

A Caribbean perspective: Quality of Life in Major Lower Extremity Amputees

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Research

Keywords: Amputee, Quality of life, Major lower limb amputation

Posted Date: August 11th, 2020

DOI: <https://doi.org/10.21203/rs.3.rs-54128/v1>

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Abstract

PURPOSE:

Lower extremity amputations and diabetic foot-related complications in the Caribbean population have been previously reported [1-3]. However, there is a lack of evidence which assesses the Quality of life experienced in such amputees. The aim of this study was to determine the health-related Quality of life (HRQoL) in patients after a major lower limb amputation.

METHODS:

All major lower limb amputations undertaken at a tertiary care institution in Trinidad and Tobago, between January 2012 to December 2016 were analysed. The quality of life was assessed using the EURO QOL 5D-5L tool. Statistical analysis was performed using t-test, ANOVA across various subgroups and Kaplan-Meier for mortality.

RESULTS:

A total of 134 individuals were still alive and willing to participate in the study. The average of HRQoL index value for the cohort was (0.598), which was significantly lower compared to the population norm $p < .05$ [4]. Statistically significant differences were also seen between patients who ambulated with a prosthesis (.759) compared to those who used another device (0.562), $p < 0.05$ and to patients who did not ambulate. A comparable Quality of life was seen between the level of amputation (transtibial versus transfemoral) and gender (males versus females), p values were .96 and 1.0 respectively. The overall mortality rate was 14% at 30-days and 27% at one year.

CONCLUSION:

Overall Quality of life after major amputation, as well as independent mobilisation with a prosthesis, continues to be problematic in the Caribbean population. Factors adversely related to Quality of life post major amputation include increasing age, problems related to mobility and non-ambulatory patients.

Plain English Summary:

A major lower extremity amputation is the removal of any part of the leg above the ankle joint. This is an area of major concern in the Caribbean due to the high rates of medical problems such as diabetes and high blood pressure. Although there are well known associated risk factors and consequences leading to an amputation, there is very little information on the quality of life experienced after such amputations. Hence the purpose of this study was to provide much needed insights in this area, which can in turn help to initiate positive change for these patients. Based on the results obtained, persons who have had an amputation has a significantly lower quality of life than a person without an amputation of same age and gender. Additionally, persons who move around with a prosthetic leg had a better quality of life than persons who used another mobility aid such as crotches, walking frames or a wheelchair. The worse

quality of life was experienced by those patients who were not able to move at all. This study highlights that amputees are at a significant disadvantage; more work is necessary to avoid amputations and for rehabilitation of those patients who have lost their leg.

Introduction:

Health-related Quality of life (HRQoL) in major lower extremity amputees remain an area of concern and thus drives rehabilitation efforts. The primary goals are to ambulate with a prosthesis, enable amputees to perform activities of daily living and optimise control of co-morbid conditions [5]. Although lower extremity amputations and associated diabetic foot-related complications have been extensively studied in the Caribbean [6–8], there is a paucity of evidence to correlate with international data which assesses the Quality of life experienced by amputees. Health-related Quality of life is an area of interest, as many daily functions are impaired, and dependency in these individuals is rampant. Ideally, once the limb stump is adequately healed, an amputee should go on to have a prosthesis within 4 to 8 weeks [5, 9]. Additionally, intensive lower limb physiotherapy is required from the early post-operative period extending beyond prosthetic acquisition [5, 10–12]. These strategies maintain range of motion at the joint in question, avoid flexion deformities, aid in muscle strengthening; inclusive of the upper limbs (required for self-transfer and ambulation). Mobility and prosthesis acquisition play a crucial role in the rehabilitation of amputees to pre-morbid functional levels. These two aspects have also been shown to have a significant impact on the Quality of life in patients after having a major lower limb amputation [13, 14]. Hence, the goal in this population of surgically treated patients should always revolve around the restoration of mobility by employing the various devices available, which are tailored to individual needs.

Objectives:

To assess the health-related Quality of life in patients after major lower limb amputation at a tertiary care institution in Trinidad and Tobago.

Methodology:

All major lower limb amputations undertaken at a tertiary care institution in Trinidad and Tobago, between January 2012 to December 2016 were reviewed. A total of 629 amputees were identified, and demographic data obtained for 603 of these. Patients' excluded were those younger than 18 years, had a minor lower limb amputation (the level below the ankle) and patients' whose records were not available for review.

