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Challenges in shared decision-making about major lower limb amputation: the PERCEIVE qualitative study

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ABSTRACT

Objectives Shared decision-making is widely advocated in policy and practice, but how it is to be applied in a high-stakes clinical decision such as major lower limb amputation due to chronic limb-threatening ischaemia or diabetic foot is unclear. The aim of this study was to explore the communication, consent, risk prediction and decision-making process in relation to major lower limb amputation.

Design A qualitative study (done as part of a broader mixed-methods study) using semi-structured interviews. Interview transcriptions were analysed using thematic analysis.

Setting Vascular centres in three large National Health Service hospitals in Wales and England, UK, between 1 October 2020 and 30 September 2022.

Participants A purposive sample of 18 patients for whom major lower limb amputation was considered as a treatment option/carried out, with interviews conducted before or within 4 months of amputation and 4–6 months after amputation. A further purposive sample of 20 healthcare professionals (including eight surgeons) involved in supporting or conducting major lower limb amputation decision-making.

Findings Five major categories were identified that highlighted the challenges of ensuring shared decision-making associated with major lower limb amputation: (i) patients' limited understanding, (ii) variable patient attitudes to decision-making, (iii) healthcare professionals' perceived challenges to sharing decision-making, (iv) surgeons' paternalism and (v) patients' and healthcare professionals' decisional regret/possible consequences of challenges.

Conclusion Amputation is a life-changing decision for both patients and healthcare professionals, with huge consequences. Despite being considered the gold standard, our findings highlight several challenges to effective shared decision-making for major lower limb amputation. Shared decision-making training for healthcare professionals is paramount if these limitations are to be addressed and patients are to feel confident in being adequately informed about the treatment decisions that they make.

Trial registration number NCT04903756.

STRENGTHS AND LIMITATIONS OF THIS STUDY

- ⇒ Qualitative interviews allow for a detailed insight into healthcare professionals' views and patients' experiences of decision-making related to major lower limb amputation.
- ⇒ There was a limited number of participating centres; other centres may have different multi-disciplinary team clinic structures and use of decision aids that could influence shared decision-making.
- ⇒ The diversity of the participant demographics was limited, and factors such as age and religious and health-related values could have impacted on views of shared decision-making and paternalism.
- ⇒ In most cases, pre-amputation and post-amputation interviews were not conducted with the same patients (as was the original objective), but rather some patients had to be matched in view of loss to follow-up of original patients.
- ⇒ Interviews were not conducted with the relatives of patients who had died, who may have had different experiences and held differing views (survivor bias).

INTRODUCTION

Decisions surrounding major lower limb amputation (MLLA) due to chronic limb threatening ischaemia (CLTI) or diabetic foot infection are complex and need to factor in many risks including cardiac complications,[1] wound infections,[1,2] hospital readmissions[3,4] and social isolation and depression.[5] Surgeons' accuracy in predicting outcomes after surgery is variable.[6] If predictions are inaccurate or unreliable, shared decision-making (SDM) is sub-optimally informed. In vascular surgery, this could lead to inappropriate debridement and/or revascularisations, amputations or unnecessary delays to major surgery, both resulting in profound effects on patient quality of life (QoL) and costs to the National Health Service (NHS).[7,8] SDM has been described as

> *a process in which decisions are made in a collaborative way, where trustworthy information is provided in accessible formats about a set of options, typically in situations where the concerns, personal circumstances, and contexts of patients and their families play a major role in decisions*[9] *p.1*

Guidelines have been produced to assist healthcare professionals (HCPs) to use SDM in day-to-day clinical practice[10] and the optimising shared decision-making for high-risk major surgery (OSIRIS) programme is currently being undertaken to ameliorate SDM for surgical patients at high risk of medical complications.[11] Despite SDM being considered the gold standard,[12] conclusions from a systematic review of the use of SDM in surgery highlighted that future studies are necessary to improve SDM during surgical consultations.[13] Little is known about how MLLA risk information is communicated and to what degree decisions are shared. Similarly, patients and HCPs' views on SDM and the potential challenges in the context of MLLA have not been described. Although there are some studies that discuss the impact that family views have on patient amputation decisions,[14–16] this study is one of only a few studies[17–19] to qualitatively examine both HCPs' views on chronic limb-threatening ischaemia associated MLLA decision making and patients' experiences of decision making on MLLA.

Study aims and objectives

The **P**r**E**diction of **Ri**sk and **C**ommunication of Outcom**E** Followi**I**ng Major Lower Limb Amputation—A Collaborati**VE** Study (PERCEIVE) is a mixed-methods (quantitative and qualitative) study looking at MLLA, risk prediction and SDM. The PERCEIVE quantitative study evaluated the accuracy of HCPs' predictions of short-term and long-term outcomes for adult patients undergoing MLLA for CLTI or complications of diabetic foot disease.[20 21] The PERCEIVE qualitative study protocol provides a full description of the qualitative study's aims and objectives.[22] Following publication of the qualitative results, a mixed methods paper, linking both methods, will be published.

This qualitative study aimed to explore the communication, consent, risk prediction and decision-making process in relation to MLLA. Secondary objectives were to explore and describe:

- How risks are communicated and options discussed with patients (±their relatives/carers) while assessing the extent of SDM.
- Patients' perceptions of SDM, the communication of risks and benefits of MLLA, expectations for rehabilitation (and whether these are met) and any decisional regret.
- How HCPs evaluate risks and outcomes when considering MLLA.

