systematic search was conducted in MEDLINE and Embase for articles (systematic reviews, RCTs and observational studies) that reported on the complications that occur in an amputation of a lower extremity and/or how these complications can be prevented. The search yielded 207 abstracts. After screening for content and study design (RCT), 16 titles underwent a full text assessment. After exclusion of items that did not relate to the initial question (n = 4), case reports (n = 2) and a study that was already described in our selected systematic review (n = 1), 10 articles remained and are discussed below.[28–37] The 10 selected articles are diverse in their design (six retrospective cohorts, three prospective cohorts and one systematic review). Besides the design, the differences in the structure of the cohorts are also large. The cohorts vary greatly in size (range 50–545 patients), in the mean age (range 28–81 years), in the reasons for amputation (only traumatic, only non-traumatic or a combination of both) and in the level of amputation (hip, knee or ankle), and the number of inclusion and exclusion criteria vary from none to many. The most common amputation was around the knee; however, again a distinction was made (above, between or below the knee). In addition, the description of co-morbidity was very different between studies. And finally, the studies generally used different outcome measures. Together, these differences prevent the drawing of an overall conclusion. In addition, in the majority of cases, the results were not categorised by amputation level, which is also not beneficial to the reliability of the results. This has resulted in a brief explanation of all 10 studies and, where possible, a combination of the scientific evidence.

It is likely that the use of prophylactic antibiotics leads to fewer stump infections in comparison with placebo or no antibiotic use (level 2).

In a general population, re-amputation is significantly more common following a TTA as compared with a TFA (level 3).

The complications following a KD amputation include perioperative mortality (<10%) and poor wound healing that often requires re-amputation (20%) (level 3).

In general, complications due to an amputation of the lower extremities include perioperative mortality (<18%) and re-amputation (<14%) (level 3).

Factors associated with wound complications (within 90 days after amputation) are TTA, the type of anaesthesia (general and epidural), home living and a preoperative haematocrit >30 (level 3).

The preservation of the patient's knee has great advantages in terms of the chances of becoming mobile. Every effort must be made to achieve primary wound healing and maintain the level of a TTA. Good surgical technique, which ensures an optimal osseous tibia stump length (10–15 cm), no excess soft tissue, no neuromas and ultimately a good blunt conical shape, mobile scars and the prevention of contractures, helps to ensure that the patient has a 10%–20%

greater chance of postoperative mobility. An experienced surgeon achieves better results, both in terms of the possibility of mobility as in a lower probability of re-amputation.[37]

The annual minimum number of procedures required of a surgeon has been a matter of much debate in medical circles in the Netherlands, a debate that is equally relevant in amputation surgery. In the learning phase, it seems appropriate that a surgeon should perform 20 major amputations with particular attention given to the composition of indicators and the complete perioperative supervision of patients. An additional important factor is not the number per year but involvement in a multidisciplinary amputation team in a hospital (see previous definition in the guideline). A figure of 5–10 amputations per surgeon per year may then be adequate to sufficiently stimulate the entire amputation team to together deliver good-quality work.

To prevent wound infection following amputation, perioperative prophylactic antibiotic treatment is recommended in the form of a preoperative bolus or for 5 days starting immediately preoperatively.

Because a good surgical technique increases the chance of postoperative mobility, amputations should be carried out by experienced surgeons who conduct a minimum number of 5–10 amputations each year. The absolute number per year is less important than permanent membership of a multidisciplinary team with sufficient incentives to jointly deliver good-quality work.

The working group recommends that a team be formed around the amputee in the hospital phase and should at least include a surgeon, a rehabilitation physician, an anaesthesiologist and physiotherapist, and preferably supplemented with a dietician, a social worker, a healthcare psychologist or pastoral worker.

Preliminary conclusion

In this part 1, the indication criteria for amputation, surgical techniques, patient information, postoperative management, pain management and complications are discussed. We were surprised that there was so little evidence in the field of indication criteria for amputation and amputation surgery. The final conclusion will be at the end of part 2 in which the early rehabilitation process is described.