Out of 629 amputees 134 individuals were found to be still alive and willing to participate in the Quality of life study. These were included in the final analysis. The Euro Qol 5-dimension 5-level (EQ 5D 5L) quality of life assessment tool was used for data collection, in addition to demographics, type of major amputation and prosthetic acquisition. The assessment was performed as a face to face interview in the surgical out-patient clinic. The 5-digit numerical code obtained can, therefore, range from 11111 to 55555,

which can be translated to an index value which gives the societal value of a health state relative to all other EQ-5D-5L states [15, 16].

There is no EQ-5D-5L value set for Trinidad and Tobago. Index values were obtained for this study by applying a crosswalk algorithm to the Trinidad and Tobago EQ-5D-3L value set [17, 18]. The EQ-5D-5L instrument also includes a visual analogue scale (EQ-VAS) on which a respondent can indicate their self-perceived level of health on a 0-100 scale (worst-to-best health imaginable).

Statistical analysis was performed using the ANOVA and t-tests across various subgroups based on age, gender, type of procedure and time since amputation. Additionally, mean values for these subgroups and the cohort were compared to population norm values for EQ-VAS and EQ-5D index. The mean differences were compared, a p-value less than .05 was considered statistically significant, and Kaplan-Meier analysis was used for mortality.

Ethical approval was obtained from the University of the West Indies Ethics Committee (**CEC079/11/15**) as well as from the relevant Health Authority for conducting this project. Licensed use was obtained from the EURO QOL committee for the use of their EQ 5D-5L assessment tool for a period of 2 years commencing November 1st, 2016. A sample size of 134 will allow a confidence interval of 95% with a margin of error of 7.5% for the total amputee population (629 individuals) for the given period.

Results:

Over a 5-year period (January 2012 to December 2016) a total of 629 major lower-limb amputations were performed of which demographic data for 602 cases were available for review. The overall average age was 63-years (range 19 to 100 years) and males accounted for 62% (371/602) of the study group. Transtibial amputation (TTA) was performed in 67% (403/602) and transfemoral amputation (TFA) 33% (199/602) of the cases. These parameters did not show any statistical difference when compared to the EURO QOL cohort Table 1.

Table 1
Comparing Euro Qol Cohort to Overall Amputee Group

Parameter	EURO QOL Cohort (n = 134)	Amputee Group (n = 602)	p-Value
Average age (years)	63	63	.959
Average Age Males (years)	62	63	.983
Average Age Females (years)	63	64	.977
Above Knee (%)	43	33	.145
Below Knee (%)	57	67	
Males (%)	62	62	1.0
Females (%)	38	38	

The overall mortality rate at 30 days was 14% which increased to 27% in one year. There were significant differences in the mortality when transfemoral amputees were compared to transtibial amputations $p < .0001$ and for female versus male amputees, $p < .009$. The Kaplan-Meier graph analysis for the overall amputee mortality rate over 80 months is shown in Figs. 1 and 2.

Figure 1 Kaplan-Meier graph of Mortality based on Gender

Figure 2 Kaplan-Meier graph of Mortality based on Type of Amputation

One hundred and thirty-four individuals fulfilled the inclusion criteria for the EURO QOL 5D-5L assessment and was analysed further. Out of the 134 amputees 88% (118/134) were diabetic and 60% (80/134) hypertensive. Ischemic heart disease and end-stage renal disease accounted for 15% (20/134) and 7% (9/134) respectively. The mean time at which the quality of life assessment was performed was 42 months (range 6 to 73 months) from the date of amputation. For the majority, the indication for surgery was sepsis in 70% (95/134) and peripheral arterial occlusive disease in 24% (32/134). Amputees who had surgery for trauma and malignancy accounted for 4% and 2% respectively.

The EQ 5D-5L index values obtained showed that overall amputees younger than 50- years reported a superior quality of life compared to those older than 50-years (mean difference 0.166), this was replicated for female amputees younger than 50-years versus those older than 50-years (mean difference 0.245), $p < .05$. Although a higher index value for males younger than 50-years was seen compared to older than 50-year males (mean difference 0.123), this difference did not reach statistical significance, $p = .059$. Comparable mean index values when all males and females of all ages were compared together (mean difference 0.021), $p = .999$ shown in Fig. 3.