METHODS

The study is reported in line with the guidelines set out in Consolidated Criteria for Reporting Qualitative Research (COREQ).[23]

Study design

The qualitative aspect of PERCEIVE was conducted at vascular centres at three large NHS hospitals: two in Wales and one in England, UK between 1 October 2020 and 30 September 2022.

The study drew on theoretical concepts of SDM such as those found in Elwyn and Colleagues' SDM model for clinical practice[24] which comprises 'choice talk', 'option talk' and 'decision talk' to inform a thematic analysis of the findings.

Eligibility

To participate in the study, patients had to be aged 18 years or over with CLTI and having MLLA discussed with them (±their relatives/carers) as a treatment option. Exclusion criteria comprised patients aged under 18 years, patients undergoing MLLA for other causes (eg, cancer) and any patient unable or unwilling to provide informed consent. HCPs had to be involved in, or supporting, MLLA decision making. These included vascular surgeons, anaesthetists, specialist physiotherapists, specialist vascular nurses, occupational therapists, geriatricians and rehabilitation physicians. Exclusion criteria comprised those who were unwilling or unable to provide informed consent.

Interviews

Semi-structured, telephone, audio-recorded interviews were conducted with patients (±their relatives/carers) before or within 4 months of amputation (using interview guide 1) and post amputation 4–6 months after the amputation (using interview guide 2) and with HCPs who were involved in supporting or facilitating MLLA decision-making (using an interview guide for HCPs and an interview guide for surgeons). Field notes were made by the interviewer following each interview. No transcriptions were returned to participants for comment.

The interviews were carried out by two experienced, female qualitative researchers with qualifications in research methods (HP MPhil) and (SM PhD) and an interest in MLLA. The only prior relationship to the patients was a telephone contact to arrange an interview. The patients knew nothing of the researchers' backgrounds and HP did not disclose to them that she was a qualified nurse. The researchers had no prior relationship to most of the HCPs apart from those interviewees who were also members of the PERCEIVE research study team. In the case of the latter interviewees, informed consent was ensured, as was their voluntary participation, and confidentiality was secured.

Interview guides were compiled by the interviewers and the team and were used to support the discussions (online supplemental appendix 1). The qualitative interviews centred on exploring how decisions about MLLA are made by patients and HCPs, particularly focusing on the study aims and objectives. Notably, they explored evidence of the use of SDM and its associated constructs, that is, choice, option and decision talk.[24] Interviews were modified iteratively as the interviews progressed until no new topics emerged.

Patient interview guide 1

Interview guide 1 (for the 'pre amputation' and 'within 4 months of amputation' patients) explored patients' (±their relatives/carers) perceptions of the risks and benefits of MLLA, influences on their decision (eg, current health/pain/mobility status) and rehabilitation expectations. Patient satisfaction with their surgeon consultation was discussed, as well as preferences regarding how risks and benefits/outcomes were communicated. The interview using interview guide 1 was carried out preferably before any treatments had been implemented or, if necessary, as soon as possible after such treatment. Questions first centred on an exploration of leg or foot problems and previous associated treatments, as well as mobility, general health and QoL. This interview also explored the patient discussion with the surgeon regarding treatment options and associated risks and benefits, input into decision making, perceptions of treatment decisions made and rehabilitation expectations. Patients were also asked about the input from the multi-disciplinary team (MDT) regarding their treatment decisions.

Patient interview guide 2

Patient interview guide 2 (for patients who were more than 4 months post amputation) explored any decisional regret regarding MLLA, whether expectations had been met, and with the benefit of hindsight, if patients would have preferred anything to be done differently regarding MLLA communication. The interview using interview guide 2 was carried out between 4 to 6 months following amputation. Questions focused on outcomes following any treatments including amputation, how patients had fared since the initial interview and an exploration of any changes relating to their current mobility, general health and QoL. Patients were also asked to discuss their rehabilitation following treatment and associated expectations and to reflect on any treatment and amputation decisions and discussions with the surgeon and MDT to help them make their decision.

HCP interview guide

The HCP interview guide recorded professional background and any training in SDM and then explored perceived patients' influence on decision-making, whether decisions about amputation are considered genuinely shared between patients and clinicians, input from the MDT, evaluation of risks and outcomes and discussions surrounding life post amputation. A separate interview guide for surgeons also focused on how amputation decisions are made and whether SDM was being carried out with patients when discussing the possibility of an amputation.

Participant sampling

Purposive sampling was used for both patients and HCPs. This type of sampling has been described as when the researcher specifically selects study respondents who will be most representative or knowledgeable about the issues that are being studied.[25] Purposive sampling was used to detect eligible patients who were identified through screening lists by their usual clinical teams. Patients who had consented to an initial audio-recording of their routine consultation with a surgeon were invited to consent also to interviews by ticking the box at the bottom of the consultation consent form. Those patients that were no longer contactable following the consultation were matched as far as possible to those that were seen during the consultation. Clinical team members (research nurses, surgical team members) identified patients and completed consent to contact forms while the qualitative researcher carried out the interview consenting, actual interviewing and analysis of the data. The research team and site PIs also used purposive sampling to identify potential HCPs who were involved in MLLA decision-making for participation in the study interviews. The interviewer then emailed interview invitations to the HCPs.

Informed consent

All participants were given a participant information sheet and had sufficient time to consider the study information before consenting to participate. Patients were only approached if their clinical condition allowed sufficient time to obtain informed consent, and if the clinical team considered that participation would be appropriate. Interview participants provided written consent to be contacted by the researcher, so that a mutually convenient time for the interview could be arranged. As the research was conducted remotely, consent was taken verbally and audio-recorded by the Good Clinical Practice trained researchers prior to the start of the interview. None of the patients' relatives or carers chose to be interviewed alongside the patient participants, so consent was not required for this group.

