ISPO Report
Major Lower Limb Amputations Due to Vascular Disease: A Multidisciplinary Approach to Surgery and Rehabilitation

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I. INTRODUCTION

Vascular disease is the most common cause of amputation, accounting for 82% of all amputations.[1] Although the incidence of amputation due to trauma and cancer has decreased,[1, 2] amputation due to vascular disease continues to increase. This report is specifically directed to the management of individuals with peripheral arterial disease (PAD) who are at risk or have undergone major lower limb amputation (above the ankle) and includes the amputation continuum from preoperative evaluation and limb salvage through surgical decision making, early postoperative rehabilitation, and residual limb healing. Assessment by a multidisciplinary team in the preoperative phase forms the basis for the policies to be followed after surgery and during the rehabilitation process. The involvement of multiple disciplines reduces the risk of complications during surgery and the postoperative phase.[3] In this report, we discuss:

- Evaluation and management of PAD and critical limb ischemia (CLI) prior to major lower limb amputation due to vascular disease
- Amputation surgery
- Postoperative dressings following amputation surgery
- Postoperative management in the immediate postoperative period
- Rehabilitation from amputation to initial prosthetic management
- Pain management following amputation
- Prosthetic prescription following lower extremity amputation due to vascular disease

This ISPO consensus report is realized thanks to ISPO International, Otto Bock, Protheor, Ossur, and Blatchford with the engagement and cooperation of the members of the ISPO consensus meeting February 2015, Basingstoke, UK. Dutch Evidence-Based Guidelines for Amputation and Prosthetics of Lower Extremity: Amputation Surgery and Postoperative Management. Part 1[4] and Dutch Evidence-Based Guidelines for Amputation and Prosthetics of the Lower Extremity: Rehabilitation Process and Prosthetics. Part 2[5] were published in 2015. Over the past few years, additional relevant papers regarding management of lower limb amputation due to vascular disease have been published. The ISPO International Consensus Group comprised of academicians, clinicians, and researchers was chosen to update the 2015 guidelines. The composition of the Consensus Group was based on profession, region of the world, and expertise. Members included surgeons (vascular and orthopedic), physicians (internal medicine and rehabilitation), prosthetists, therapists, engineers, and a psychologist all with expertise in amputation surgery and/or prosthetic rehabilitation. The goal of this report is to provide an updated international version of the previous Dutch guidelines. This report is created for care providers throughout the world who are involved in the care of people with lower limb amputation due to vascular disease. Resources and expertise differ widely in many parts of the world. We hope that updating the Dutch guidelines to create an international report will help nations establish their own care directives.

II. METHODS

DATA SOURCES AND SEARCHES

In 2015, the Netherlands Society of Physical and Rehabilitation Medicine (VRA), a national society for medical specialists in rehabilitation medicine, and the Utrecht-Based Dutch Institute for Healthcare Improvement (CBO) developed the Dutch Guidelines for amputation and prosthetics of the lower extremities.

The recommendations in the 2015 Dutch guidelines[4, 5] were 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. Additional information on the systematic review can be found in the Dutch Evidence-Based Guidelines for Amputation and Prosthetics of the Lower Extremity: Amputation Surgery and Postoperative Management.[4]

The current report was developed by a consensus process and is based on additional relevant references found through a consensus meeting February 2015, in Basingstoke, UK. We sought to capture the highest quality of literature available regarding major lower limb amputation due to vascular disease. The text was reviewed and revised by the consensus group. We formulated updated recommendations of key points for daily practice based both on available evidence and expert opinion.

The first draft of this report was presented in 2017 at the ISPO World Congress for public comment. Subsequent drafts were revised based on those comments. The updated recommendations are listed below.

III. EVALUATION OF THE PERSON WITH VASCULAR DISEASE PRIOR TO LOWER LIMB AMPUTATION

Dutch Guidelines:

-To prevent amputation, it is critical that patients with peripheral arterial disease (PAD) at risk of amputation are detected at an early stage. (Level 4)[4]

-To prevent amputation it is recommended that patients with critical limb ischemia receive a multidisciplinary evaluation and treatment. (Level 4)[4]

-All diabetic patients with ulcers should be assessed for PAD using objective tests, such as duplex ultrasound and ankle-brachial indices. (Level 4)[4]

-Early amputation may be indicated in critical limb ischemia, with the aim of achieving better long-term function and a lower risk of comorbidities.[6, 7](Level 4)[4]

-An amputation is indicated if there is: a severe (life threatening) infection, tissue loss due to extensive necrosis, intractable pain. (Level 4)[4]

-Immediate amputation should be considered in cases of acute ischemia and/or sepsis.[8] (Level 4)[4]

-If the vascular status is not yet established or if demarcation of the region for amputation has not yet taken place, it is advisable to postpone amputation. (Level 4)[4]

-In addition to the clinical assessment, anatomic localization of vascular disease can be obtained with segmental blood pressure or pulse volume recordings. (Level 4)[4]

-Arterial calcification may result in non-compressible vessels with the inability to obtain ankle brachial indices (ABIs). (Level 4)[4]

- When a discrepancy between clinical findings and non-invasive vascular studies arises, vascular imaging should be considered.[8] (Level 4)[4]

