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patient's QoL by insisting on the quality of services at a lower cost.

The World Health Organisation (WHO) has defined QoL as an individual's perception of his or her place in life, in the context of the culture and value system in which he or she lives and in relation to his or her goals, expectations, norms and concerns[8]. The QoL of patients with MLLA was generally impaired[9–11] in both physical [10,12,13] and mental health[10,12]. Several instruments have been used to measure aspects of QoL in lower limb amputees (LLA)[14]. Most studies have used the SF-36 either alone or in combination with a specific questionnaire [3,15,16] to describe the QoL of LLA.

To the best to our knowledge, the SF-12 has never been used to assess the QoL after MLLA regardless the cause and level of amputation. Our study was the first to be conducted in Morocco to describe the QoL of patients with MLLA in the immediate postoperative period (T0) and three months after discharge (T1).

Patients and methods

MLLA was defined as amputation above the ankle creating instability in walking due to the absence of foot talent[17]. The level of amputation was classified into three categories: transtibial (TT), transfemoral (TF), and hip disarticulation[18].

Study design: A prospective monocentric observational study was conducted in the trauma and vascular surgery departments of the Ibn Sina Hospital in Rabat between October 1, 2019, and January 1, 2021. The SF-12 was translated into Moroccan Arabic and its psychometric properties were assessed on 141 subjects at the University Hospital of Fez. The results showed good reliability and validity, making the SF-12 a valid tool for assessing the quality of life of the Moroccan population[19]. The patients were provided with information about the study and signed the consent. Face-to-face interviews with amputee patients were conducted by the researcher. Patients had an initial assessment during the first 48 hours after amputation (T0) and a second assessment three months after discharge (T1).

We included patients aged 18 years or older with unilateral or bilateral MLLA. These patients had vascular, traumatic, tumoral, and infectious causes of amputation. Patients who had undergone a first amputation before the study period and who had received a re-amputation within the study period were also included. The first evaluation during our study period of these latter patients was considered as T0. We excluded patients who refused to participate in the study, those with neuro-psychiatric disorders, and those with a postoperative complication requiring a stay in the intensive care unit (ICU). Patients with difficulties in understanding the Arabic language, those who were not screened at T0, and those who were not assessed within the first 48 hours were also excluded.

Study variables: Variables collected at admission were sociodemographic variables related to the patient (age, sex, marital status, education level, occupation, body mass index, comorbidity, smoking habit), variables related to the amputation and variables related to the QoL assessment questionnaire. Variables related to the amputation were the type of amputation, amputated side, cause of amputation, amputation level, complications related to the amputation, stump pain, phantom limb pain, displacement, and fitting.

Measurement tools: The QoL was measured using a generic self-administered QoL questionnaire the MOS (SF-12)[20], if the patient is unable to answer on their own, an interview is administered by the researcher themselves. The SF-12 is a shortened form of the SF-36[21]. The SF-36 has been used to measure QoL in patients with MLLA[2,3,16,22,23]. The SF-12 contains 12 items that measure health status along eight dimensions: physical activity (PF), role physical (RP), bodily pain (BP), general health (GH), vitality (VT), social functioning (SF), role emotional (RE), and mental health (MH). The first four dimensions of the aforementioned SF-12 contribute to the physical component summary (PCS), and the last four dimensions to the mental component summary (MCS), where a higher score (more than 50) indicates better QoL. The SF-12 questionnaire underwent cross-cultural validation of the Moroccan dialect language[19]. The SF-12 has been used only to assess long-term outcomes in patients with bilateral transtibial LLA for diabetic or vascular causes[24].

Statistical analyses: Statistical analyses were performed using the SPSS version 23. Descriptive analyses were performed for sociodemographic and amputation-related factors. The categorical variables are presented as frequency with percentage and continuous variables are expressed as mean with standard deviation if the distribution is normal, when it is skewed, a median and interquartile range will express the variable. Comparisons of continuous variables were made with Student's t-tests. The confidence interval was 95% and the two-sided significance level was 0.05. A correlation between two groups of the same sample was used for the eight dimensions of the SF-12 and between PCS and MCS after an immediate MLLA (T0) and three months after hospital discharge (T1). A paired-sample t-test was used for variables with a normal distribution and a nonparametric Wilcoxon test for variables with an abnormal distribution. The study of factors associated with PCS and MCS was performed by the simple and then multiple generalized linear models. We included in the multivariate model those variables that had a $p \leq 0.3$. Gender and age were forced into the multivariate analysis because of their importance in previous studies[5,10,16,25].