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Author contribution

All authors contributed equally in the preparation of this manuscript.

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References

1. Geertzen JHB and Rietman JS. *Amputatie en prothesiologie van de onderste extremiteit* [Amputation and prosthetics of the lower extremity]. Den Haag: Lemma Publishers, 2008.
2. Van der Linde H. *Prosthetic prescription in lower limb amputation: development of a clinical guideline in the Netherlands*. PhD Thesis, University of Groningen, Groningen, The Netherlands, 2004.
3. Norgren L, Hiatt WR, Dormandy JA, et al.; on behalf of the TASC II Working Group. Inter-society consensus for the management of peripheral arterial disease (TASC II). *J Vasc Surg* 2007; 45(1): S5a–S66a.
4. The Rehabilitation of Lower Limb Amputation Working Group, Department of Veterans Affairs and Department of Defense. *VA/DoD clinical practice guideline for rehabilitation of lower limb amputation*. Version 1.0, 2007, http://www.healthquality.va.gov/amputation/amp_v652.pdf
5. *Guideline of diagnostics and treatment of vascular disorders of the lower extremity* (in Dutch). Dutch Society for Surgery and the Radiological Society of the Netherlands, 2005. Van Zuiden Communications BV, Alphen aan de Rijn.
6. Ruckley CV, Stonebridge PA and Prescott RJ. Skewflap versus long posterior flap in below-knee amputations: multicenter trial. *J Vasc Surg* 1991; 13(3): 423–427.
7. Fisher DF Jr, Clagett GP, Fry RE, et al. One-stage versus two-stage amputation for wet gangrene of the lower extremity: a randomized study. *J Vasc Surg* 1988; 8(4): 428–433.
8. Termansen NB. Below-knee amputation for ischaemic gangrene. Prospective, randomized comparison of a transverse and a sagittal operative technique. *Acta Orthop Scan* 1977; 48(3): 311–316.
9. Choksy SA, Lee CP, Smith C, et al. A randomised controlled trial of the use of a tourniquet to reduce blood loss during transtibial amputation for peripheral arterial disease. *Eur J Vasc Endovasc Surg* 2006; 31(6): 646–650.
10. Wolthuis AM, Whitehead E, Ridler BMF, et al. Use of a pneumatic tourniquet improves outcome following transtibial amputation. *Eur J Vasc Endovasc Surg* 2006; 31(6): 642–645.
11. Murdoch G, Jacobs NA and Wilson AB Jr. *Report of ISPO consensus conference on amputation surgery, University of Strathclyde, Scotland, 1–5 October, 1990*. ISPO, Copenhagen,1992.
12. Tisi PV and Callam MJ. Type of incision for below knee amputation. *Cochrane Database Syst Rev* 2004; 1: CD003749.
13. Baumgartner R. *Amputation und Protheseversorgung der untere Extremität*. Stuttgart: Enke Verlag, 1995.
14. Deutsch A, English RD, Vermeer TC, et al. Removable rigid dressings versus soft dressings: a randomized, controlled study with dysvascular, trans-tibial amputees. *Prosthet Orthot Int* 2005; 29(2): 193–200.