Figure 3 Quality of Life Indices based on Age and Gender

Amputees (transtibial and transfemoral combined) who ambulated with a prosthesis scored higher index values than those who ambulated with some other device and those who did not ambulate (mean difference 0.197 and 0.490), $p < .05$. All amputees (TTA and TFA combined) who ambulated with some form of mobility device versus those who did not ambulate had a higher mean index value (mean difference 0.293), $p < .05$. A similar trend was observed for the transtibial amputee group (prosthesis versus other device and non-ambulation, another device versus non-ambulation; mean difference 0.270, 0.665 and 0.395) $p < .05$. In the TFA group patients who did not ambulate had a significantly lower index value when compared to those who ambulated with a prosthesis or another device (mean difference 0.356 and 0.294 respectively), $p < .05$. Although the TFA prosthetic group did have a higher mean index than the other device group, this difference did not achieve statistical significance (mean difference 0.062) $p = 1.0$. The TTA group who ambulated with a prosthesis recorded higher index values than the TFA group who also ambulated with a prosthesis (mean difference 0.1480 $p = 0.27$ shown in Fig. 4).

Figure 4 Quality of Life Indices based on Mode of Ambulation and Type of Amputation

When the dimensions (mobility, self-care, usual activity, pain/discomfort and anxiety/depression) were individually assessed, Mobility as well as Usual Activity scored worse (mean 3). Regarding other dimensions (self-care, pain/discomfort and anxiety/depression) the frequency of no problems versus any degree of problems were comparable (mean 2), shown in Table 2.

Table 2
Frequency of the 5-Level scores for each of the 5-Domains of health assessed

n = 134	EQ Dimensions					
EQ Levels	Mobility	Self-Care	Usual Activity	Pain and Discomfort	Depression and Anxiety	Mean
1	31	74	45	63	62	3
2	37	17	28	42	29	2
3	15	10	12	18	16	3
4	5	8	9	9	18	2
5	46	25	40	2	9	2

The EQ-VAS scores ranged from 0 to 100, with a mean of 64 (SEM 2) and a standard deviation of 23. Sub-group analysis of EQ-VAS scores showed significantly lower scores for patients who did not ambulate when compared to ambulation with a prosthesis and another device (mean difference 30 and 27 respectively) $p < .05$.

Figure 5 EQ-VAS scores for subgroups based on Gender, Age, Mode of Ambulation and Type of Amputation

Discussion:

Quality of life for patients who have undergone a major lower limb amputation is an issue of great concern. Hence there has been quite an extensive investigation into this facet of the post-operative experience. The overall Quality of life in this study was determined to be below standard when compared to population norms for Trinidad and Tobago [4]. Additionally, individuals who ambulated with a prosthesis were found to have a better quality of life than those who did not. However, no statistical difference was seen for above versus below-knee amputees. Although this provides some insight into the post-amputation Quality of life, caution should be exercised as there can be some misconception. Poor Quality of life for the entire cohort was obtained, and therefore this is one possible reason no difference was observed between above knee and below-knee amputees. Admittedly, many of the countries for which the average overall index values were compared to are of the first-world status, with superior health care systems. This cohort had a higher overall index value when compared to Scottish, Swedish and Chinese data [19–21]. Although many of these studies have used the EQ 5D-5L or 3L Quality of life assessment tools, there is a variation of the time elapsed post amputation and when the assessment was performed. This poses a significant barrier to comparison as the time to prosthetic acquisition as well as rehabilitation programs varies across all health systems and regions. The considerable degree of disparity regarding demographic, geographic, social and economic factors amongst the populations studied, unfortunately with no real solution.

Furthermore, there are several Quality of life assessment tools which have been developed and used to obtain this information. These include SF-36, WHO BREF, EQ 5D, just to name a few [17, 18, 22, 23]. Due to this high degree of variability amongst the population and the absence of a standard assessment tool, the applicability of findings established internationally cannot be extrapolated to our population [24]. In the Caribbean, there has been several studies which have characterised and placed perspective on major lower limb amputations [1–3]. Several reports highlighting the challenges of limb amputations have emerged from countries such as Barbados, Jamaica and Trinidad [2, 25–27]. Despite this, there remains a paucity of data assessing the Quality of life experienced by amputees and remains uncharted territory for the Caribbean region.

