Minor amputation and quality of life: is it time to give the patient a voice?

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Article points

1. Minor amputation rates continue to rise, possibly due to minor amputations being used as limb salvage procedures.
2. Studies using generic health measures have found quality of life (QoL) is better for those with healed minor amputation than with chronic ulceration.
3. Little research has been done to understand if these measures accurately capture QoL for people with minor amputation.
4. Further qualitative research is needed to explore the impact minor amputation has on QoL for patients with diabetes.

Key words

- Diabetes
- Literature review
- Lower extremity amputation
- Minor amputation
- Quality of life

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This article provides an overview of the research that has been undertaken and presents the methods that have been used to determine the impact of minor amputation on quality of life and the findings of published research. It concludes that further research into this topic is necessary. The corresponding author is currently involved in data collection exploring this issue and intends to produce an original research article exploring patient perceptions of the impact that minor amputation has upon quality of life.

Despite the rising incidence, there has been little research exploring the impact minor amputation has upon quality of life (QoL). Where explored, generic health measures have been used to determine impact. The findings appear to indicate that minor amputation is preferable to ongoing chronic ulceration (Boutoille et al, 2008; Pickwell et al, 2016). However, the generic health outcome measures may not be giving a full picture of the effect that minor amputation has on QoL. This article presents an overview of the findings of current research and recommends that more qualitative research is undertaken to understand what impact — positive or negative — minor amputation has on QoL for individual patients.

Minor amputation: a management option or a failure of care?

The National Diabetes Audit report on complications and mortality (Health and Social Care Information Centre, 2015) demonstrates that the risk of minor amputation has continued to rise since 2010. These figures are perhaps unsurprising for clinicians involved within care of the diabetic foot, who perceive minor amputation as being utilised in two manners: to prevent the spread of infection where antibiosis has been ineffective or as a treatment option to resolve chronic ulceration. If viewed as a management option rather than as a failure of care, the number of minor amputations performed cannot in isolation demonstrate the success of a service or the quality of patient care provided. Additional factors also require consideration.

This perspective is supported by several authors, who have cautioned that the incidence of amputation alone is not sufficient to judge the success of care. As early as 2004, Jeffcoate and van Houtum suggested that amputation incidence data required careful interpretation, and that a constant focus on reducing the incidence of all amputation could harm patient choice. They argued that this approach could conceivably result in minor amputation not being offered at a timely interval, resulting in inappropriate conservative management, thereby lowering QoL and leading to enhanced suffering. Vamos et al (2010) have suggested that the increased minor amputation rate reflects the rationale that minor amputation is being undertaken to prevent loss of limb and enables a patient to maintain physical function. This is echoed by Holman et al (2012), who explored the variation in amputation rates in England and highlighted the importance of exploring the rationale for amputation. The authors concluded that the high incidence of amputation may indicate effective early intervention rather than deficiencies in care, and should not be used to adversely judge the quality of a service in isolation. Rajendran et al (2012) have suggested that the rise in minor amputation rates may be in part

attributed to better survival rates of patients with multiple complex morbidities, resulting in a greater necessity for amputation. Their study recommended that amputation trends, mortality and QoL measures would be better indicators of effective management than amputation rates alone.

The question arises as to whether amputation rates are an appropriate key performance indicator. Other aspects of care may be more appropriate to determine effective clinical performance. The National Diabetes Foot Care Audit (Health and Social Care Information Centre, 2016) benchmarked time to first expert assessment and alive and ulcer-free at 12 and 24 weeks, the term "ulcer-free" incorporating those who have had minor or major amputation provided all wounds have healed. The audit clearly accepts that amputation may be a necessary aspect of diabetic foot management. There is still a lack of patient voice present, however, in exploring how successful management has been.

Minor amputation and patient-reported outcomes

It is perhaps surprising that minor amputation continues to be expressed in numerical terms alone when the value of subjective assessment is evident within the consciousness of the NHS and patient-reported outcomes have emerged as a core component of service evaluation. In 2001, the National Service Framework for diabetes (Department of Health, 2001) recommended that patient experience should be incorporated into auditing the effectiveness of care provided. The framework recommended that subjective measures of health status, psychological well-being, satisfaction with services and QoL should be documented.

The Patient-Reported Outcome Measurement Group (2009) reviewed QoL tools for diabetes and concluded that no single tool encapsulated the entire spectrum of experiences within diabetes. The group recommended that a combination of the health-generic EuroQol Quality of Life Scale (EQ-5D) and a diabetes-specific instrument should be used. The group also concluded that instruments should be used that captured specific diabetes patient group experiences.