Recruitment

We anticipated that our recruitment numbers would be sufficient to reflect general topics of importance to participants and a sufficient level of data thickness and richness to achieve our aims.[26]

Patient recruitment

The study protocol highlighted our aim to include interviews with 10–15 patients at two time points; pre and post amputation, which would result in 20–30 patient interviews. However, in practice, this was not possible for most patients due to some not being well enough for interview or others that had died, while others again required emergency amputations. Furthermore, there were difficulties in contacting patients who had been admitted to hospital. Matched patients were therefore necessary to make up the number of study patients. These were matched as far as possible in terms of gender, age and MLLA type (above knee/below knee/no amputation, within 4 months of amputation and more than 4 months post amputation). These additional patients were either recruited face-to-face in the hospital by a research nurse or contacted by telephone. Interview guide 1 was used with 11 patients, four of whom had been matched. Two of these patients had not received an amputation, and nine had received an amputation within 4 months. Interview guide 2 was used with 11 patients, seven of whom had been matched. These patients were interviewed at more than 4 months post amputation. Patients were interviewed by telephone when they were either at home or on a hospital ward. Only one patient highlighted a carer being present at an interview, although some patients were accompanied by a family member.

The age range of patients ranged between 48 and 93 years with an average age of 69 years. Patient interviews using Interview Guide 1 (seven male and four female) lasted between 11 and 70 min, averaging 41 min. Patient interviews using Interview Guide 2 (eight males and three females) lasted between 11 min and 69 min, averaging 32 min.

HCP recruitment

Our protocol aimed to interview 12–20 HCPs. In practice, interviews were carried out with 20 HCPs in the areas of surgery, anaesthesia, vascular nursing, physiotherapy, occupational therapy and rehabilitation gerontology. Exact numbers within each HCP group are not reported to retain anonymity. The duration of the HCPs' interviews was between 25 and 61 min and averaged 35 min. These interviews were carried out by telephone while HCPs were at their place of work. All but two HCPs were interviewed alone, whereas two HCPs who worked in the same team were interviewed together.

Data analysis

All interviews were transcribed verbatim by a professional service and the anonymised transcripts were uploaded to NVivo 12 software.[27] Thematic analysis[28] was used to identify key patterns in the data which consisted of carrying out a series of steps: familiarisation with data, generating initial codes, and searching, reviewing and defining themes. Themes were identified that related to the objectives of the research, but analysis also allowed new, unpredicted themes generated by interviewees themselves to be identified. Also identified were contradictory data as points of contrast, as well as similarities, in order to understand views. A second researcher analysed 10% of the interviews to ensure validity of the analysis and to verify interpretation. Interviews were analysed and recruitment continued until no new themes emerged.

Patient and public involvement

The PERCEIVE qualitative study management group included two patient and public involvement representatives, who provided valuable input throughout the project, one who had undergone MLLA and the other was a carer for a relative who had undergone MLLA. Both representatives had been involved in the PERCEIVE quantitative and qualitative studies from the development stage, and their experiences of MLLA decision-making directly informed the aims and the development of the research.

FINDINGS

Thematic analysis identified five major themes which highlighted the challenges of ensuring SDM associated with MLLA. They include (i) patients' limited understanding, (ii) patients' varied attitudes to MLLA decision making, (iii) HCPs' perceived challenges to delivering SDM, (iv) surgeon paternalism and (v) decisional regret/possible consequences of challenges. Figure 1 highlights all themes that were identified. Participants did not provide feedback on the themes due to study time constraints but were given the opportunity of receiving results on completion of the study. The main differences in findings highlighted between the use of patient interview guide 1 and patient interview guide 2 related to rehabilitation issues reported using interview guide 2. A lack of a discussion with a surgeon concerning rehabilitation post-amputation was reported as well as inadequate rehabilitation information from physiotherapists and occupational therapists. However, most patients felt that they had made the right decision following an amputation and were now enjoying a better QoL. Patient quotations are labelled with their participant identification number and whether they were interviewed using interview guide 1 or interview guide 2. HCP quotations are labelled with profession type and participant identification number.

Patients' limited understanding and unrealistic expectations

Patients' limited understanding of complex medical decisions was highlighted by HCPs, who explained that some of the issues surrounding amputation could not be fully appreciated without first-hand experience. Specific challenges related to patient understanding were raised.

Perceived patient difficulty in understanding complex information within a short period of time

Several surgeons mentioned that understanding risk and options is a gradual process for some patients and that patients do not always have a good understanding after discussions. This led to some situations where patients would get confused regarding the type of amputation that was being discussed, that is, a below knee or above knee amputation.

Cognitive impairment

Some HCPs described cognitive impairment as a challenge which is sometimes associated with this patient group and may hinder patients' understanding of risks and options. A surgeon described a situation where a patient had forgotten that they had agreed to an amputation and woke up the next morning in extreme distress because their leg was missing. Furthermore, patients may