-Where arterial imaging is necessary for treatment decisions, the following imaging techniques are recommended: duplex examination, digital subtraction angiography (DSA), magnetic resonance angiography (MRA) and computed tomography angiography (CTA). (Level 4)[4]

-When revascularization is not an option or revascularization will not result in a functional limb, amputation should be considered. (Level 4)[4]

-The goal of an amputation is to achieve (initial) wound healing as distal as possible with the highest possible post-amputation function.[8] No clear criteria are given in the literature for the clinical assessment of the amputation level.[9] (Level 4)[4]

-When determining the level of amputation, preoperative mobility and the prospects for postoperative mobility should be taken into account. (Level 4)[4]

Updated Evidence:

Decision-making regarding limb salvage versus amputation remains complex. When an important decision like amputation needs to be made, the patient's opinion should be incorporated into the decision. Multidisciplinary evaluation and treatment (surgeon, anaesthesiologist, pain specialist, rehabilitation physician, and vascular medicine specialist) preoperatively is important for treatment of pain, cardiovascular risks, comorbidities, and to determine the level of amputation. The first step to evaluate the vascular status involves physical examination including skin temperature, capillary refill, venous refill, pulse exam and assessing ischemic changes (atrophy of the skin, hair loss, dystrophic nails, purpura, necrosis). In patients with PAD and diabetes, claudication may be masked due to neuropathy.

The European Consensus document defines critical limb ischemia (CLI) as persistently recurring ischemic rest pain or ulceration, or gangrene of a foot or toes lasting greater than two weeks.[10]

It is estimated that 5%-10% of patients with peripheral arterial disease older than 50 years develop CLI within five years.[11]

Critical limb ischemia is associated with high morbidity and mortality. Evaluating 13 studies enrolling 1,527 patients with a median follow up of 12 months, all-cause mortality was 22% and major amputation rate was 22%.[12] 30% of patients with CLI require amputation within the first year after diagnosis. The five-year mortality rate for CLI patients is 70%. Most of the deaths are cardiovascular related.[11]

Arterial disease can be demonstrated by either non-invasive or invasive vascular tests. The vascular laboratory plays an important role in non-invasive studies. The ABI is not accurate when the systolic blood pressure cannot be abolished using a blood pressure cuff. The incidence of non-compressible (artifactually high), calcified conduit arteries is highest in diabetic, elderly, and chronic renal failure patients. The resulting ABI values can be falsely elevated. Despite high recorded systolic pressure, these individuals may have severe disease. In this population, a greater importance should be attached to toe pressures and $TcPO_2$ measurements.[11,13] The use of transcutaneous oxygen pressure ($TcPO_2$) may provide an important tool to make clinical decisions regarding an appropriate level of amputation.[14]

According to TASC II[8] the following indicate CLI:

- Ankle pressure < 50 mm Hg
- Toe pressure < 30 mm Hg
- $TcPO_2$ < 30 mmHg

Revascularisation (surgical or endovascular) is effective in the prevention of amputation.[15] Because evidence indicates that blood flow to the lower limb improves in the first three weeks after revascularisation, deferred amputation following revascularisation is preferred.[16]

An amputation should be performed when a subsequent vascular reconstruction is no longer possible or if, despite successful revascularization, progressive ischemia is noted. In general more distal surgery provides a better functional outcome, but has increased risk of non-healing, re-ulceration, and re-amputation. Technical factors, aspects of wound healing, deconditioning and existing comorbidities are all factors that determine whether a patient is suitable for amputation.

In wet gangrene (whether local or generalised) immediate surgery is indicated to remove the infection. A guillotine amputation is used in this situation. Urgent amputation prevents further deterioration of the patient's clinical condition, resulting in an increased chance of recovery. A subsequent definitive amputation is then performed following recovery from sepsis syndrome. This leads to better results than a single intervention in this patient population.[17]

For individuals with end-stage renal disease (ESRD), revascularization is more expensive and less beneficial than in the general CLI population.[18] Two characteristics of individuals with end stage renal disease make limb salvage very challenging (1) limb salvage fails more frequently in the ESRD population than in non-ESRD critical limb ischemia; (2) the perioperative survival and long-term survival of patients with ESRD are both significantly lower than those of the non-ESRD CLI population.[19, 20] Studies suggest that local wound care and endovascular intervention may be more cost effective than primary amputation for individuals with critical limb ischemia and end-stage renal disease.[18, 21]

An important question is which subgroups of patients with critical limb ischemia would ultimately benefit more from amputation than revascularisation. It is important to weigh the chances of successful vascular reconstruction and subsequent mobility – against the chance of healing and mobility following initial amputation. Amputation, rather than revascularisation, may offer patients a more rapid return to an acceptable quality of life.

Evidence suggests that there is no significant difference in function at two years when comparing revascularization versus amputation, although limb salvage is associated with higher risk of complications, additional surgeries, and re-hospitalizations.[22] Some patients may weigh the risks of a reduced rate of healing of a distal amputation as acceptable if they have a higher likelihood of mobility. Others may prefer an amputation where the probability of primary healing is better and mobility may be adequate.[23]

Predicting whether a patient will use a prosthesis is a clinical judgement taking many factors (physical, medical, psychological, and social) into account. The perioperative consultation should address the likelihood of successful prosthetic fitting and use. This can assist the team to determine the optimal level of amputation.