Extensive literature searches indicate that to date little research has specifically aimed to explore the experiences of individuals with diabetes and minor amputation. Where explored, generic rather than specific QoL tools have been used to determine the impact of minor amputation. This has important consequences for the clinician exploring the impact of management decisions by reviewing the results of current patient-reported outcome measures used in practice. There may be factors that are important to QoL for those who have undergone minor amputation that are not included in these generic health measures and we may not truly comprehend the effect of minor amputation upon an individual's QoL.

Studies exploring QoL and minor amputation

There are no current studies that have minor amputation as their main focus Within published research, minor amputation has been used as a comparator to issues such as chronic ulceration. The following sections summarise research exploring QoL in those who have undergone minor amputation. The characteristics of the tools used are summarised in *Table 1*. Only one study, from the US, has explored the impact of minor amputation from a qualitative perspective. The rest of the research presented has utilised generic health measures, highlighting the need for more qualitative exploration of the impact of minor amputation.

Assessing psychosocial adjustment

Carrington et al (1996) explored the psychological aspects of QoL for people with or without chronic foot ulceration or unilateral amputation. Structured interviews were completed with a purposive sample of 52 people. The structured interview comprised the completion of a range of tools aimed at capturing factors related to QoL (the Psychosocial Adjustment to Illness Scale [PAIS], Hospital Anxiety and Depression Scale [HADS], the foot questionnaire and the QoL Ladder; see *Table 1* for details). Individuals with healed amputation were found to have a better QoL than those with chronic ulceration.

Sickness Impact Profile

Peters et al (2001) published the results of their case-control study of 124 patients utilising the Sickness Impact Profile to determine the impact of amputation on functional status. The findings revealed that any amputation negatively impacted upon functional status; and that the greater the extent of the limb

Page points

1. The National Diabetes Foot Care Audit accepts that amputation may be a necessary aspect of diabetic foot management.
2. Patient experience should be incorporated into auditing the effectiveness of care provided
3. There is currently no single quality of life tool that encapsulates the entire spectrum of experiences within diabetes..
4. The use of the EuroQol EQ-5D and a diabetes-specific instrument should be used in combination to assess patient experiences.

Table 3. Characteristics of tools used in the research.

Name of tool	What the tool measures	Domains assessed	Scoring system
EuroQoL Quality of Life Scale (EQ-5D)	Generic measure of health-related quality of life	Five dimensions: • Mobility • Self-care • Usual activities • Pain/discomfort • Anxiety/depression	Likert scale: • no problems • some problems • severe problems Visual analogue scale (0 = worst imaginable health state; 100 = best imaginable health state). Single numeric index of health produced from a possible 243 health states. An index <0 indicates a worse state than death; 1 indicates full health.
Foot questionnaire	Explores how individuals have felt about their feet during the past month	Twelve pairs of opposites: • Painful/painless • Healthy/unhealthy • Weak/strong • Comfortable/uncomfortable • Important to me/not important to me • Worthless to me/valuable to me • Attractive/unattractive • Useless/useful • Definitely part of me/ not really part of me • Not worth looking after/worth looking after • Easy to keep clean/difficult to keep clean • Unpleasant/pleasant	Rated on a seven-point scale
Hospital Anxiety and Depression Scale (HADS)	Detects states of anxiety and depression in a non-psychiatric setting	Two subscales assessed by 14 questions to assess anxiety and depression	Rated on a three-point scale: • No • Doubtful • Definite case
Psychosocial Adjustment to Illness Scale (PAIS)	Measures psychological adjustment to current illness	Forty-six questions measuring seven domains of adjustment: • Healthcare orientation • Vocational environment • Domestic environment • Sexual relationships • Extended family relationships • Social environment • Psychological stress	Rated on a four-point scale, where a higher rating indicates poorer adjustment
Quality Of Life Ladder (QOLL)	Measures of life satisfaction	A scale measuring worst possible to best possible life satisfaction	Score: 0–10 Mean score for population as a whole is 6.6
Thirty-six-item Short-Form Health Survey (SF-36)	Generic health status measurement instrument	Thirty-six questions covering eight domains: • Physical functioning • Bodily pain • Role limitations – physical health problems • Role limitations – personal or emotional problems • Emotional wellbeing • Social functioning • Energy/fatigue • General health perceptions	Overall score: 0–100 Separate physical and mental component summary scores

Table 3. Characteristics of tools used in the research (continued).

