QUALITY OF LIFE FOLLOWING A MAJOR LOWER LIMB AMPUTATION IN JOHANNESBURG, SOUTH AFRICA.

Godlwana L (MSc Physio)[1]
Stewart A (PhD)[1]
Musenga E (MA Stats)[1]

[1] **University of the Witwatersrand, South Africa.**

ABSTRACT: *To determine the impact of lower limb amputation on quality of life in people in the Johannesburg metropolitan area of South Africa, during their reintegration to their society/community of origin.*

A longitudinal pre- test- post test design was utilized. Consecutive sampling was used to recruit and interview participants (n=73) who met the inclusion criteria. Ethical clearance was obtained. The hospitals and participants gave informed consent.

The EQ-5D, Barthel Index, and Modified Household Economic and Social Status Index were used to collect data. Participants were interviewed preoperatively and then followed up three months post-operatively. Data were analysed using STATA version 10. Categorical data were analysed using Chi-square/Fischer's exact test and continuous data were analysed using Wilcoxon signed rank and median regression.

Most (n=21, 52.5 %) participants had no income. One participant was homeless, 17.5% (n=7) lived in shacks.

The preoperative and postoperative median VAS of the EQ-5D was 60 and 70 respectively showing no significant improvement in QOL (median EQ-5D VAS). The preoperative and postoperative median total BI score was 20 and 19 respectively, showing a significant reduction in function (median total BI) three months postoperatively ($p<0.001$). Preoperative mobility was a predictor of postoperative quality of life. Being female was a predictor of higher quality of life.

The average EQ-5D VAS score and overall function (total BI) were generally scored high both preoperatively and postoperatively but there was no significant improvement in EQ-5D VAS score and there was a significant reduction in function after three months. Higher scores in mobility preoperatively is a predictor of higher quality of life postoperatively.

KEY WORDS: *LOWER LIMB AMPUTATION, OUTCOME, QUALITY OF LIFE, FUNCTION, SOCIOECONOMIC, SOUTH AFRICA.*

INTRODUCTION

Lower limb amputation (LLA) results in a wide range of outcomes (Bosmans et al 2007; Taylor et al 2005; Zidarov et al 2009; Eiser et al 2001). Amputation generally results in poor physical function, physical role performance, social function, vitality, general health, and more pain compared to population norms (Eiser et al 2001). Functional independence tends to decrease with age for both males and females following lower limb amputation but males usually have better physical function than females (Eiser et al 2001). People with amputation who have the following features also tend not to be able to live independently in their homes after the amputation: being over the age of 70, a high anatomical level of amputation, dementia or those who had a homebound ambulatory status preoperatively (Taylor et al 2005).

People with a lower limb amputation show significantly worse scores of quality of life compared with population norms (Eiser et al 2001). They are mostly unsatisfied with their physical functioning and they tend to expect an improvement before discharge and in the months to come (Zidarov et al 2009). They report similar quality of life outcomes as those with a limb salvage procedure (Eiser et al 2001). However, they can also report a high subjective well-being (Bosmans et al 2007). Lower limb amputation is also associated with morbidity and mortality (Nehler et al 2003). The survival rate varies across countries but mortality rate is generally high, 10.4% within 30 days (Nehler et al 2003) and 14.7% of participants with diabetes and 21.3% of participants without diabetes within six months (Papazafiropoulou et al 2009)

In South Africa, there is limited information on the outcome following LLA in people who have had a lower limb amputation. Thus this population needs to be studied bearing in mind the nature and availability of the resources

Correspondence Author:
L Godlwana
Lecturer, Co-ordinator -Third year & Postgraduate Ortho Course
University of the Witwatersrand
Department of Physiotherapy
Email: Lonwabo.Godlwana@wits.ac.za

in South Africa as well as considering environmental factors (including the socioeconomic conditions) so that appropriate interventions can be introduced. Thus, as part of a bigger study, this paper sought to determine the impact of lower limb amputation on QOL in participants from the Johannesburg metropolitan area, South Africa, during their reintegration to their society/community of origin. In addition this paper established the socioeconomic status and the factors influencing QOL.