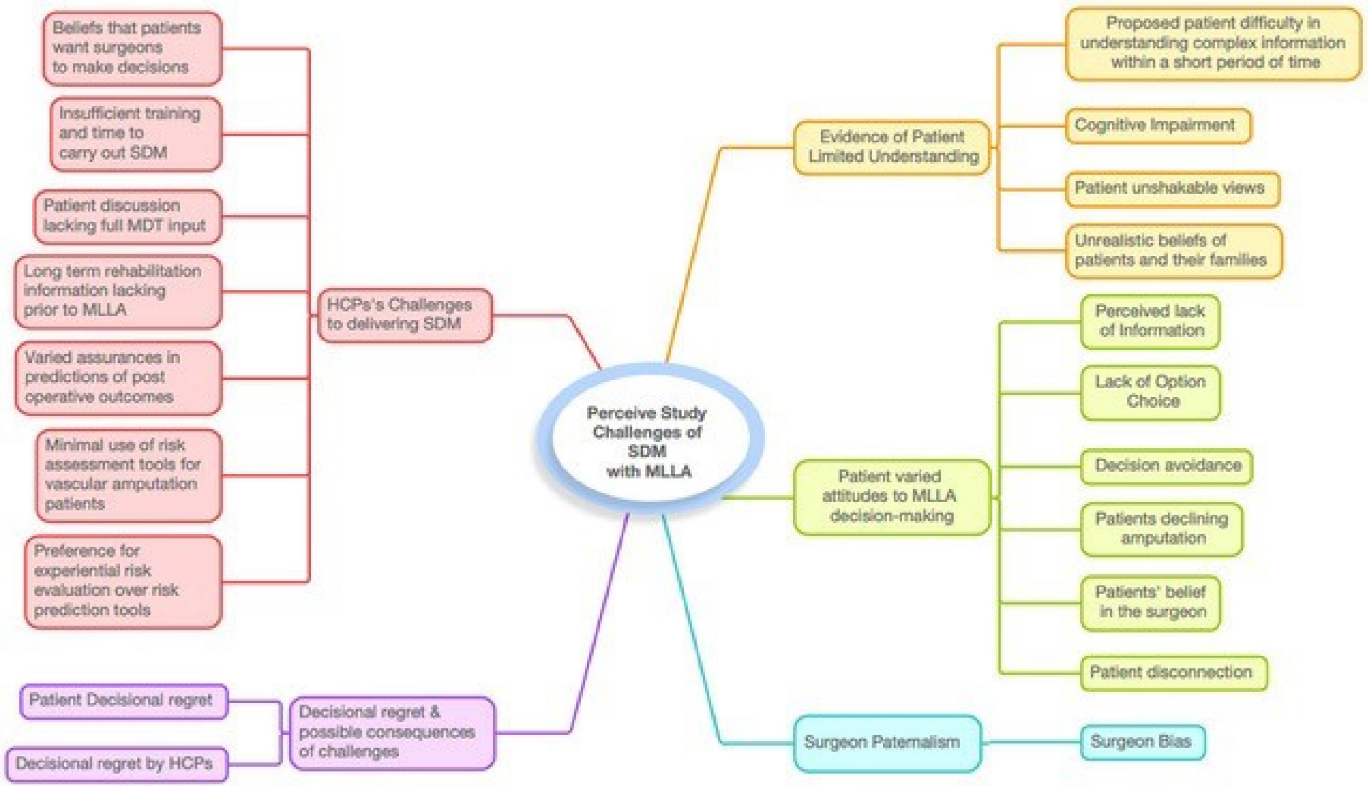

Figure 1 Challenges of carrying out SDM associated with MLLA: themes and sub-themes. HCPs, healthcare professionals; MDT, multi-disciplinary team; MLLA, major lower limb amputation; SDM, shared decision-making.

be under the influence of strong analgesic medication, which may impair thinking. Several surgeons considered that it was inappropriate to tell some patients with a limited mental capacity that without an amputation, they will very soon die; however, talking to a patient's family or carer can take considerable organisation. Lastly, a surgeon reported that for those patients with severe dementia, it may be better not to amputate, as this could hasten mortality.

Patients' unshakable views

HCPs identified that some patients declined to discuss options in view of their existing '*unshakable*' views, with some arriving at consultations having already decided they would not want an amputation at any cost.

Unrealistic beliefs of patients and their families

Several HCPs reported that some patients are unrealistic in their expectations about life post MLLA.

> *'Most patients above everything they want to be better, they want to get better than compared to what they were like before, while most of them want to get back into a way like they were like 25 years ago, sometimes* [laughs] *it's unrealistic'* (Anaesthetist, HCP 8)
>
> *'They're just completely unrealistic, and again it doesn't matter how explicit you say to them, you're going to be based in a wheelchair, they still think they're going to be up and about and walking in two months'* (Surgeon, HCP 1)
>
> *'A lot of [patients] are quite, you'd say aspirat-aspirational is probably fair to say, so they think* [a prosthetic limb is] *going to be a fix to all their problems almost and that their mobility is going to be sometimes better than what it was before amputation, which is hard for us to try and manage I'd say'* (Physiotherapist, HCP 17)

A physiotherapist participant reported that sometimes it was the patient's family that was unrealistic about rehabilitation, which required family education. No participating patients reflected in their second interview that they had had unrealistic expectations of rehabilitation, but rather raised the issue of a lack of support in rehabilitation (described later).

Patients' varied attitudes to MLLA decision-making

Perceived lack of information

Although most patients felt they were fully informed of treatment options, several raised that there had been inadequate discussions with the surgeon. It was reported that they would have liked to have known if there was any other option other than amputation, but they did not get the chance to ask; another wished they had had more time to ask questions.

'I didn't really have a discussion with any doctor' (Patient 7, interview guide 1 interview)

'There was only a couple of seconds I think' (Patient 3, interview guide 1 interview)

A patient's perceived lack of information pre-operatively left them contemplating whether they had made the correct decision to proceed with an amputation.

Although several patients said that discussions about risk had been sufficient, some reported that there was no talk of risks or that discussions about risk were not specific enough and the surgeon had only talked about the basics of risk. Others could not remember if there had been discussions about risk.