Ethical consideration: The approval was obtained from the ethics committee for biomedical research of the faculty of medicine and pharmacy of the Mohammed V University of Rabat, Morocco (approval number: 7/20). The ethics committee is registered with the Office for Human Research Protections of the U.S. Department of Health and Human Services under the number IORG0006594.

SD: standard deviation; BMI: body mass index; SA: spinal anesthesia; GA: general anesthesia; PNB: peripheral nerve block; T0: assessment at immediate post-amputation; T1: assessment three months after hospital discharge; TT: transtibial; TF: transfemoral; HD: hip disarticulation.

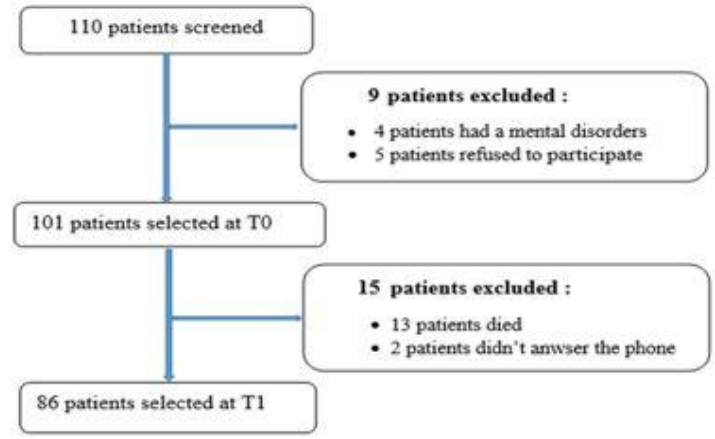

Figure 1: Flow-Chart of the selection of patients with MLLA.

Table 2: Clinical evaluation of patients with Major lower limb amputation at T0 and T1.

Variables	**T0** (n=101)		**T1** (n=86)		*P-value*
	Frequency (No)	**Percent (%)**	**Frequency (No)**	**Percent (%)**	
Stump pain	58	57,4	32	37,2	**0,01**
Phantom limb pain	39	38,6	77	89,5	**< 0,001**
Toilet use					**< 0,001**
Alone	11	10,9	49	57	
Partial assistance	46	45,5	28	32,6	
Total assistance	44	43,6	9	10,5	
Dressing					**0,001**
Alone	23	22,8	62	72,1	
Partial assistance	43	42,6	19	22,1	
Total assistance	35	34,7	5	5,8	
Mobility					**< 0,001**
Alone	8	7,9	36	41,9	
Partial assistance	39	38,6	35	40,7	
Total assistance	54	53,5	15	17,4	
Home help n (%)	-		41	47,7	
Fitting n (%)	-		8	9,3	
Occupation n (%)	-		16	18,6	

T0: immediate post-amputation assessment; T1: assessment three months after hospital discharge

Quality of life scores of participants

Comparison of SF-12 dimensions scores at T0 with T1 showed a significant increase in all dimensions (Figure 2). The mean scores of the SF-12 QoL questionnaire at T0 and T1 were 31.93±6.9 and 39.58±5.2, respectively (p=0,0001). The mean scores of all health domains of the SF-12 scale were below the limit of the normal range (figure 2). The dimensions with a lower score in the PCS at T0 were RP and GH, and in the MCS were RE and SF. However, the low score in the PCS at T1 were PF, RP, and BP, and in MCS was SF.