METHODOLOGY

An observational longitudinal pre-test (amputation) post-test (amputation) study design was used. Participants were interviewed preoperatively (ranging from a day to a week prior to the amputation) and at three months post operatively at three tertiary level academic hospitals in Johannesburg, South Africa. These hospitals are part of the University of the Witwatersrand teaching complex. Consecutive sampling was employed to enter participants into the study (n=73). Potential participants were included if they were due for a first time major unilateral LLA or simultaneous bilateral LLA. Potential participants were excluded if the cause of amputation was traumatic or a congenital birth defect, or if they had co-morbidities that interfered with function pre-operatively. Examples included stroke, paraplegia, as well as cognitive impairments.

Instrumentation

EQ-5D

The EQ-5D is a generic measure of health related quality of life. It is a five item instrument used to measure the participant's quality of life (Finch et al 2002). The instrument covers the areas of mobility, self-care, usual activities, pain/discomfort, anxiety/depression. Each of the five items is scored by placing a tick in one of the three boxes available in each of the items where the respondent indicates which statement best describes their own state of health on that particular day. At the end, the respondent is given an opportunity to rate their own state of health on that day by marking a number line scale (VAS) ranging from zero to one hundred where zero indicates their worst imaginable state of health and one hundred indicates their best imaginable state of health. Permission was given by the EuroQol Executive Office to use the instrument. The EQ-5D is a reliable and valid tool (Finch et al 2002).

Modified HESSI

This instrument was developed in Soweto, South Africa and was used to establish the household economic and social status of the respondent. The method of administration is a personal interview (Barbarin and Khomo 1997). Generally the questionnaire covers social and economic aspects of adequacy of food, shelter, utilities, durable consumer goods, social status, occupation, level of education and family structure. The frequency of responses is calculated using percentages (categorical data) (Barbarin and Khomo 1997). This instrument was developed for use in South Africa and has been widely used in South Africa (Barbarin and Khomo 1997 Barbarin and Richter 2001).

There was no need to have a Zulu and a Sotho version of this tool because of the close proximity and frequent interactions among speakers of the eleven most common languages in South Africa, the vernacular of urban African is not a pure form of any single language. Therefore in daily usage, words from multiple languages, including English can be interspersed with one another (Barbarin and Richter 2001). Thus in this study the researcher did not use the translated versions of the index and also because the data were collected by the same person with the exception of the Sotho interviews. This allows the advantage of using colloquial speech in the wording during interviews (Barbarin and Richter 2001).

Modifications done to the HESSI

QUESTION Ia. Marital status of "mother" was changed to marital status of "participant"

QUESTION IIa. "Mother's" education was changed to "participant's" education

QUESTION IIb. Education of "mother's" partner was changed to education of "participant's" partner.

Barthel Index

The Barthel Index (BI) is a 10 item functional scale used to measure functional independence and amount of nursing care needed (Finch et al 2002). In this scale the participant is examined in the areas of bowel function, bladder function, personal hygiene, moving from wheelchair to bed and return, toileting, bathing self, walking on level surface/ propelling a wheelchair, ascending and descending stairs, dressing and feeding. This tool has been used in participants with a lower limb amputation among other conditions (Finch et al 2002). The instrument requires about five minutes if the interviewer is recording verbal information. In this scale the participant can score anything from zero to 20 points where 20 is the maximum full normal functional independence. The BI is a reliable and valid tool (Finch et al 2002).

PROCEDURE

After institutional (University of the Witwatersrand and the three participating hospitals) ethical approval was obtained and participants gave informed consent, a pilot study was conducted to familiarize the researcher with the instruments. Following a pilot study which was done to familiarize the first author with the instruments, interviews for the main study commenced.

STATA Version 10 was used to analyse the data. Pre and post operative differences were analyzed using the Wilcoxon Signed-rank test for continuous data. A median regression analysis for both univariate and multivariate factors was done to establish the factors influencing QOL. Pre and post operative differences in the EQ-5D items and the BI items were analyzed using either the Chi-square/ Fischer's exact test. Data are presented as frequencies, means and standard deviations, medians, and confidence intervals (CI 95%). The significance of the study was set at $p \leq 0.05$.

RESULTS

Seventy three participants who met the inclusion criteria participated in the study. Thirty three percent of the original sample (n=24) had died by the time of the follow up while 9% (n=12) were

lost to follow up leaving 55% (n=40) for analysis. This paper will only cover the analysis of the participants who survived. Data on the participants who died has already been published (Godlwana et al 2011)

Table 1: Demographic description of participants (n =40)

Sixty percent (n=24) of the participants had hypertension, 64% (n=26) had diabetes, and 48% (n=19) reported peripheral vascular disease and 4% (n=2) chronic heart diseases. Other clinical conditions reported (a combined category), (15%, n=6) included renal failure, presence of a retroviral disease and oncology.