Lack of options

Some patients said that they had discussed options with their surgeon, but many felt that there was no choice regarding MLLA because it was necessary

> *it came down to pragmatic decisions as to, really, whether I lived or died* (Patient 2, interview guide 2)
>
> *when you're left with an alternative which could kill you in the end, you've got to get it done haven't you* (Patient 18, interview guide 2)

Some patients had been advised by surgeons that MLLA was necessary as antibiotics would not halt their infection, that pain relief was no longer an option, that their health would otherwise deteriorate or that they might die. Some patients reported that the surgeon was adamant that they should have an MLLA.

> *'There was no alternative really. It's like, either we do it or the infection will take over. You will die, simple as that'* (Patient 5, interview guide 1)
>
> *'I just felt that* [the surgeon] *was pushing and pushing for it. But it didn't really matter what I thought'* (Patient 10, interview guide 2)

Several HCPs claimed that they believed that patients are given the choice about treatment discussions, for example, a surgeon believed that some patients know exactly what treatment they want. Some surgeons advised that they would actually tell the patient that it is their choice. It was also reported by a vascular nurse that the patient and family would receive an information booklet before an amputation while also seeing the occupational therapist and physiotherapist if the patient was undecided about treatment. Furthermore, most HCPs felt that decisions were genuinely made with patients. A surgeon also stated that amputation decisions with patients are genuine as they do not undertake amputations lightly and that patients were given plenty of time to understand the options and reflect on the decision. A rehabilitation geriatrician also reflected that patients do have a choice in their treatment decisions even though they feel there is none. For example, patients can choose what level of amputation and type of skin flap to have. They expanded that patients can also choose the type of rehabilitation they would like after the treatment, whether to use a wheelchair or have choices related to prosthetic rehabilitation. However, HCPs advised that sometimes choices are limited, due to the danger of sepsis, for example. An anaesthetist and several physiotherapists explained that patients often do not understand that they do not have a choice as other treatments have already been tried to save the leg, and other than amputation, the only option is palliation.

Decision avoidance

HCPs offered that sometimes patients do not want to be involved in the decision even though they are encouraged to be.

> *'I think sometimes, it's a bit cruel to push the idea that they need to be involved when they don't want to. I mean some patients just openly tell you they don't want you to talk to them about risk even though* [the surgeon] *tries to get some basic concepts over to them. But where they, where they have capacity and refuse further information, it seems inappropriate to carry on pushing things'* (Anaesthetist, HCP 14)

Patients disconnecting

It was reported that many patients appeared to disconnect with the conversation as soon as amputation was mentioned and at that point, the only thing HCPs could do was to allow the patient time to digest the information, thereby requiring a later visit.

Patients declining amputation

Two of the patients interviewed declined to have amputations. The first said they planned to avoid having a foot amputation by having weekly podiatry treatment, antibiotics and strong pain relief, despite the surgeon advising amputation. Their request for revascularisation had been turned down by the surgeon due to them being medically unfit for this operation. The second patient chose to continue with frequent wound dressings and pain relief, although they acknowledged that pain was still a problem and something more needed to be done.

HCPs advised that patients sometimes disagree with a HCP's opinion, which can lead to difficult conversations. In this instance, they would tell the patient the reasons why they do not recommend what the patient has chosen. Vascular nurses said that they would need to talk to the patient and family about conservative or palliative management. Furthermore, it was proposed that sometimes the patient may need more information about the rationale of recommendations.

> *'A lot of that [disagreement] will be kind of tried to be alleviated by a lot of education to the patient as to why, why we're not on the same thinking. And also, I think a lot of delving into the person's beliefs as to kind of why they do or don't want an amputation and why we don't think that might be the best way forward'* (Physiotherapist, HCP 5)

It was reported that a second opinion is sought when a patient disagrees with a surgeon's preference to amputate. A surgeon reported that rather than coercing a patient into having an amputation, they would wait for the patient to comprehend that an amputation is the only option. This may involve discharging the patient and waiting for them to be readmitted as an emergency admission.

Patients' belief in the surgeon

Most patients believed that if the surgeon thought that it was best to amputate, then that is what should happen. A patient reported arguing with the surgeon that it should be the surgeon who should make the decision and not them.

> *So, I said, It's not!* [my decision]). *It's based on your knowledge of what my decision will be based on, not on my knowledge, on yours* (Patient 12, interview guide 2)

HCP challenges to delivering SDM

Belief that patients want surgeons to make the decision

Several HCPs believed that patients preferred the surgeon to choose the treatment option.

> *'Some patients don't really want to be involved in the decision even though you and most of the surgeons try to involve them'* (Anaesthetist, HCP 14)

It was described by an anaesthetist that continually attempting to push the patient into being more involved in decision-making may be unethical, but they are legally and duty-bound to ensure patients understand the basic concepts of any high-risk procedure they embark on. A physiotherapist reflected that many of the mainly older patients hold the surgeon in high esteem, agreeing to whatever the surgeon recommends. Indeed, a surgeon reflected that although options are discussed with patients, the patient will ask the surgeon what they suggest as they are the doctor. Another reported that patients may not have the psychological mindset to accept responsibility for the decision or to retain the information presented to them and that is why they often transfer responsibility to the surgeon to do what is best for them.

Insufficient training and time to carry out SDM

Few HCPs had received formal training in SDM. Some said they had heard of the method in conference workshops, while others had learnt about it via online tutorials. Only one surgeon had been required to learn SDM through a mandatory course. It was perceived by a surgeon that they were not taught SDM as a medical student because a paternalistic model of medicine was in place and SDM was something that had developed during their career. Furthermore, several thought that its use could be challenging due to the time restraints of working in a busy hospital.