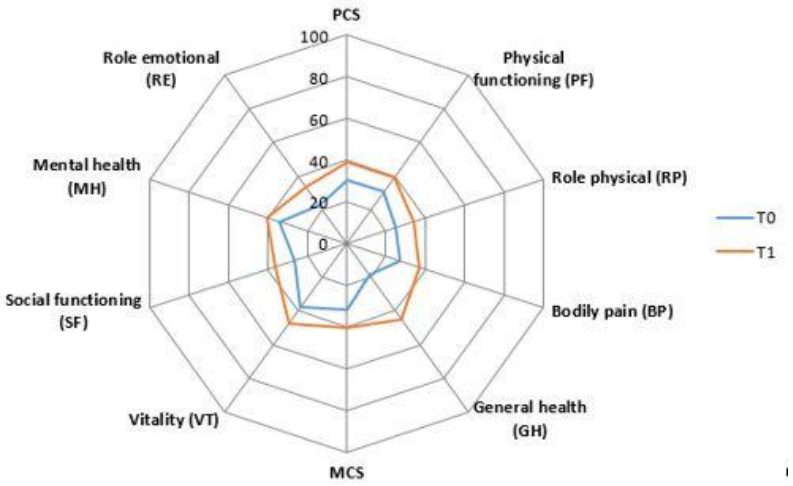

Figure 2: Graphical representation of the MOS SF-12 dimensions at T0 and T1.

SF12: medical outcomes short form 12; PCS: Physical Component summary; MCS: Mental Component Summary; T0: immediate post-amputation assessment; T1: assessment three months after hospital discharge.

Multivariate analysis of factors associated with QoL

The independent factors associated with poor quality of PCS were limitation of mobility, age, general anesthesia, and a long length of stay at T0, reamputation and stump pain at T1 (Table 3). The variables associated with poor quality of MCS were female gender, limitation of mobility and peripheral nerve block at T0, heart disease, and limitation of mobility at T1 (Table 4).

Table 3: Univariate and multivariate regression of PCS of SF-12 in immediate (T0) and 3-month of major lower limb amputation (T1).

	Associated factors	Univariate analysis				Multivariate analysis			
		β	CI à 95 %		P-value	β	CI à 95 %		P-value
			Lower	Upper			Lower	Upper	
PCS0	Gender (male)	-1,031	-4,802	2,740	0,592	-2,814	-5,902	0,274	0,074
	Age	-0,149	-0,252	-0,046	0,004	-0,097	-0,194	-0,001	**0,049**
	Total mobility assistance	-8,491	-14,529	-2,453	0,006	-7,264	-12,707	-1,820	**0,009**
	Partial mobility assistance	-1,888	-8,074	4,298	0,550	-2,228	-7,770	3,314	0,431
	GA	0,679	-5,270	6,629	0,823	-7,340	-13,053	-1,627	**0,012**
	SA	-3,188	-8,349	1,973	0,226	-3,518	-7,935	0,900	**0,119**
	Urgent surgery	5,962	2,406	9,518	0,001	6,572	3,290	9,854	**0,000**
	Stump pain	3,032	-0,407	6,471	0,084	2,962	0,092	5,832	**0,043**
	Hospital stay	-0,087	-0,169	-0,005	0,038	-0,073	-0,142	-0,004	**0,039**
	HD	6,194	-2,637	15,025	0,169	11,205	2,867	19,543	**0,008**
	ATF	-1,038	-4,710	2,634	0,580	-1,315	-4,565	1,935	0,428
PCS1	Gender (male)	1,382	-1,697	4,461	0,379	2,935	0,476	5,393	**0,019**
	Age	-0,112	-0,199	-0,025	0,012	0,005	-0,087	0,098	0,910
	Reamputation	-4,116	-7,798	-0,435	0,028	-4,504	-7,619	-1,388	**0,005**
	Urgent surgery	2,616	-0,460	5,693	0,096	3,432	0,671	6,192	**0,015**
	Early Mobility	4,642	1,941	7,343	0,001	5,495	2,958	8,032	**0,000**
	Vascular cause	3,806	0,750	6,862	0,015	2,793	0,116	5,470	**0,041**
	Traumatic cause	5,251	0,413	10,088	0,033	-0,919	-5,506	3,668	0,695
	Tumor cause	6,182	1,765	10,600	0,006	4,470	0,019	8,921	**0,049**
	Stump pain	-2,663	-5,578	0,253	0,074	-2,634	-4,944	-0,323	**0,025**
	SA	7,231	2,490	11,972	0,003	4,745	0,287	9,203	**0,037**
	PNB	3,542	-0,630	7,713	0,096	1,429	-2,173	5,031	0,437

HD: hip disarticulation; TFA: transfemoral amputation; CI: confidence interval; GA: general anaesthesia; SA: Spinal anaesthesia; PNB: peripheral nerve block; PCS: physical component summary; SF-12: Medical Outcomes Short Form12; PCS0: assessment of PCS in the immediate post amputation period; PCS1: assessment of PCS three months after hospital discharge.