Table 2: Pre and postoperative EQ-5D quality of life item scores (n=40)

There was a decline in mobility and usual activities but an improvement in pain/discomfort after three months.

Comparison of EQ-5D VAS scores pre and postoperatively (n=40)

The preoperative and postoperative median VAS score was 60 and 70 respectively. The preoperative and postoperative VAS 25th percentile was 50. The preoperative and postoperative VAS 75th percentile was 80. There was no significant improvement (p=0.6) in QOL three months postoperatively.

Table 3: Comparison of pre and postoperative BI item scores (n=40)

There was a decline in the items of bowel function, mobility and ability to negotiate stairs three months postoperatively.

Percentile rankings of total BI pre and post operatively (n=40)

The preoperative and postoperative median BI score was 20 and 19 respectively. The preoperative and postoperative VAS 25th percentile was 19.5 and 16 respectively. The preoperative and postoperative VAS 75th was 20. There was a significant decline in overall function three months postoperatively (p<0.001).

Table 4 Household economic and social status (n=40)

There was a change in the number of

Table 1: Demographic description of participants (n =40)

Demographic description of participants	n= 40
Age Mean (SD)	 52.9 SD 8.61
Gender Male Female	 n=27 (67.5%) n=13 (32.5%)
Race Black White Coloured Indian	 n=30 (75%) n=5(12.5%) n=5(12.5%) n=0 (0%)
Level of amputation Unilateral BKA Unilateral AKA	 n=26(65%) n=14(35%)

Table 2: Comparison of EQ-5D VAS scores pre and postoperatively (n=40)

	Preoperative	Postoperative	
	n=40	n=40	p-value
EQ-5D Mobility No problem Some problems Extreme problems	 n= 35(87.5%) n= 4 (10%) n= 1(2.5%)	 n= 30 (75%) n= 2 (5%) n= 8 (20%)	0.04
EQ-5D Usual activities No problem Some problems Extreme problems	n= 31 (77.5%) n= 6 (15%) n= 3 (7.5%)	n= 14 (35%) n= 14 (35%) n= 12 (30%)	0.001
EQ-5D Pain/discomfort No problem Some problems Extreme problems	n= 10 (25%) n= 13 (32.5%) n= 17 (42.5%)	n= 12 (30%) n= 24 (60%) n= 4 (10%)	0.003

p≤0.05 significant

Table 3: Comparison of pre and postoperative BI item scores (n=40)

Item score	Preoperative	Postoperative	
	n=40 (100%)	n=40 (100%)	p-value
BI-Bowel 0 1 2	 n=0(0% n=0(0%) n=40(100%)	 n= 30 (75%) n= 2 (5%) n= 8 (20%)	0.04
BI-Mobility 0 1 2 3	 n=2(5%) n=1(2.5%) n=0(0%) n=37(92.5%)	 n=2(5%) n=8(20%) n=0(0%) n=30(75%)	0.04
BI-Stairs 0 1 2	 n= 4 (10%) n= 3 (7.5%) n= 33 (82.5%)	 n= 14 (35%) n= 13 (32.5%) n= 13 (32.5%)	p<0.001

p≤0.05 significant

Table 4: Household economic and social status (n=40)