Patient discussions lacking full MDT input

HCPs highlighted that the MDT was sometimes involved in treatment discussions. However, pre-amputation consultations were frequently only carried out with the surgeon. Non-surgeon HCPs were more likely to be involved in giving information to patients and their families. Some believed that discussing treatment decisions with patients was the role of the surgeon, while others felt that they should be more involved pre-operatively. It was also described that surgeons sometimes make decisions without knowing all options as they do not involve the Artificial Limb Service. A surgeon reflected that the MDT should be more involved in pre-amputation discussions as this group knowledge of patients would help to speed up their discharge.

Most HCPs, including surgeons, believed that physiotherapists and occupational therapists were better placed than surgeons to predict long-term outcomes post amputation, with some believing this to be due to the therapists' role in better exploring in depth a patient's history.

> *'I think sometimes surgeons are too led by the fact that the person has come in in a wheelchair or has come in with a very low functional status. And sometimes, won't unpick to realise that actually they've only been like that for six weeks, when their leg started getting painful. And three months ago, they were walking the dog. So, I think sometimes we just do a little bit more digging that can inform our decisions'* (Physiotherapist, HCP 5)

Moreover, it was related by a rehabilitation geriatrician that surgeons' expectations about a patient's rehabilitation are often not realistic as they are not experts in amputee rehabilitation. Therefore, it was preferred that the surgeon give patients vague answers about rehabilitation expectations, otherwise the surgeon may be setting up the rehabilitation team to fail.

Long-term rehabilitation information lacking prior to MLLA

Most patients highlighted that the surgeon had not mentioned long-term outcomes or rehabilitation during pre-amputation discussions, apart from general predictions of a better QoL. A patient even said that it was not for the surgeon to discuss rehabilitation

> *I wouldn't expect them to, because it's not really their department* (Patient 2, interview guide 2)

Conversely, surgeons highlighted a focus on the key patient outcomes of pain relief, maintenance or resumption of mobility, a healed wound, an improvement in QoL and good palliative care. A patient reported that the surgeon had told them they would need to live in a care home following the amputation, but this had not been the case. Another did not place much trust in the surgeon's predictions of rehabilitation.

> *'[The surgeon] said, I expect you to be walking within two months, and I knew that when he said walking he meant standing and doing that, it's a typical surgeon's response, isn't it, they do their job and then they, they hand you over'* (Patient 16, interview guide 2)

Some patients related that it was the physiotherapists and occupational therapists who had been the most helpful regarding rehabilitation information, although this input had been insufficient. Several HCPs also thought surgeons were not effective in predicting long-term outcomes for patients undergoing amputation. It was suggested by a physiotherapist that surgeons are better at predicting short-term outcomes such as mortality post amputation. An occupational therapist suggested that surgeons were more pessimistic regarding patients' rehabilitation ability because they did not know the patient's details.

Although several HCPs thought their opinions were taken into account by the surgeon, a physiotherapist felt that surgeons did not communicate with them enough. When asked about patient rehabilitation and longer-term outcomes, several surgeons reported that most patients had only one post-amputation outpatient appointment. This was sometimes a telephone appointment which may occur several weeks after the operation, mainly to assess stump pain and healing. Further follow-up appointments would only occur if the patient was experiencing problems. Much of the follow-up of patients was transferred to other HCPs such as the referral team, the nurses or the rehabilitation team. Surgeons were therefore mostly unaware of a patient's abilities post-amputation. Since it was reported that it is the surgeons for the most part who carry out pre-amputation discussions with patients, this lack of knowledge and experience may impact on amputation decisions.

Confidence varied in predictions of post-operative outcomes.

HCPs appeared to have more confidence in predicting long-term mobility than patient mortality and morbidity. This was especially true for physiotherapy, rehabilitation, gerontology and surgery. Surgeons' perceptions of their ability to predict mortality and morbidity varied. Some felt that their predictions were accurate as few patients died and that they used knowledge of a patient's co-morbidities and presence of infection as good indicators of survival. Others cited the national registry data relating to vascular mortality, discharge and length of stay which showed that their outcomes were better than average. Others reported that they used both experience and the opinions of the MDT. Some surgeons advised that they did not predict mortality and morbidity because of crude prediction methods often failing to predict patient complications. Another stated that inaccurate predictions were due to a focus on short-term outcomes.

Minimal use of risk assessment tools for patients undergoing vascular-related amputation

The use of risk prediction tools by HCPs appeared to be minimal. Anaesthetists were most likely to say they used a risk prediction tool; however, one claimed that they did not think there were any specific assessments for patients undergoing vascular-related amputation. If they deemed a patient to be high risk, they used pre-operative risk assessment such as the Surgical Outcome Risk Tool [29 30] in conjunction with discussions with surgeons about the patient's medication to determine the preferred anaesthesia. Other tools that were highlighted included the Acute Care Surgery National Surgical Quality Improvement Program (ACS NSQIP) tool,[31] which compares an individual's risk profile to a standardised one, although it was advised by a surgeon that this tool requires talking to patients initially about quality vs quantity of life. Another anaesthetist promoted the use of the NHS QRISK calculator; an algorithm which calculates an individual's 10-year risk of having a heart attack or stroke.[32] They related that this was not perfect but helped to aid patient discussion regarding morbidity, mortality and ability to return to normal activities.