Table 4: Univariate and multivariate regression of MCS of the SF-12 in immediate (T0) and 3 months of major lower limb amputation (T1).

	Associated factors	Univariate analysis				Multivariate analysis			
		β	CI à 95 %		P-value	β	CI à 95 %		P-value
			Lower	Upper			Lower	Upper	
MCS0	Gender (male)	3,851	0,227	7,476	0,037	3,329	0,430	6,229	**0,024**
	Age	-0,025	-0,129	0,080	0,643	0,044	-0,046	0,135	0,338
	Urgent surgery	3,820	0,229	7,410	0,037	3,422	0,339	6,504	**0,030**
	HD	14,073	5,778	22,368	0,001	12,912	5,083	20,742	**0,001**
	TFA	2,185	-1,264	5,635	0,214	0,658	-2,395	3,710	0,673
	SA	0,844	-4,732	6,420	0,767	-4,134	-9,495	1,227	0,131
	PNB	-5,780	-10,617	-0,943	0,019	-7,304	-11,421	-3,187	**0,001**
	Stump pain	6,141	2,937	9,345	0,000	6,146	3,451	8,842	**0,000**
	Total mobility assistance	-8,261	-14,490	-2,032	0,009	-7,535	-12,640	-2,430	**0,004**
	Partial mobility assistance	-6,411	-12,792	-0,030	0,049	-6,906	-12,089	-1,722	**0,009**
MCS1	Gender (male)	-0,052	-3,374	3,269	0,975	-0,881	-3,698	1,936	0,540
	Age	-0,036	-0,132	0,061	0,466	0,026	-0,068	0,120	0,584
	Heart disease	-2,974	-6,081	0,134	0,061	-3,089	-5,959	-0,218	**0,035**
	Patient information	9,153	-0,891	19,198	0,074	11,146	2,494	19,798	**0,012**
	Explanation of amputation procedure	7,255	0,096	14,413	0,047	8,229	2,052	14,406	**0,009**
	Total mobility assistance	-5,134	-9,380	-0,888	0,018	-4,747	-8,834	-0,660	**0,023**
	Partial mobility assistance	-2,581	-5,860	0,699	0,123	-3,209	-6,285	-0,132	**0,041**
	Fitting	9,211	3,920	14,503	0,001	8,271	3,380	13,161	**0,001**
	Length before amputation	0,045	-0,036	0,126	0,276	0,165	0,018	0,312	**0,028**

HD: hip disarticulation; TFA: transfemoral amputation; CI: confidence interval; SA:Spinal anesthesia; PNB: peripheral nerve block; MCS: mental component summary; SF-12: medical outcomes short form12; MCS0: assessment of MCS in immediate post-amputation; MCS1: assessment of MCS three months after hospital discharge.

Discussion

This prospective and observational study assessed the QoL of Moroccan patients who have undergone a MLLA that has been studied for the first time to our modest knowledge. The aim of this study was to assess the QoL of patients with MLLA, regardless of the cause, and to determine the factors associated with QoL at T0 and T1. The QoL of patients with MLLA was low at T0 and T1. The most common cause of amputation in our study was the diabetes. The factors associated with poor QoL at T0 were gender, age, limitation of mobility, technique of anesthesia and stump pain. Whereas, the factors associated with lower QoL at T1 were reamputation, stump pain, heart disease and limitation of mobility.

The male patient was most affected by MLLA (more than two-thirds of the studied population). A similar prevalence has been observed in other studies[26–29]. The mean age of our population is in agreement with the literature[13,27–29]. Concerning the comorbidity, our population had one or more comorbidities and the most common was diabetes, these findings are similar to the literature[16,27,28]. The causes reported by several publications are vascular disease, diabetes, trauma, or tumor[16,22] and predominantly affect the TT level[10,27,30], as shown in our study.