	Preoperatively	Postoperatively
Participant's marital status		
Never married, not now living with a partner.	n=6 (15%)	n= 6 (15%)
Married, but not living now with a partner (e.g. divorced, separated)	n= 7(17.5%)	n= 9 (22.5%)
Widowed	n= 5 (12.5%)	n=5(12.5%)
Never married, but now living with partner	n= 5 (12.5%)	n=5 (12.5%)
Married and currently living with partner	n= 17(42.5%)	n=15 (37.5%)
Nature of Income		
No income	n= 16(40%)	n= 21 (52.5%)
Still employed	n= 12(30%)	n= 2 (5%)
Receiving a disability grant	n= 4 (10%)	n= 7 (17.5)
Receiving old age pension	n= 7 (17.5%)	n= 8 (20%)
Private pension	n= 1 (2.5%)	n= 2 (5%)
Participant's level of education		
Less than grade 5	n= 10(25%)	n= 10(25%)
Primary school (grade5-6)	n= 1(2.5%)	n= 1(2.5%)
Junior Secondary (grade 7-9)	n= 10(25%)	n= 10(25%)
Senior Secondary (grade 10-11)	n= 14(35%)	n= 14(35%)
Matric/ High School graduate/vocational	n= 4(10%)	n= 4(10%)
training diploma.	n= 1(2.5%)	n= 1(2.5%)
1-2 yr College, Technikon	n= 0(0%)	n=0 (0%)
3-4 years of University	n= 0(0%)	n=0(0%)
PhD; M.D; D.D.S, or other doctoral degree.		
Housing status		
None- homeless	n= 1 (2.5%)	n= 1 (2.5%)
Shack	n= 7(17.5%)	n= 7 (17.5%)
Hostel	n= 1(2.5%)	n= 1 (2.5%)
Room, Garage	n= 3(7.5%)	n= 3 (7.5%)
Flat Cottage	n= 5(12.5%)	n= 3 (7.5%)
Home shared with other family(ies)	n= 3(7.5%)	n= 3 (7.5%)
Home that is not shared with other families.	n= 20(50%)	n= 22 (55%)
Other (please specify):----------	n= 0(0%)	n=0 (0%)

p≤0.05 significant

participants who were married, but not living now with a partner (e.g. divorced, separated) from n=7 (17.5%) to n=9. (22.5%). There was an increase in the number of participants with no income from n=16 (40%) to n=21 (52.5%). The number of participants who remained employed decreased from n=12 (30%) to n=2 (5%). The number of participants receiving a disability grant increased from n=4 10% to n=7 (17.5%).

Table 5: Factors affecting QOL, a VAS median regression analysis (n= 40)

Participants who had extreme problems with mobility preoperatively had a median VAS score of 30 less than those who had no problem with mobility in the EQ-5D item postoperatively (p<0.001). When the mobility in the EQ-5D was adjusted for gender in the multivariate analysis, female participants had a median VAS score of 15 greater than their male counterparts postoperatively (p=0.05) at a 95% CI. However, females who either had some problems or extreme problems with mobility had a median VAS score of 23 less than those that had no problem with mobility (p=0.04) at a 95% CI and (p<0.001) at a 95% CI respectively.

Participants who were independent in mobility as measured by the BI preoperatively had a postoperative median EQ-5D VAS score of 20 greater than those who were dependent (p=0.004). When the mobility on the BI was adjusted for gender in the multivariate analysis, female participants had a median VAS score of 16 greater than their male counterparts postoperatively (p=0.03) at a 95% CI.

Participants who were independent with transfers on the BI preoperatively had a postoperative median EQ-5D VAS score of 30 greater than those who were dependent (p<0.001).

DISCUSSION

Participants generally reported high scores in terms of their overall quality of life both pre and postoperatively. However there was no significant improvement (p=0.6) in the overall quality of life over the study period as measured by the VAS score in the EQ-5D. At the assessment period three months postoperatively both the mobility item and the usual activity item on the EQ-5D were reduced indicating that these patients were less mobile than previously. This study was not able to determine if this was because they were mostly unemployed and therefore not able to pay for transport to a hospital for a rehabilitation programme which should have improved their mobility levels. The high overall scores on quality of life post three months may be due to the fact that there was a reduction in pain and discomfort in this group possibly leaving participants feeling more comfortable (Bosmans et al 2007). These findings are consistent with those by Zidarov et al (2009) and Bosmans et al (2007) who also found a high quality of life post amputation.

Conversely Tennvall and Apelqvist (2000), showed that participants with major amputation have lower EQ-5D index scores (0.31) and VAS scores (54). However these inferior scores were compared with participant groups of people with a primary healed ulcer without amputation and participants with a maximal minor amputation.