At 1 year post-amputation, functional prosthetic use is reported in 47%-70% of persons with limb loss.[24-30] Persons with trans-tibial level amputation were more likely to be prosthetic ambulators (60-70%) than those with trans-femoral level amputation (40-50%).[27, 28] In one study, 5 years post-amputation, the number of prosthetic ambulators decreased to 17%.[25] The total one year mortality was 40% (17% among patients who received a prosthesis and 67% among those who did not prosthesis or had undergone reamputation).[30]

Chronic obstructive pulmonary disease, end-stage renal disease requiring hemodialysis, diabetes, hypertension, alcohol use disorder and history of treatment for anxiety or depression are all associated with worse functional outcomes.[27, 31] On the contrary, white race, being married and having at least a high school education are associated with better outcomes.[27]

The main factors associated with mobility are age, length of stay in a rehabilitation facility, and the mobility level prior to surgery.[29, 32] Wound complications,[32] a higher amputation level,[28, 33] older age[28, 29, 32, 33] and a low level of mobility before surgery often result in unsuccessful prosthetic fitting.[28, 29] Factors associated with functional status include age,[29], presence of diabetes mellitus,[34] standing balance and cognition.[29]

Patients undergoing lower extremity amputation due to vascular disease have often been functionally limited by peripheral arterial disease, foot ulcers, infections, and weight-bearing restrictions (sometimes for years prior to amputation). As a result, definitive management with amputation surgery can sometimes improve their function.

A subset of patients experience improvement in their functional mobility after amputation. Norvell reported that 37% of individuals with amputation returned to or exceeded their premorbid level of function at 1 year post-amputation.[31] Johnson also reported that many persons with unilateral trans-tibial amputation are able to maintain or improve their function after amputation.[35]

It has been suggested that persons with amputations comprise 2 distinct groups: the fit (often traumatic amputation); and the older, medically unfit patient who has a poorer prognosis.[36] Among this latter group, there is a great variation in functional outcome dependent on age, medical status and other factors. The ability to predict which among these patients are prosthetic candidates may reduce the costs and burden of care resulting from unsuccessful prosthetic fitting and allow earlier focus on interventions that will increase the patient's independence and quality of life.

Premorbid function is also predictive of post-amputation function.[35] Patients who are non-ambulatory prior to amputation are unlikely to resume ambulation after amputation.[24]

Every effort must be made to achieve initial wound healing at the trans-tibial level to preserve the knee. A trans-femoral level amputation increases the metabolic cost of ambulation. An initial trans-femoral level amputation (without prior vascular intervention) is performed in rare cases (non-ambulatory patients). The indication for this will be determined by:

- the risk of surgery due to medical comorbidities
- surgical options
- the patient's function and possible rehabilitation

With a knee flexion contracture, a knee disarticulation or long trans-femoral amputation may provide a superior option. Conversely, a knee disarticulation is an option worth exploring when a trans-femoral amputation is being considered.

If a patient is not a prosthetic candidate, they may be better served with a trans-femoral level amputation. For patients with limited mobility, dementia, end-stage renal disease and/or severe coronary artery disease; a knee disarticulation or trans-femoral amputation is considered.[28]

When prosthetic fitting patterns were examined for geriatric patients over 40 years, no marked changes in the rate of fitting or prosthetic wear occurred, despite technologic developments, advances in revascularization procedures, and provision of rehabilitation services. This suggests that a physiologic limit to successful prosthetic fitting may exist due to advanced age and comorbidity.[37]

IV. SURGICAL TECHNIQUE IN MAJOR LOWER EXTREMITY AMPUTATION DUE TO VASCULAR DISEASE

Dutch Guidelines:

-Good surgical technique (no excess soft tissue, no neuromas, a good residual limb shape, mobile scars and no joint contracture) helps ensure a 10-20% greater chance of postoperative mobility. An experienced surgeon achieves better results, both in terms of mobility and lower risk of re-amputation.[38] (Level 4)[4]

Updated Evidence:

Amputation surgery should be viewed as a reconstructive procedure carried out by an experienced, prosthetically aware, surgeon. The working group believes that patients facing amputation require subsequent supervision and treatment by a multidisciplinary team in the hospital, with continued outpatient rehabilitation in a rehabilitation center, nursing home or at home.

Surgical technique including: use of a tourniquet; osseous length; residual limb length; trans-tibial skew, long posterior, or sagittal flaps; transtibial, trans-femoral and knee disarticulation level amputations; and bone bridge synostosis are discussed in the Dutch Guidelines.[4] Surgical technique varies between region and country. Obtaining consensus on optimal surgical technique would be challenging is beyond the scope of this project.

V. POSTOPERATIVE COMPLICATIONS FOLLOWING AMPUTATION SURGERY

Dutch Guideline:

-Complications can be divided into disorders that lead to delayed wound healing (wound edge necrosis, dehiscence and infection) and those that are more severe (progressive ischemia with extensive necrosis, infection, revision, venous thromboembolism, sepsis and death). (Level 4)[4]

Updated Evidence:

Robertson[39] reviewed the literature regarding the effectiveness of thromboprophylaxis in preventing venous thromboembolism in people undergoing major lower extremity amputation. Only two studies were included in this review, each comparing different interventions. There is inadequate evidence to make any conclusions regarding the most effective thromboprophylaxis regimen in patients undergoing lower limb amputation.