Only a minority of surgeons reported that they used risk prediction tools, with one example being the Vascular Physiological & Operative Severity Score for the enumeration of Mortality and Morbidity [33] which was reported as being well validated, easily available online and helpful in determining the risk of major morbidity and 30-day mortality. Surgeons appeared to rely more on experience, with a surgeon reporting being unaware of adequate tools to predict mobility for amputation patients. Several HCPs, in particular surgeons and anaesthetists and a rehabilitation geriatrician, highlighted little confidence in the trustworthiness of risk prediction tools. It was related that these tools simply give a broad picture or a general impression of risk compared with a baseline rather than a specific percentage risk, since it is difficult to predict individual patient risk.

Preference for experiential risk evaluation over risk prediction tools

Surgeons reported that they carried out several assessments in order to evaluate patient risk for an operation, for example using the patient's current state of health, their co-morbidities and capacity to tolerate anaesthesia. Most surgeons reported that they prioritised experience over the use of risk prediction tools in decision-making, with some stating that these tools should be used in conjunction with experience. A surgeon advised that these tools are not required anyway as an amputation is the last option for a patient.

Frailty was also acknowledged as this presupposes a patient's rehabilitation chances and post-amputation QoL. Other assessments included considering the implications of no treatment for a patient and the possibility of palliation being a better option for QoL. A surgeon believed though that an amputation operation is not a particularly high-risk procedure, especially since both the surgeon and anaesthetist are consultants, thus proposing that risk prediction tools are not required. To encourage use of risk prediction tools, it was suggested that they should be proved to be trustworthy and should be validated or else they could be misleading.

> *'Because you essentially give people numbers that are best guesses, where you're better off just explaining the situation to the patient and allowing them to come to their own decision. Would use them if they were demonstrated to work well though'* (Surgeon, HCP 16)

Several physiotherapists claimed that although they used tools such as the Blatchford Leicester

Allman-Russell tool [34] to predict prosthetic use, and the SIGAM Mobility tool,[35] they would not use a tool in isolation of their experience, but rather as a rough guide alongside patients' social and medical histories and the surgeon's opinion. They reflected that the tools were useful for less experienced members of physiotherapy staff, especially if the patient has co-morbidities. The vascular nurses interviewed did not use risk prediction tools, with a vascular nurse querying their trustworthiness and another believing that they were used by the rehabilitation consultants but probably not prior to amputation.

Surgeon paternalism

Surgeon bias

Although it was noted by a surgeon that many patients have a strong view on their preferred option, several HCPs believed that surgeon paternalism was at play. Indeed, a patient suggested that the discussion was '*one sided'* (Patient 1, interview guide 1 interview). A surgeon queried the notion of genuine SDM, since the surgeon gives biased information to the patient.

> *'Their decision is very biased on how you present your evidence to them. So can it ever be truly patient delivered decision making, I'm not sure'* (Surgeon, HCP 16)

Examples from patients highlight surgeons advising them that without an amputation, the only option is conservative management with pain relief which would cause illness and a shorter life. It was suggested by a surgeon that surgeons and geriatricians often form a view based on risk and likely outcome, and this view is then communicated with the patient but in a biased way. Surgeons offered that they have a duty to inform the patient of their professional opinion. Indeed, some surgeons believed that they knew what the best option was for a patient and it was acceptable to tell the patient this, with a surgeon stating that they would tell the patient if they thought they had made the wrong decision. Another surgeon also reported that they didn't think they had ever made a wrong decision, and that they would not carry out an operation unless they felt that it was the right thing to do. A surgeon felt that although SDM sounds beneficial, it is an 'academic construct', as the patient ultimately wants the surgeon to make the decision'

> '…the principles of it are brilliant, you go through all the information with all the decisions, with the patient and their family, you make sure they're involved, you make sure they understand everything and then that involvement of the patient makes them feel empowered about the decisions they make. That, that is something you write on a piece of paper. When you do it in real life, the vast majority of the time the patient says what do you think I should do?'
>
> (Surgeon, HCP 9)

Decisional regret and possible consequences of challenges

Patient decisional regret

Most patients felt they had made the right decision to have an amputation, as they experienced better health and QoL in general, and improved mobility especially due to no further pain, apart from some phantom pain. Two patients had amputation regrets, the first wishing that they had tried revascularisation initially, while the second believed that an above-knee amputation would have been preferable before their failed below-knee amputation. Despite few patients regretting an amputation, some felt that they no longer had a good QoL since their MLLA and were disappointed in their lack of mobility. Some felt very depressed, stating that they were now completely wheelchair users and could not leave the house.

> *'I hate my life at the moment. I hate being stuck in the house. I hate being stuck in the chair. I can't stick it'* (Patient 7, interview guide 1)

Associated grievances though appeared to be related to a lack of rehabilitation services and equipment and the wait for a prosthetic limb.

> '*And what did happen was nothing. They sent me to a rehab hospital and nobody ever done anything there……Went to one ward, then they said, you're going to go down to another ward for rehab. Went to another ward, didn't do anything there. Everything I learnt to do like getting in and out of cars, standing up, going to the toilet, everything I done off my own back'* (Patient 7, interview guide 2)

Indeed, a patient who had been extremely low in mood felt much better since receiving a prosthesis.

HCP decisional regret

Most HCPs reported that at times a wrong decision with a patient is made. Examples include the team needing to amputate sooner to enable better outcomes and carrying out higher amputations straight away rather than a lower amputation level which then needs a second operation to revise it, which can have negative implications for a patient's rehabilitation. Other examples included carrying out a complicated, lengthy revascularisation procedure which either failed or resulted in the patient dying shortly afterwards, when an hour-long amputation surgery would have been preferable. Moreover, it was proposed that palliation may have been the better option when a patient dies soon after an operation. Some HCPs felt though that sometimes making a wrong decision is inevitable as it is impossible to predict all outcomes correctly.