There was a reduction in overall functional status three months post amputation and specifically in the areas of mobility and the ability to negotiate stairs. Although not tested, the lack

Table 5: Factors affecting QOL, a VAS median regression analysis (n= 40)

		Univariate			Multivariate		
Item score	**Median EQ-5D VAS**	**Coefficient**	**p-value**	**95% CI**	**coefficient**	**p-value**	**95% CI**
EQ-5D mobility							
1- Constant	70	70	Reference	-	53.57	Reference	-
2-	65	-20	-	-58.82	-23.39	0.039	-45.58
3-	40	-30	p<0.001	18.82	-23.03	p<0.001	-1.21
				-43.58	Female 14.7	0.049	-33.73
				-16.42			-12.34
							0.06
							29.23
BI mobility							
0- Constant	50	50	Reference	-	-	Reference	-
1-	40	-10	-	-	4.56	-	-20.50
2-	-	-	-	-	-	-	29.62
3-	70	20	0.004	6.76 33.24	27.06	0.029	-
					Female 15.6	0.029	2.88
							51.24
							1.7
							29.48
BI transfer							
0- Constant	40	40	Reference	-	40	Reference	-
1-	45	10	-	-	-5.35e-14	-	-14.49
2-	50	10	-	-	-5.66e-14	-	14.49
3-	73	30	p<0.001	15.03 44.97	30	0.003	-27.56
							27.56
							11.12
							48.89
BI stairs							
0- Constant	50	50	Reference		56.67	Reference	-
1-	80	30	-	-19.49	46.33	0.005	15.18
2-	70	20	-	79.49	15.33	-	77.49
3-	-	-	-	-12.90	-	-	-11.22
				52.90			41.89
				-			-

p≤0.05 significant

of post amputation rehabilitation is a potential explanation as these are the type of activities that are taught in rehabilitation programmes (Zidarov et al 2009). This may have contributed to the decline in function after the operation rather than just being a pure outcome of lower limb amputation. People with lower limb amputation need intensive rehabilitation to optimize their recovery (Zidarov et al 2009). Participants in this study were compromised both in their ability to get around and their ability to participate in their usual activities. Most notable is that, the function was significantly reduced.

Most participants were single both preoperatively and postoperatively and generally, were of a low socioeconomic status. Similar findings by Godlwana et al (2008), showed that, having a low income and being single (whether divorced, widowed, or never married) are associated with a high incidence of lower limb amputation in people with diabetes and those with vascular diseases. Most were unemployed both preoperatively and postoperatively and had low or no formal education. This has also been shown in other studies by Burger and Marincek (2007) Amosun et al (2005). This would then make it difficult for them to either return to work if they had a physically demanding occupation or to find alternative employment (Burger and Marincek 2007).

Being independent with mobility and independent with transfers preoperatively predicted a higher quality of life (postoperative EQ-5D- VAS) compared to the participants who were dependent or had problems with these functions preoperatively. This suggests that functional independence should be maintained both pre and post-operatively (Zidarov et al 2009; Bosmans et al 2007).

There were more males than females in the study and this is consistent

with the literature (The Global Lower Extremity Study, 2000) and the majority were black (71%). In addition studies show an association between the incidence of LLA and race (Dillingham et al. 2002, Feinglass et al 2005). Dillingham et al (2002) and Feinglass et al (2005) reported that black people are twice as likely to have a LLA as a result of PVD than other races. It is however difficult to conclude that LLA is more prevalent in this community compared to the white, coloured and Indian populations in Johannesburg as we do not know if this finding could largely (but not entirely) be because black participants are recipients of public hospital services compared to other races who tend to be able to afford private health care or rather the setting for this study was in facilities used mainly by black people.

Thirty three percent (n=24) of the original 73 participants had died by the time of follow up at three months. In this study, participant who died had poor function pre operatively, they were older and they were smokers and drinkers (Godlwana et al 2011). Generally, lower limb amputation has been seen to have a high mortality rate. Other studies show that the survival rate varies across countries but the mortality rate is generally high (Papazafiropoulou et al 2009, Nehler et al 2003). None of these studies were conducted in Africa but a high mortality rate in a study done in Brazil, which is a developing country, may reflect a similar picture to that of South Africa. The above studies had follow ups ranging from two weeks to five years postoperatively.

Some participants in this study could not be followed up, owing to the poor geographical settlements seen in some parts of the Johannesburg metropolitan area. In informal settlements and other areas with shacks, there are no street names and often people live on plots which have many shacks and different families making the location of study participants difficult.

LIMITATIONS OF THE STUDY

The study had a high mortality rate. This was a huge problem as the study lost 33% of the participants. All efforts were made to trace the participants but it was at times impossible as some did not have phones, other phones were not connected, and in some instances the physical addresses were not traceable, leading to a 9% dropout rate.

CONCLUSION

There was no change in quality of life in this sample. There was a decline in functional independence three months post operatively. Functional independence preoperatively predicted a better quality of life outcome postoperatively and female participants had a better quality of life outcome than males.

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