Wound healing is of primary importance after amputation due to the morbidity associated with delayed wound healing and re-amputation. Wound care, edema management, diabetic control, smoking cessation and adequate nutrition are all important factors. Optimally, wound healing takes 6-8 weeks after amputation. Amputations due to vascular disease may have a more prolonged course. Healing at 100 and 200 days was 55% and 83% for trans-tibial and 76% and 85% for trans-femoral amputations.[24]

Mortality after amputation is very high in the population with PAD. 30 day mortality after amputation is 8-10%.[24, 40, 41] 1 year survival is 60-70% and 5 year survival is 35% following amputation due to vascular disease.[40, 42] A cohort study by Stone[43] retrospectively evaluated 380 patients (median age 67 years) following recovery from trans-tibial or trans-femoral amputation. The exclusion criterion was amputation due to trauma. The results showed a perioperative mortality of 15.5% (n=59) in this population, with a prevalence of wound complications after 90 days of 13.4% (n=51). Reamputation was performed significantly more often in patients who underwent trans-tibial amputation, while patients with a trans-femoral amputation often underwent a local revision (p =0.0006). The same result was seen in a study by Cruz;[44] in 229 patients (average age 68.8 years) who required amputation (trans-tibial (n=119), trans-femoral (n=177)), a significant difference in revision of the original amputation was seen in the group with a trans-tibial amputation (P> 0.0001).

Nehler[24] studied a cohort of 154 patients (median age 62 years) who had one or more amputation(s) (trans-femoral amputation (n=78), trans-tibial amputation (n=94)). Reasons for exclusion were non-ambulatory, dementia, or neurologic disorders. The results showed a perioperative mortality of 10%. 57 revision surgeries were required (trans-tibial amputation (n=23); trans-femoral amputation (n=16); trans-femoral reamputation in 18 patients (19%)).

Campbell[45] retrospectively studied a cohort of 312 patients with one or more lower extremity amputation(s) (trans-tibial, n=192; trans-femoral, n=122; Gritti-Stokes, n=34; hip disarticulation, n=1). The study looked at the overall revision rate (12%) and perioperative mortality within 30 days (18%). Although no statistical analysis comparing the different levels of amputation was reported, individual percentages showed that the trans-tibial group had the highest revision percentage (19%), and perioperative mortality was highest in the groups that required trans-femoral or Gritti-Stokes amputation (both 24%).

Johannesson[46] prospectively followed 190 patients undergoing lower extremity amputation over a period of 4 years. The results showed that 27 patients died within one month of surgery, 24 patients required reamputation (16 trans-femoral, 8 trans-tibial), and 5 patients with trans-femoral amputation, required reamputation twice.

Certain comorbid conditions increase risk. Perioperative sepsis, congestive heart failure, renal failure and liver disease were associated with higher mortality in hospital, at 30 days and at 1 year.[40, 47] 1 year and 5 year survival was found to be comparable in patients with diabetes (69.4% and 30.9% survival at 1 and 5 years), but much worse in patients with either end-stage renal disease (51.9% and 14.4% survival at 1 and 5 years) or renal insufficiency (55.9% and 19.4% at 1 and 5 years).[40] Patients with renal insufficiency were also more likely to undergo repeat amputation within 30 days.[48]

Higher level of amputation is also associated with increased mortality. Mortality from in hospital to 5 years is higher for those with trans-femoral compared to trans-tibial amputation.[40, 47] 1 year survival was 75% in persons with trans-tibial compared to 50% with trans-femoral amputation. 5 year survival was 38% with trans-tibial level amputation compared to 23% with trans-femoral amputation.[40]

Given the high mortality after amputation due to vascular disease, it is important to identify appropriate interventions and rehabilitation goals to improve mobility, independence and quality of life early following amputation. Delayed wound healing will mean more time spent in the hospital, more medical appointments, and greater burden of care over many months. It is important to discuss prognosis and realistic goals with the patient and their family to avoid a prolonged period trying to heal a distal amputation or attempting prosthetic rehabilitation, if they are unlikely to be a functional prosthetic user. Some may be better served by a more proximal amputation, successful healing, and wheelchair mobility.

VI. **POSTOPERATIVE DRESSINGS IN THE EARLY POSTOPERATIVE PERIOD**

Dutch Guidelines:

-The benefits of soft dressings are ease of application, low cost and easy access to the wound. The drawbacks include: they become loose and fall off; they do not prevent joint contracture; they cause risk of a “choke” of the distal residual limb if too much compression is applied proximally and they do not protect the limb in the event of a fall. (Level 4)[4]

-Rigid dressings help optimize wound healing, control edema, shape the residual limb, prevent contracture (when they extend above the knee), protect the limb and control pain. (Level 4)[4]

-There is a small difference in favour of the (semi-) rigid dressing (RD) in comparison with a soft dressing (SD) in terms of a reduction in the number of days to prosthetic fitting (Level 2)[4]

-A RD is favored in comparison with SD in the time required for wound healing.(Level 3)[4]

Updated Evidence:
Different types of dressings are used around the world (elastic bandage, socks, SD, RD, compression garments or liners) to help protect the limb and control edema. The advantages of the classic elastic stump dressing as described in the literature are based on the simplicity of this method, the minimal time required, the use of widely available materials and possibility for frequent wound inspection.[49, 50] Different kinds of soft or compressive dressings include self-adherent compressive bandage, figure of 8 compressive wrap, and a postoperative prosthetic sock with a garter belt suspension.