DISCUSSION

The PERCEIVE quantitative work encompassed two published papers. However, there were sufficient data to additionally publish the qualitative work. This qualitative study set out to explore patients' and HCPs' experiences, opinions and perceptions of the communication, consent, risk prediction and decision-making process in relation to MLLA, through individual interviews. It is one of only a few studies[17–19] to qualitatively examine both HCPs' views and patients' views. Findings highlighted many shortcomings relating to these areas, including issues that are at odds with the principles of SDM set out by Elwyn and colleagues.[24] The study has methodological limitations. We used a finite number of participating centres which could possibly highlight specific MDT clinical structures as well as the use of certain decision-making tools. Similarly, there may be limited insight into the views of a more generalised sample of participants, for example, those of a wider range of religious beliefs and age-related values. It would also have been beneficial to seek the comments of relatives of participants who had died to avoid results of 'survivor bias' whereby the views of only those that survived MLLA are reported.

This qualitative study, along with the PERCEIVE quantitative study results,[20 21] has shown that few HCPs have confidence in the utility of risk prediction tools and that many prefer to use personal experience to determine risk. A systematic review and narrative synthesis to determine how accurately a surgeon's 'gut feeling' and perception of risk correlated with patient outcomes and risk scoring systems highlighted that (i) surgeons overpredicted mortality rates and were often outperformed by risk scoring tools; (ii) surgeons' prediction of general morbidity was equivalent to, or better than, pre-existing risk prediction models and (iii) long-term outcomes of risk were poorly predicted by surgeons.[6] Overall, a key finding of this study was that surgeons' (and prediction models') accuracy was highly variable depending on the pathology and the outcome being predicted. It is therefore paramount that surgeons identify better risk predictive information to integrate when trying to improve SDM.

Our findings highlight a disconnect between patients' experiences and perceptions of SDM and what constitutes quality SDM; for example, several patients mentioned a lack of information and a feeling of either being excluded from the treatment decision or 'abandoned' to make it without sufficient support. This disconnect was also identified by HCPs, who encountered challenges such as difficulty in explaining complex risk/benefit information to patients, their lack of time to counsel patients, the lack of input from the associated MDT and unrealistic expectations of patients and their families. Sometimes communication was reported as sub-optimal, with insufficient accurate information, mis-match of agendas and the issues, goals and expectations that were important to patients not being identified by HCPs. There was evidence of a lack of understanding among HCPs about what SDM is and is not, differentiating it also from informed consent. Studies in other health-related areas however have highlighted interventions that can improve information sharing for decision-making, such as patient decision aids[36 37] as well as the use of novel multidimensional methods of videos, booklets and coaching to help patients and primary care providers to communicate more openly.[38]

Although methods to improve information sharing with patients may enable better decision making for patients, our data show that some patients are reluctant to participate in treatment decisions, preferring instead that the surgeon decides. Joseph-Williams and colleagues[12] however point out that although clinicians report patients not wanting to be involved in decisions, they should not presume that all patients feel this way, with some preferring greater levels of involvement and that it is hard to predict from patient characteristics which individual patients want to be more or less involved. Furthermore, they state that this preference to not be involved in the decision should itself be informed. It should also be said that although some surgeons claim that patients may require more time to reflect on an amputation decision, it is questionable that giving patients more time is really addressing why they are unwilling to discuss the decision. It is possible that what patients require is more support to engage in decision-making, for example by acknowledging their fears of morbid discussions frequently found in vascular illness experience.

Our findings highlight that many patients felt they had no choice but to have an amputation, as alternatives had already been tried. Furthermore, they believed that the choice they had was either to have an amputation or to continue to experience pain and have their health deteriorate. Several surgeons also reported that the only option left to many patients was to have an amputation or the patient would die. This is illustrative of the term Hobson's choice, which the Merriam Webster online dictionary defines as *'i. an apparently free choice when there is no real alternative and ii. the necessity of accepting one of two or more equally objectionable alternatives'*. This term was also highlighted in Howard *et al*'s study[39] which explored consent for acute surgical interventions, whereby a patient reported that they had no choice but to have a left hip hemiarthroplasty. Despite this reality for many patients however, a HCP in our study claimed that there are choices regarding amputations too, for example, the type of amputation. Indeed, as Columbo *et al*[8] describe in their focus group study with 20 amputees, all those participants expressed the desire to have an active role in the decision to undergo amputation, even while acknowledging that limb salvage options were exhausted. The conceptualisation of SDM in this high-stakes context needs to account for the issue of Hobson's choice while still engaging patients and families in decisions about their care and rehabilitation to try to match options with patients' goals and what is important to them. This will be an important element of further SDM training development for vascular surgery.

CONCLUSIONS

There is disparity between patient and HCP perceptions of SDM when contemplating MLLA. Our data have highlighted several challenges to the experience of SDM for

MLLA. These include patient, HCP and systemic challenges. Clinicians should be made aware of the discordance apparent in MLLA SDM. Moreover, they can learn from the challenges highlighted in this paper and implement this knowledge into their practice to potentially improve patient outcomes.

These qualitative findings will be utilised in conjunction with results from the quantitative aspect of PERCEIVE in the form of triangulation to develop a logic model to propose strategies for example education for HCPs to improve SDM and risk perception/communication for MLLA.

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