Name of tool	What the tool measures	Domains assessed	Scoring system
12-Item Short-Form Survey (SF-12)	Generic health status measurement instrument	Shorter than the SF-36 to reduce the burden of completion on the participant. Twelve questions cover the same 8 domains as SF-36	Separate physical and mental component summary scores
Sickness Impact Profile (SIP)	Generic health status measure	One-hundred-and-thirty-six questions in 3 sections covering 12 dimensions. Sections: • Independent (sleep and rest, eating, work, home, management, recreation and pastimes) • Physical (ambulation, mobility, body care and movement) • Psychosocial (social interaction, alertness behaviour, emotional behaviour, communication)	Provides a health status score
Trinity Amputation and Prosthesis Experience Scales (TAPES)	Benchmarks the psychosocial process of adjusting to having and using a prosthesis	Sixty-four items split between 4 sections: • Psychosocial scale (general adjustment, social adjustment, adjustment to limitation) • Activity restriction scale • Satisfaction with the prosthesis (aesthetic and functional characteristics) • Pain and other medical conditions	Calculated as 6 subscores No overall score total Aims to assist in determining issues with adjustment to the prosthesis Scale also available for those without a prosthesis
World Health Organization Quality of Life Brief Scale (WHO-QUAL-BREF)	Generic short-form version of the WHOQOL-100	Two items assessing overall quality of life and general health. Twenty-six questions split over 4 domains: • Physical health • Psychological wellbeing • Social relationships • Environment	Likert scale There are four subscale scores – the higher the score, the better the quality of life

loss, the greater the impact upon functional status. It was found that patients who had undergone a toe or midfoot amputation did not report a significantly higher total impairment score than patients who had not undergone amputation. Further studies are needed, however, as the Sickness Impact Profile was unable to differentiate between the psychosocial functioning scores for those with and without amputation. This may be a true reflection upon the impact of amputation, but may highlight the tool's insensitivity to identifying status change for amputees. Peters et al concluded that more foot salvage procedures should be undertaken prior to considering major amputation.

The 36-Item and 12-Item Short-Form Survey

The 2005 study by Willrich et al indicated that amputation impacted negatively upon the physical aspects of QoL as measured by the 36-Item Short-Form Survey (SF-36). The preliminary study aimed at developing a screening system that would enable practitioners to be able to compare health-related QoL, cognitive function and depression for those who had a chronic ulceration, Charcot arthropathy or had undergone amputation. The authors explored cognitive function by using the clock drawing test and mini-mental state examination on the Zung self-rating depression scale and health-related QoL by using the SF-36. The results from the 60 participants indicated that any lower limb complication impaired health-related QoL within the domains of physical function and role limitations due to physical health. The study found no significant difference between whether the complication was ulceration, Charcot or amputation. This was a preliminary study, however, and major and minor amputation results were presented together. It would have been interesting if the groups had been divided further to see whether

"Physical quality of life deteriorated if individuals failed to mobilise, whether or not they had undergone amputation (Patel et al, 2014)."

the level of amputation altered the impact upon physical function, as had been found in previous studies (Peters et al, 2001).

These findings were corroborated by a retrospective study undertaken by Boutoille et al (2008), which compared the impact that chronic ulceration or lower limb amputation had upon QoL as measured by SF-36. The study included nine individuals who had chronic ulceration and 25 amputees (19 of whom had undergone minor amputation). The study identified that those who had undergone minor amputation had statistically significantly better physical role scores than individuals with chronic ulceration. The study also indicated that the more minor the amputation, the smaller the impact upon physical functioning scores.

Winkley et al (2009) prospectively followed 253 people with diabetes and first foot ulceration for 18 months, mapping the outcome of the ulceration and determining the impact on QoL by using the SF-36. All individuals with ulceration and critical limb ischaemia or calcified arteries were excluded from the study, therefore the rates of amputation presented in this paper may be lower than in the actual population. At 18 months, 15.5% of the population had undergone amputation. The authors found no significant deterioration in summary physical functioning score.

The 2014 study by Patel et al demonstrated that minor amputation did not impact upon physical or mental QoL, provided that the surgery was successful and the patient was able to ambulate post-operatively. The retrospective study of 57 patients who had undergone lower-extremity reconstruction or minor amputation examined QoL by reviewing the physical and mental component scores derived from participants who had completed the SF-12. The study found that physical QoL deteriorated if individuals failed to mobilise, whether or not they had undergone amputation. Patel et al reported no deterioration within mental QoL whether individuals were able to mobilise or not.

The pilot study undertaken by Quigley et al (2016) explored the impact that minor or major amputation had upon QoL for 33 individuals in Australia who had undergone amputation due to underlying vascular compromise. A combination of generic and specific disease assessment tools were used, namely the SF-36v2 and the Trinity Amputation and Prosthesis Experience Scale (Gallagher and MacLachlan, 2004). The authors posted the SF-36 and Trinity Amputation and Prosthesis Experience Scale to 33 individuals, 10 of whom had undergone partial foot amputation and 23 of whom had transtibial amputation. The results indicated that amputation, regardless of level, appeared to have little impact upon QoL when compared to the population norms for SF-36; rather, QoL was negatively affected by the long-term complications associated with diabetes. Quigley et al concluded that a larger study would be required to corroborate the findings.