Known disadvantages are the experience required (in application of the dressing), high resting pressure, the potential for local or proximally generated pressures that may negatively affect healing, the required frequency (4 to 6 times daily) of application, the tendency of the dressings to loosen and sag and the limited protection of the amputation stump.[49, 50] A number of these disadvantages can be overcome by the use of elastic compression socks (stump shrinkers), or silicone liners, when tolerated, however these methods do not adjust to volume change. No comparative studies were found on this subject. The treatment team's experience with a particular method is of obvious importance.[50] Education is provided to optimize positioning and avoid dependent edema.

There is a considerable body of evidence in the literature in favor of rigid dressings applied directly after the amputation.[51] The comparison between a rigid removable dressing (RRD) and an elastic bandage on the reduction of stump volume was investigated by Janchai.[52] A clear but non-significant trend (p =0.064) was observed in favour of the RRD, but only in the first 2 weeks of use. These findings are also supported by the systematic review by Nawijn,[53] which further notes that most studies were particularly weak in terms of patient numbers. Advantages of rigid dressings include edema management prevention of contracture (when they extend above the knee), and protection in case of a fall. Studies of rigid dressings show that they decrease time to prosthetic fitting compared to other management.[51, 54-56]

Although it is generally assumed (and reported in some descriptive and case studies) that rigid dressings achieve better pain reduction than elastic bandages, no significant evidence for this was found in the selected controlled trials. This may be due to the lack of power in these studies or the lack of suitably sensitive instruments to quantify postoperative pain.[49] Thus far, this pain-reducing effect has not been demonstrated.

The drawbacks of a non-removable plaster cast are that it requires weekly application by a skilled professional, prevents access to monitor the incision and is heavier and more costly than a soft dressing. A rigid removable dressing can be taken off to monitor the incision and is less heavy and costly than a non-removable rigid dressing.

A nonremovable rigid dressing allows the attachment of an immediate (or early) postoperative prosthesis (pylon cast), which includes a connector, pylon and foot. The pylon cast has been purported to allow patients with trans-tibial amputations an opportunity for early ambulation without increased complications compared with other postoperative dressings.[57, 58] A study showed that despite a pylon cast, patients were mostly sedentary and had a low quality of life in the first six weeks after trans-tibial amputation.[59]

At the trans-femoral level, an early postoperative, provisional prosthesis can be used with a locking knee and toe-touch weight-bearing to avoid excess forces at the surgical incision.

The impact of early weight-bearing on wound healing is unclear. Potential complications include a pressure injury/ischemia if incorrectly applied and mechanical tissue trauma inside the cast.[49]

Before initiating any type of dressing, the team should be well prepared and trained. Before switching to using rigid dressings for postoperative management, all logistical obstacles should be overcome. If there is a lack of experience, choose the easiest method with least risk of complication.

For trans-tibial amputations, either a rigid or a soft dressing can be used. The consensus group recommends a rigid dressing as the treatment of choice during the early postoperative phase for persons with trans-tibial level amputations. When using a rigid dressing, compression is used, in the last few weeks, to shape the limb prior to prosthetic fitting. With trans-femoral level amputation, rigid dressings can be challenging (incontinence, suspension). Following trans-femoral amputation, typically soft dressings are used.

VII. THE REHABILITATION PROCESS FROM AMPUTATION TO INITIAL PROSTHETIC MANAGEMENT

Dutch Guidelines:

-Treatment should be consistent, consistently implemented, and follow a set framework or care plan. Information is a vital part of any medical treatment. Any information must be tailored to the specific needs of the individual and included in their medical record. (Level 4)[5]

-Optimal learning methods, coping styles, and skills should be determined during initial evaluation and reassessed during the course of rehabilitation. (Level 4)[5]

-Patients should be educated about stretching and positioning to avoid joint contracture. (Level 4)[4]

-Intensive physical therapy following lower limb amputation results in better load-bearing capacity and an improved 2-minute walk test, when compared to a less intensive treatment program.[60] (Level 3)[5]

-The multidisciplinary rehabilitation team determines the discharge destination following lower limb amputation based on the individual's expected function, social situation, and medical comorbidities. (Level 4)[5]

-Patients who receive inpatient rehabilitation after lower extremity amputation have a better 1-

year survival rate, greater success with prosthesis fitting, and are more likely to return home than patients not receiving inpatient rehabilitation.[42, 61, 62, 63] (Level 2)[5]

-Following amputation, a patient needs to adapt to an altered body image, postoperative management (possibly a prosthesis), and an altered future. (Level 3)[5]