The EURO QOL 5D-5L assessment tool was used in this study as it was simple, easy to understand, short and assessed the major aspects of Quality of life (mobility, self-care, usual activity, pain/discomfort, depression/anxiety and overall health). Several studies have been performed evaluating various populations in an attempt to document standard population utility indices [28–31] Moreover, this is an international, validated health-related quality of life assessment tool, which an index value can be obtained and used to cross-reference with several other countries internationally [24]. The real value of using the EQ 5D tool is derived from the existing value indices for Trinidad and Tobago published by Bailey et al. Although the population norm indices were obtained using the older version of the EQ 5D tool, this was easily overcome by translation of the EQ 5D-3L indices into the EQ 5D-5L equivalent [4, 18]. There have been several of the statistical methods used for this purpose, which have been studied as well as validated internationally and has been deemed acceptable by the Euro QOL Study Group [17].

This study demonstrated that amputees below the age of 50 years experienced a better quality of life than those over 50 years. These findings are not surprising as Quality of life tends to decrease with advancing age [4]. Furthermore, older patients are more likely to have co-morbid conditions which can all contribute to delayed rehabilitation, affect mobility and therefore result in a poor quality of life. Rehabilitation of the older patient, therefore, needs to be performed in a tailored, aggressive manner, which may require pre-operative conditioning/or selection of these patients. The goals for rehabilitation should, therefore, be set in the pre-operative phase, we believe all other aspects of care even the surgical intervention necessary be tailored to this.

Mobility is of one of the most critical aspects of quality of life post-amputation, as it is most directly affected, and it influences all other elements. Limb preservation is the single most influential factor on the degree of mobility in a patient having either a minor or major lower limb amputation. The literature is clear and has proposed that having a below-knee amputation is more favourable as mobility, attaining for a prosthesis is more likely, and less energy is required when compared to an AKA [6, 32, 33]. Although the overall mean index value (.627) for transtibial amputees (TTA) was higher than the mean index value (.568) for transfemoral amputees (TFA) this difference was not significant (p value = .96). This trend can be explained by the fact that the amputee population in the study had a poor quality of life overall and therefore, differences between the two groups were indistinguishable.

Further subgroup analysis revealed that the method of ambulation impacted significantly on Quality of life. Quality of life index values for amputees who ambulated with a prosthesis (overall, TTA and TFA, 0.759) were higher than other modes of ambulation (0.562) as well as non-ambulant patients (0.269), p value .0003 and .0004 respectively. Additionally, those amputees who were non-ambulant had significantly worse Quality of life than the other two groups who ambulated. Based on this information, we can, therefore, infer that the ideal mode of ambulation for an amputee is with a prosthesis. Furthermore, mobilisation with another device such as a Zimmer frame, crutches or a wheelchair, although not ideal is superior to not ambulating at all. There is strong evidence in the literature to suggest that ambulating with a prosthesis is the most influential factor on an amputee's Quality of life [14]. Hence adaptation of a similar approach to major lower limb amputation as proposed by the Vascular Society in their guidelines for holistic care is a step in the right direction [12]. One of the primary goals of this programme which involves a multi-disciplinary team, with multiple stages of interventions (pre-operative to rehabilitation), was to reduce the 90-day mortality rate to less than 10%. There have also been other reports which have emphasised a multi-staged, multi-disciplinary approach in an attempt to achieve better outcomes of Quality of life [5].

The 30-day mortality rate observed for this cohort of patients was 14%, which doubled to 27% at 1 -year. These rates are comparable to those from Sweden, New Zealand study as well as several other regions [19, 34, 35]. Moreover, the hospital mortality rate of 9% was marginally lower to that published by Solomon et al. in a locally conducted study [1]. These rates are higher than the target, which has been set by the Vascular Society and therefore, further highlights that significant improvement is necessary.

To date, this study is one of very few evaluating the of Quality of life in major lower limb amputees emerging Anglo-speaking Caribbean. Several factors have been identified such as age, ambulation and prosthetic use which is positively associated with a better quality of life. Hence this data can be used to change the approach to major lower limb amputees locally and regionally. Finally, the use of the Euro Qol 5D-5L tool has been shown to be of value in the amputee population. The authors would recommend including it prospectively in the future for any amputee to address issues which may arise in the five domains of health-related Quality of life. This will allow these issues to be addressed in a timely manner and achieve better outcomes. Additionally, this study can pave the way for further investigation into health-related Quality of life in other sub-groups of surgically treated patients.