15. Woodburn KR, Sockalingham S, Gilmore H, et al. A randomised trial of rigid stump dressing following trans-tibial amputation for peripheral arterial insufficiency. *Prosthet Orthot Int* 2004; 28(1): 22–27.
16. Wong CK and Edelstein JE. Unna and elastic postoperative dressings: comparison of their effects on function of adults with amputation and vascular disease. *Arch Phys Med Rehabil* 2000; 81(9): 1191–1198.
17. Vigier S, Casillas JM, Dulieu V, et al. Healing of open stump wounds after vascular below-knee amputation: plaster cast socket with silicone sleeve versus elastic compression. *Arch Phys Med Rehabil* 1999; 80(10): 1327–1330.
18. Johannesson A, Larsson GU, Oberg T, et al. Comparison of vacuum-formed removable rigid dressing with conventional rigid dressing after transtibial amputation: similar outcome in a randomized controlled trial involving 27 patients. *Acta Orthop* 2008; 79(3): 361–369.
19. Janchai S, Boonhong J and Tiamprasit J. Comparison of removable rigid dressing and elastic bandage in reducing the residual limb volume of below knee amputees. *J Med Assoc Thai* 2008; 91(9): 1441–1446.
20. Halbert J, Crotty M and Cameron ID. Evidence for the optimal management of acute and chronic phantom pain: a systematic review. *Clin J Pain* 2002; 18(2): 84–92.
21. Nikolajsen L, Ilkjaer S, Christensen JH, et al. Randomised trial of epidural bupivacaine and morphine in prevention of stump and phantom pain in lower-limb amputation. *Lancet* 1997; 350: 1353–1357.
22. Nikolajsen L, Ilkjaer S, Jensen TS, et al. A randomized study of the effects of gabapentin on postamputation pain. *Anesthesiology* 2006; 105(5): 1008–1015.
23. Hayes C, Armstrong-Brown A and Burstal R. Perioperative intravenous ketamine infusion for the prevention of persistent post-amputation pain: a randomized, controlled trial. *Anaesth Intensive Care* 2004; 32(3): 330–338.
24. Bone M, Critchley P and Buggy DJ. Gabapentin in post-amputation phantom limb pain: a randomized, double-blind, placebo-controlled, cross-over study. *Reg Anesth Pain Med* 2002; 27(5): 481–486.
25. Lambert AW. Randomized prospective study comparing preoperative epidural and intraoperative perineural analgesia for the prevention of postoperative stump and phantom limb pain following major amputation. *Reg Anesth Pain Med* 2001; 26(4): 316–321.
26. Pinzur MSG. Continuous postoperative infusion of a regional anesthetic after an amputation of the lower extremity: a randomized clinical trial. *J Bone Joint Surg Am* 1996; 78(10): 1501–1505.
27. Wilson JA, Nimmo AF, Fleetwood-Walker SM, et al. A randomised double blind trial of the effect of pre-emptive epidural ketamine on persistent pain after lower limb amputation. *Pain* 2008; 135: 108–118.
28. Stone PA, Flaherty SK, Aburahma AF, et al. Factors affecting perioperative mortality and wound-related complications following major lower extremity amputations. *Ann Vasc Surg* 2006; 20(2): 209–216.
29. McIntosh JE. Antibiotic prophylaxis for the prevention of infection after major limb amputation. *Eur J Vasc Endovasc Surg* 2009; 37(6): 696–703.
30. Cruz CPE. Major lower extremity amputations at a Veterans Affairs hospital. *Am J Surg* 2003; 186(5): 449–454.
31. Morse BCC. Through-knee amputation in patients with peripheral arterial disease: a review of 50 cases. *J Vasc Surg* 2008; 48(3): 638–643.
32. Kock HJF. Long-term results of through-knee amputation with dorsal musculocutaneous flap in patients with end-stage arterial occlusive disease. *World J Surg* 2004; 28(8): 801–806.
33. Nehler MRC. Functional outcome in a contemporary series of major lower extremity amputations. *J Vasc Surg* 2003; 38(1): 7–14.
34. Campbell WBM. Factors influencing the early outcome of major lower limb amputation for vascular disease. *Ann R Coll Surg Engl* 2001; 83(5): 309–314.
35. Johannesson AL. From major amputation to prosthetic outcome: a prospective study of 190 patients in a defined population. *Prosthet Orthot Int* 2004; 28(1): 9–21.
36. Ten Duis K, Bosmans JC, Voesten HGJ, et al. Knee disarticulation: survival, wound healing and ambulation. A historic cohort study. *Prosthet Orthot Int* 2009; 33(1): 52–60.
37. Awopetu AI, Moxey P, Hinchliffe RJ, et al. Systematic review and meta-analysis of the relationship between hospital volume and outcome for lower limb arterial surgery. *Br J Surg* 2010; 97: 797–803.