-Social support positively influences the adjustment process.[64-68] (Level 3)[5]

-Cognitive decline reduces the chance of successful rehabilitation.[69] (Level 4)[5]

-Although the majority of patients who require amputation due to vascular disease are retired, some are working at the time of amputation. One year after the amputation, 42% of have resumed work.[70] and after more than one year 58-79% have returned to work or have stopped working for reasons unrelated to the amputation.[70-74] A subset of patients (approximately 30%) require adjustments in their work situation to return to work.[75] Of working patients, 60-80% resume work after lower extremity amputation. (Level 2)[5]

-Higher amputation level leads to poorer prognosis for return to work. (Level 3)[5]

Updated Evidence:

The main objective in the period from amputation to initial prosthetic fitting is to focus on recovery from the surgery, achieve medical stability, prevent complications and optimize mobility. This includes pain management, surgical site management, residual limb management (edema control, strengthening, and range of motion), and care of the contralateral limb.[50]

Maintaining knee mobility is of great importance in the postoperative phase. There is a tendency to keep the knee bent, particularly in the presence of postoperative pain. Education is provided to optimize positioning (avoid lying supine with a pillow under the knee). Dependent edema and knee flexion contractures can be prevented by using an elevated leg rest on the wheelchair, a residual limb support, and by educating the patient in proper positioning. To prevent hip flexion contracture, patients are educated to spend time prone with a pillow or towel under the anterior thigh (if tolerated).

Although the focus is usually on the amputated side, attention should also be paid to the contralateral side. It is important to ensure that the contralateral leg (heel) is protected against pressure ulcers, during surgery and postoperatively.

Specific attention should be paid to hip strengthening training. In a twice weekly hip strengthening program, the training group increased hip strength and decreased oxygen consumption compared to a control group, who continued their usual activities. Hip strength was reduced in the group not following the training program.[76] Another study showed improvement of functional performance and balance confidence following intense hip abductor strength training during an 8-week program of twice weekly hip abductor strength training or arm ergometry.[77]

The most frequently described adjustment issues are mood disorders and anxiety. In the course of rehabilitation, the adaptation process and associated psychosocial issues need to be considered.

Cognitive impairment appears to be more prevalent among persons with lower limb amputations than in the general population and is negatively associated with mobility, prosthetic use, and maintaining independence following amputation.[78] Cognitive screening prior to rehabilitation could assist in determining patients' suitability for a prosthesis versus wheelchair use and decision making for a specific rehabilitation program.[78]

The following factors are assessed: the patient's ability to return to their previous level of functioning; identification of resources previously used or those necessary to facilitate continuity of care; social/family support, psychological support; therapy; medical needs. The team works with social services to develop and implement the discharge plan. The discharge plan is documented in the medical record including the patient assessment and a plan for continuing care.

The relationship between shared decision-making and evidence-based practice is becoming increasingly recognized.[79] Shared decision-making provides a process for bringing evidence into the consultation and incorporating it into discussions with the patient, along with discussions about the patient's values and preferences. Shared decision-making may also help reduce the unwarranted variation in care.[80]

Discussions should take place not only in the presence of the patient, but also with the involvement of family members and other caregivers. Verbal information should be supported in other formats, as patients and their relatives (and other parties involved) often do not hear and/or remember everything. The format (oral, digital, leaflets) in which the information is provided will need to be tailored to the patient. Information resources should be developed at the local level.

Verbal education and printed materials are provided by various members of the rehabilitation team throughout the hospital stay. Education includes adjusting/adaptation to limb loss, optimizing functional mobility (bed mobility, wheelchair mobility, ambulation, and transfers), optimizing daily living skills, obtaining appropriate adaptive and durable medical equipment, caregiver support, communication with other care providers, decision-making on health risks, optimizing care options (including prosthetic fitting, sock management, prosthetic adjustments, prosthetic training, cardiovascular conditioning, risk factor prevention, and accessing emergency care if necessary).

The person with limb loss and their family are instructed in measures to avoid further limb loss, risk factors, the timeline for use of a prosthesis, fall prevention and management, home modifications, home safety, energy conservation, and expenditure, and the importance of follow up to prevent complications. 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. Developing 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. Since treatment involves multiple disciplines, it is advisable that items discussed are recorded in a manner that is clear to all disciplines. If the patient cannot safely function in their home environment after amputation, discharge to a rehabilitation setting is necessary.

Following lower limb amputation, discharge planning should be based on the degree of function, social situation, and the patient's health. A large population-based study in the U.S.[81] showed that 41% of patients with vascular disease requiring amputation are discharged to their homes, 37% to a skilled nursing facility, and 10% to a rehabilitation facility.

The discharge summary includes an acute medical history, rehabilitation medical history, description of the rehabilitation course, and ongoing care needs. The discharge summary outlines the plan for community-based services (pedorthotic services, foot care, health or psychosocial issues that require follow up). Also provided and documented in the medical record is information about consumer groups, and peer support (self-advocacy, financial assistance, emotional support, and support groups) including how to access them (phone numbers and names of contact persons), in the local community.