Conclusion:

Major limb amputations continue to affect the Caribbean population significantly. Overall Quality of life after major amputation, as well as independent mobilisation with a prosthesis, continues to be problematic in this population. Factors adversely related to Quality of life post major amputation include increasing age and non-ambulatory patients. The overall mortality rates remain high in the major amputation population, with significantly higher rates in female and transfemoral amputees.

Declarations

CONFLICTS OF INTEREST: There are no conflicts of interest related to this manuscript

FUNDING: There are no sources of funding or sponsorship related to the research done relating to this study

ETHICAL APPROVAL: Formal application and request from the relevant local Ethics Committee was obtained in conducting this study

CONSENT: Written approval from each patient was obtained for the collection, use and publication of data obtained for this study.

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Figures

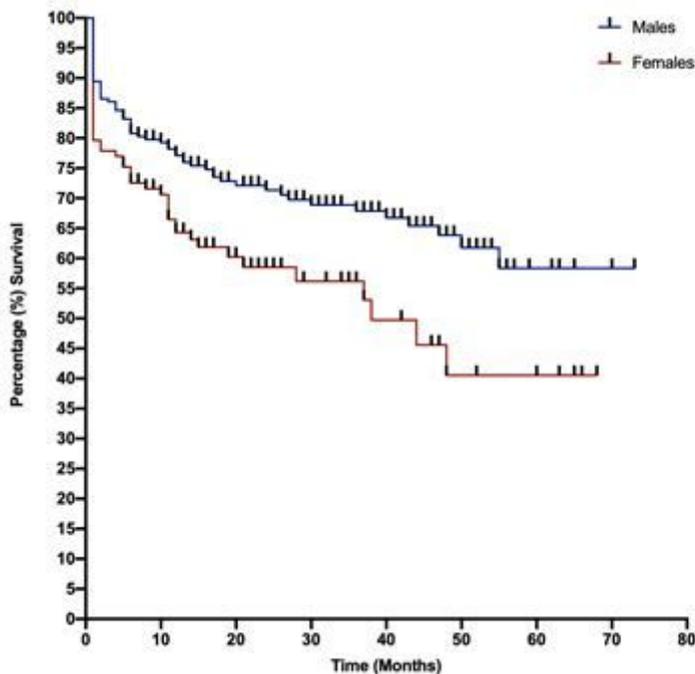


Figure 1

Kaplan-Meier graph of Mortality based on Gender

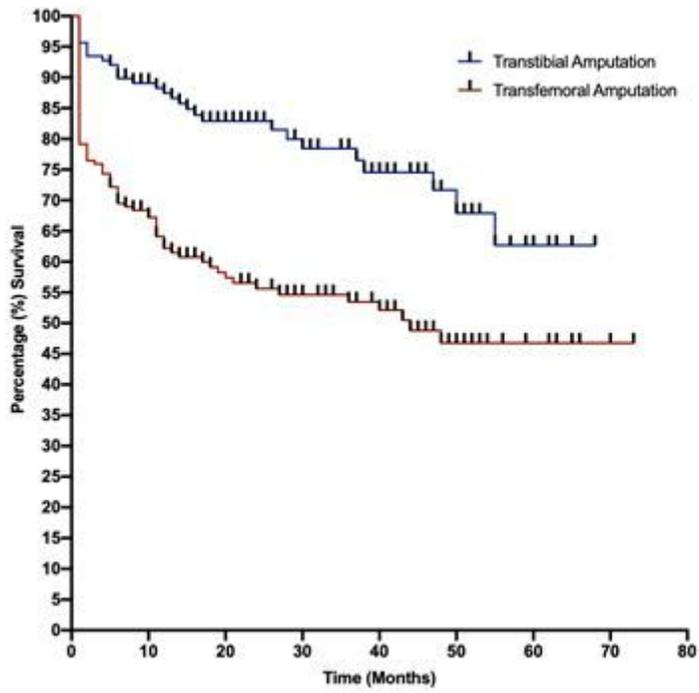


Figure 2

Kaplan-Meier graph of Mortality based on Type of Amputation

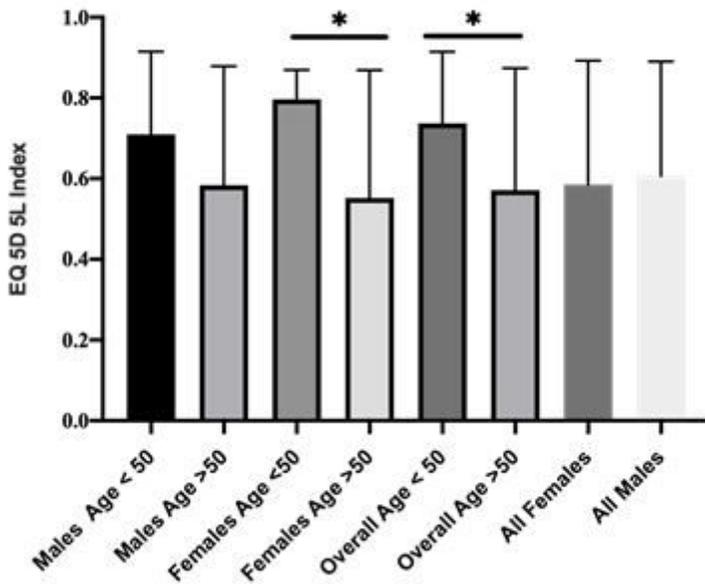


Figure 3

Quality of Life Indices based on Age and Gender

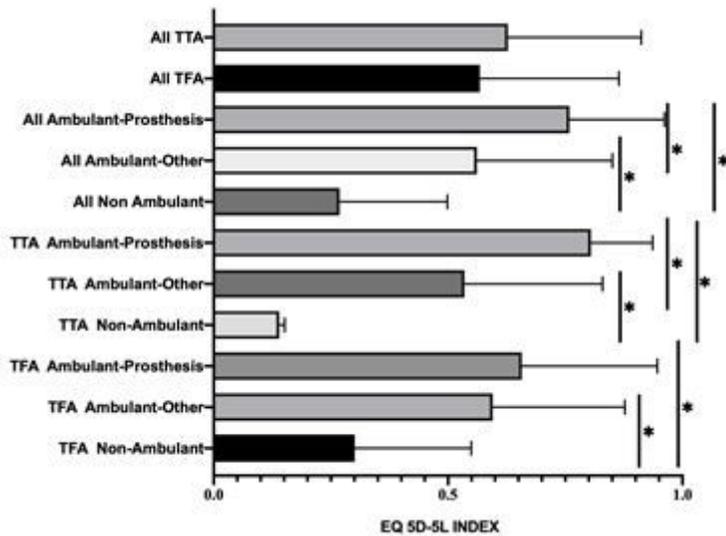


Figure 4

Quality of Life Indices based on Mode of Ambulation and Type of Amputation

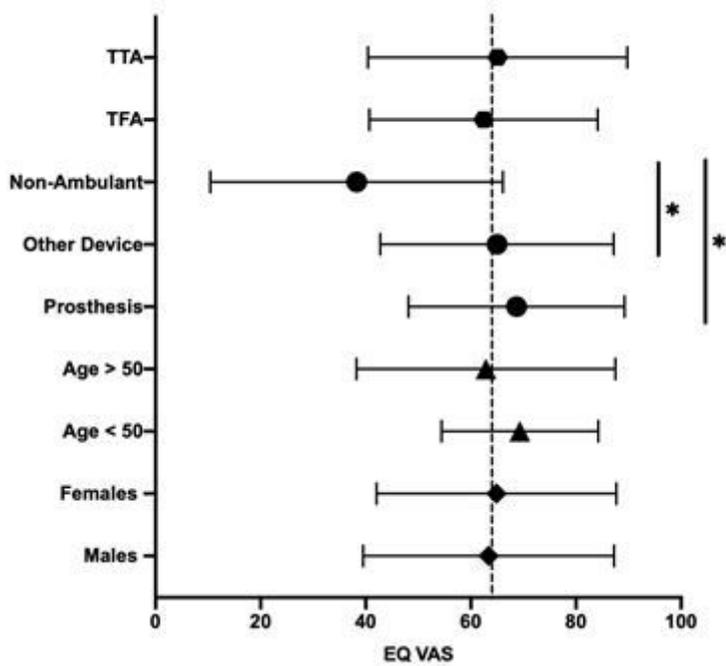


Figure 5

EQ-VAS scores for subgroups based on Gender, Age, Mode of Ambulation and Type of Amputation

Supplementary Files

This is a list of supplementary files associated with this preprint. Click to download.

- [PLAINENGLISHSUMMARYHQOL.docx](#)