Hospital Anxiety and Depression Scale and WHO Quality of Life Brief measure

A 2014 study of Australian individuals with diabetes by McDonald et al found that amputation had little impact upon QoL when assessed using HADS and the physical and psychological subscales of the World Health Organization Quality of Life Brief measure. The study used a control group and undertook multivariate analysis to control for demographic and medical elements, such as time since diagnosis of diabetes, severity of diabetes, diabetes-related micro- or macrovascular complications and medical comorbidities. The findings demonstrated that amputation had no impact upon QoL, but did have a negative impact upon body image perception.

EuroQoL

The EuroQoL scale is the generic tool recommended for use in the UK. A study by Ragnarson Tennvall and Apelqvist (2000) aimed to determine the impact of foot ulceration on health-related QoL by using the Swedish version of the EuroQoL: the EQ-5D (Kind, 1996). The researchers justified the use of the EQ-5D as there was no specific diabetic foot-related tool which had been validated at the time, and wished to explore if the simple to complete EQ-5D had sufficient scope to compare the impact chronic ulceration or amputation had upon QoL. Purposive sampling was used to send a postal questionnaire to all patients who had been treated by a multidisciplinary foot care team at one hospital location in Sweden (n=440). The study found that patients with active ulceration rated their overall health-related QoL as being worse than individuals with healed ulceration or healed minor amputation.

The results of a prospective cohort multicentre study carried out by Pickwell et al (2016) indicate

that minor amputation does not negatively affect health-related QoL. The authors concluded that minor amputation should cease to be viewed as a failure of care and should instead be considered a viable treatment option. Despite utilising the EQ-5D, Pickwell et al are critical of the measure, as they perceived it to be "generic and rather crude". They concluded that additional research needed to be undertaken to validate and confirm the findings of their study.

Qualitative research

To date, only one interview study has been published, and it has focussed upon individuals within the United States. Foster and Lauver (2014) undertook semi-structured interviews exploring the lived experiences of 15 patients who had undergone minor or major amputation (toes, transmetatarsal, below-knee and above-knee) following chronic ulceration. The study found that participants were concerned with being socially and economically productive. The authors identified five themes in this area:

- Financial burden
- Powerlessness
- Social support
- Blaming
- Uncertainty.

Some of the themes identified are specific to the US population, such as concerns about the financial burden of healthcare and paying for medical care. Other aspects such as grief, loss of social activity and financially supporting the family may, however, reflect the thoughts of individuals within the UK. A UK study would need to be undertaken to explore whether these factors represent visualisation

"Patients with active ulceration rated their overall health-related quality of life as being worse than individuals with healed ulceration or healed minor amputation" (Pickwell et al, 2016).

"Patient perception of quality of life, and the factors that are important to quality of life for individuals who have undergone minor amputation, have not been fully explored from a qualitative perspective in the UK."

of QoL for UK individuals who have undergone minor amputation.

Interestingly, many of the factors documented in Foster and Lauver's work are not domains measured by the EQ-5D, which again raises issues about the suitability of a generic measure to determine the impact of amputation upon QoL, and supports the Patient-Reported Outcome Measurement Group's 2009 recommendations that a combination of generic and specific tools are required to fully capture patient experience.

Conclusions

There is no clear conclusion as to the effect that minor amputation has upon QoL. Some of the studies appear to indicate that there is no impact upon QoL, while others conclude that minor amputation may impact negatively upon physical elements of QoL. None of the research has used a combination of generic (EQ-5D) and problem-specific measures, as recommended by the Patient-Reported Outcome Measurement Group. Those that have utilised the EQ-5D have commented upon how generic and crude a measure the tool is.

An extensive search of the literature has indicated that no specific tool for evaluating the impact of minor amputation exists at this time. It is also evident that patient perception of QoL, and the factors that are important to good QoL for individuals who have undergone minor amputation, have not been fully explored from a qualitative perspective in the UK population. Without this core of information, we will continue to question the validity of research findings explored using existing QoL tools and will not be able to truly understand the effect minor amputation has on QoL.

It is the authors' intention to try to develop new knowledge within this area by exploring from a qualitative perspective patients' perception of why the amputation occurred and the effect it has had upon QoL. It is hoped that this research will add a patient voice to the annually-reported minor amputation rates, assist patients and clinicians in making decisions around minor amputation, and contribute to the future development of specific patient-reported outcome measures to incorporate into audits of diabetic foot services. These patient-reported outcome measures may assist teams in gathering more relevant information about the actual impact amputation has upon QoL and aid with determining its true cost, both from a patient and health economics perspective. ■

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