The discharge summary is reviewed by the patient and their family/support system. The discharge plan is updated throughout the course of the patient's stay and is reassessed frequently to ensure that the patient's continuing care needs are identified. A copy of the discharge summary is sent to the primary physician as designated by the patient and/or the healthcare facility to which the patient transitions.

VIII. PAIN MANAGEMENT FOLLOWING AMPUTATION

Dutch Guidelines:

-In addition to physical limitations, pain plays a major role (both stump pain and phantom pain) in determining the quality of life.[64, 69, 82-92] (Level 4)[4]

-Epidural or perineural administration of bupivacaine, compared with placebo, has no significant effect on the intensity or incidence of stump and phantom pain in the early perioperative period up to six months and long-term (12 months).[93, 94, 95] (Level 2)[4]

-Epidural treatment has a place in the perioperative management of pain. (Level 4)[4]

-Compared with placebo, gabapentin has no effect on the incidence and intensity of stump and phantom pain in the perioperative period up to 6 months.[96, 97] (Level 3)[4]

-Use of amitriptyline can be considered for patients with phantom pain. (Level 4)[4]

-Ketamine (epidural or intravenous), compared with placebo, has no significant effect on the incidence and intensity of stump and phantom pain in the perioperative period up to 6 months and long-term (12 months).[98, 99] (Level 2)[4] (Due to neurotoxicity, epidural infusion of ketamine cannot be recommended.)

Updated Evidence:

Careful consideration of several patient factors can improve success in medical therapy for phantom and postoperative pain. The patient's medical comorbidities should be considered. Limiting factors such as pulmonary, cardiovascular, renal, or hepatic impairment should be identified as these may influence medication choice.

Patients who undergo an amputation will experience moderate to severe acute postoperative pain. In addition to oral and intravenous medications in the treatment of acute postoperative pain, epidural or perineural pain control may also be used.

In addition to acute pain following amputation, a considerable number of patients develop chronic pain syndromes. Phantom pain, experienced as painful sensations in the amputated limb, is a neuropathic pain syndrome probably caused by central and peripheral neural mechanisms. There is no evidence to outline the prevention of phantom pain.

Anticonvulsants are often used in the treatment of neuropathic pain. Perioperative administration of gabapentin appeared to have no effect on the incidence of phantom pain and chronic stump pain.[96] In a recent Cochrane Review,[100] these agents showed no benefit in the relief of phantom limb pain. In a small study by Bone,[97] gabapentin may have shown an effect on longstanding phantom pain. Pregabalin's mechanism of action is similar to gabapentin. No studies were found on the effect of pregabalin on phantom pain and chronic stump pain.

A study by Wilder-Smith[101] suggested that, in addition to tramadol, amitriptyline may be effective in patients with phantom pain. Amitriptyline and nortriptyline have been shown to be effective against neuropathic pain. Their role in the treatment of phantom pain has been poorly investigated.

A randomized double-blinded pilot study by Wu[102] showed that both Botox and Lidocaine/Depo-Medrol injected intramuscularly and subcutaneously at local tender points resulted in immediate improvement of residual limb pain (not phantom limb pain) and pain tolerance, which lasted for 6 months in persons with amputation who failed conventional treatments.

Medication side effects can be a barrier to treatment success. A frank conversation discussing common or serious side effects should be performed prior to starting a new treatment. Many of the treatment side effects can decrease over time due to progressive tolerance. Each medication should be maintained at the lowest effective dose. Topical medications, behavioral strategies, and physical modalities can be particularly beneficial in combination with other treatments due to their negligible side effect profiles.

While pain following amputation can prove difficult to treat, there are a variety of therapeutic options including behavioral therapies, physical modalities, topical and oral medications, and implantable devices. Mirror therapy (MT) has been shown to be an effective, non-pharmacologic, treatment for PLP.[103] Augmented Reality (AR) has the ability to create a high fidelity version of MT that may improve the effect and duration of pain reduction in patients experiencing PLP.

Pain research has shown that cognitive behavioral therapy is effective in the perioperative period. Third generation behavioral therapy (Acceptance and Commitment Therapy (ACT) and Mindfulness) also appear to be of benefit and indicate that future research into these treatment methods is necessary.

IX. PROSTHETIC PRESCRIPTION FOLLOWING LOWER LIMB AMPUTATION DUE TO VASCULAR DISEASE

Dutch Guidelines:

-Ideally, a prosthetic prescription should be generated with a multidisciplinary team including a physician familiar with rehabilitation requirements, a prosthetist, and a physical therapist. (Level 4)[5]

-The most fundamental question when developing a prosthetic prescription is the patient's need and their ability to use the prosthesis. The key point is the anticipated level of mobility with a prosthesis is the guiding factor in the choice of prosthetic components. (Level 4)[5]

-Choosing between the various components of a prosthetic prescription should be based on reliable information on the characteristics of these components. Using the product information provided by the manufacturer alone is insufficient. The determination of the specific characteristics and functional quality of a prosthesis should be based on clinical and biomechanical research. The use of clinically evaluated systems is recommended. (Level 4)[5]

-Baars, et al., concluded that silicone liners seem to lead to better suspension and better walking performance than a conventional supracondylar socket suspension.[104] (Level 2)[5]

-In a RCT involving 36 patients with trans-tibial amputation, no differences were found in the outcomes 'prosthetic function' and 'satisfaction' when comparing a total surface bearing socket (TSB) and a conventional patellar-tendon bearing (PTB) socket.[105] (Level 3)[5]

-Individuals with trans-femoral amputation using a microprocessor knee (MPK), are better able to walk down a slope.[106] (Level 3)[5]

-Persons with trans-tibial level amputation due to trauma walk at a higher speed with an energy-storing (dynamic response) foot.[107] No study was found in which a difference in patient satisfaction was reported with regard to a specific prosthetic foot.[107] (Level 2)[5]

Updated Evidence:

Prescribing a prosthesis is a process which involves assessment, production, delivery and evaluation of a prosthetic leg. Prescription and fitting processes vary significantly between countries. The way national public health insurances are organized also influence the processes and available choices.

Schaffalitzky[108] stresses the importance of psychosocial outcomes in prosthesis prescription and use. A limited improvement in physical capabilities may provide important gains in psychosocial outcomes and independence.

If the decision is made to prescribe a prosthesis, details of the prosthetic prescription including socket design, suspension, interface, pylon, knee, and foot components (with input from the prosthetist and the patient) is provided.

Prosthetic training should be arranged when the initial prosthesis is prescribed. Options include outpatient physical therapy, subacute rehabilitation, or inpatient rehabilitation. A well-fitting prosthesis with appropriate components, supervised training, and ongoing follow-up optimizes prosthetic use and function.

The individual with major limb loss must understand that successful prosthetic rehabilitation is a prerequisite for optimal performance. A state-of-the-art prosthesis will not provide optimal performance to a user who is not physically capable of taking advantage of its features. Conversely, optimal performance will not be achieved with a prosthesis that does not provide a level of technical sophistication that matches or challenges the user's physical capabilities.

There are significant limitations of the objective clinical knowledge available on the impact of different prosthetic components on performance with a prosthetic leg. Further, it is challenging to predict an individual's response to a specific component on clinical variables alone. Therefore, empiric knowledge and individual judgement remain indispensable to determine the appropriate prosthetic prescription. The measurement and documentation of clinical performance is recommended.

The socket is where the prosthesis and the body connect. It is the most critical element in prosthetic design. Unlike the plantar tissues of the intact foot, residual limb soft tissues are not accustom to bearing loads.[109] Loads imparted on the residual limb by the prosthetic socket can cause wounds and other skin conditions. This is problematic as treatment may require stopping the use of the prosthesis. To help cushion the transfer of load between the prosthetic socket and residual limb, soft prosthetic liners have been used. High-quality research is needed to inform decisions about liner prescription based on user experience.[110]

Microprocessor controlled knee components have been investigated over the last decade. Independent systematic reviews by Samuellson, et al.,[111]; Highsmith, et al.,[112] suggest that hydraulic microprocessor knees (MPKs) are associated with improved patient satisfaction, safety, energy consumption, and are cost effective. A systematic review by Kannenberg, et al.,[113] concludes that the benefits of a MPK are also apparent with subjects of limited mobility. As MPKs vary in type,[114-116] different designs maybe associated with different effects.[117, 118] A systematic review by Sawyers, et al., found moderate evidence of improved confidence, mobility, and decreased cognitive demands. They also concluded that no evidence could be found where non-microprocessor knees were associated with clinical advantages over MPKs. Larger observational studies suggest that the benefits of the MPK are not limited by age, mobility grade, etiology, BMI, and other clinical variables.[119, 120]

In a Cochrane Review on the effectiveness of ankle foot mechanisms, Hofstad, et al., concluded that in trans-tibial amputations, there appears to be greater stride length with a dynamic response foot in comparison with a conventional fixed prosthetic foot. At high activity levels, there also seems to be a better gait efficiency.[121]

Hydraulic and microprocessor controlled feet (MPF) have recently become available in some countries. Such devices are associated with a reduction of internal stress of the amputated limb[122] and optimize pressure distribution at the residual limb.[123] They are also associated with an increase in toe clearance[124, 125] which may contribute to a reduction in the risk of falling. Patients reported feeling safer during ramp descent.[126]

There are limitations in the objective clinical knowledge available on the impact of various prosthetic components on performance with a prosthetic leg. In addition, it is challenging to predict an individual's response to a specific component on clinical variables alone. Empiric knowledge and individual judgement remain indispensable to determine the appropriate prosthetic prescription. The measurement and documentation of clinical performance is recommended. Specific issues of prosthetic components/prescription are beyond the scope of this report.

The rehabilitation consultant will attempt to optimize the patient's achievable level of function. This depends on both the amputation level and premorbid function.[28] When indicated, the demands of a patient's workplace should be taken into account when prescribing a prosthesis.

X. CONCLUSION

The Dutch Guidelines[4, 5] established that there are gaps in knowledge and need for future research regarding amputation and prosthetic rehabilitation. As our consensus group met to expand the Dutch Guidelines for a larger audience, these gaps are again apparent. The rehabilitation process and the value of multidisciplinary treatment need to be further delineated. The opinion of the working group is that the rehabilitation process for a person with major lower limb amputation due to vascular disease is best accomplished with a comprehensive, multidisciplinary, specialized treatment team.

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