In developing countries, wearing a prosthesis after MLLA improves muscle tone and strength, develops cardiovascular health, and increases functional mobility[31,32]. Approximately 90% of our patients did not have prostheses, and used crutches or wheelchairs for displacement, this was due to the high cost of the prosthesis, complications related to the stump (infection, delayed healing, pain) and the restriction of access to healthcare due to the fear of COVID-19 and the reallocation of resources to fight this pandemic. This result explains the low scores of PCS and MCS at T1 (PCS: 40.8 and MCS: 49.1).

The prevalence of phantom limb pain was significantly increased between the immediate post amputation and three months after discharge from 55% to 84% (P<0,001) [33–36]. Our findings are similar to those reported by the literature (from 38.6% to 89.5%). While, other studies observed that the prevalence of phantom limb pain decreases six months after amputation (between 18,2% and 20%)[3,16,31,33]. Concerning the stump pain, we reported that it was significantly decreased from 57.4% to 37.2% (P=0,01), this results were in line with the literature[25,37]. The persistence of stump pain could be explained by postoperative complications related to stump infection, delayed healing, stump neuromas, and inadequate postoperative analgesia.

In developing countries, the PCS measures of patients with MLLA were lower (between 33,3 and 40,8)[12,13,27] and the MCS measures were also lower than the normal range (between 44,8 and 48,6) [12,27]. The PCS measures of our patients were more affected than the MCS measures. Our results are concomitant

with the literature. Several studies have described that the QoL of patients with MLLA was lower for both men and women in physical and mental health[2,9,10,12,13,16,32,37–39]. Our findings are in line with the literature.

Concerning the QoL associated with the cause of MLLA, Riis Madsen et al. reported that a patient with a vascular cause of MLLA had a high risk of complications and loss of basic physical functioning in post amputation[39]. The same findings are described by Endoh et al [40]. Our results reported that the QoL of patients with vascular and/or diabetic causes were poor compared with the QoL of patients with traumatic or tumor causes T0 and T1. This was explained by the patients with vascular and diabetic causes were older than the patients with traumatic and tumor causes. Regarding the QoL linked to the level of amputation, the study by Knežević et al. showed that the QoL of patients with transtibial amputation was better compared to those with transfemoral amputation. [15], those results are not in line with the current study, in which the level of amputation was not related to QoL. Furtado et al confirmed in a national survey of 100 patients with LLA due only to tumor cause that the level of amputation was related to physical functioning, but not to QoL[41]. The systematic review conducted by David-Smith et al concluded that TF amputation is negatively associated with QoL[5]. The decrease in the QoL score of patients with MLLA is related to their limitations due to physical status[37], general health, and limitation due to emotional status as shown in the correlation table of SF-12 dimensions between T0 and T1.

Jomli et al had shown in a study of 60 disabled people who were interviewed with a questionnaire including a multidimensional QoL scale WHOQoL-100, that the advanced age impacted physical health[32]. Other studies reported that advanced age and limitation of mobility affected the PCS[5,18,42], which is in line with the current study, which showed the same results. Whereas, the factors that were associated negatively with a low score of PCS in T1 were reamputation and stump pain. The same findings were described by Matos et al, who stated that pain was associated with poor physical health[42]. In addition to previous factors, general anesthesia and a long period of hospitalization were linked negatively with poor scores of PCS.

Multiple regression of independent variables by the generalized linear model showed that female gender, locoregional anesthesia, mobility limitation, and stump pain, had a negative impact on the MCS of patients with MLLA at T0. After three months, heart disease and mobility limitation were negatively associated with MCS. Hisam et al. reported that females had better mental health than male amputees[10], which is not in line with our study. Whereas, Lam et al. showed that females had better scores of QoL compared to mal amputees[25]. Other studies reported that decreased mobility had negative effect on MCS[9,16]. The same result was found in our study and showed that peripheral nerve block and heart disease were also associated with poor scores of MCS, and the only factor associated with poor PCS and MCS scores was a limitation of mobility.

Concerning the variables associated positively with QoL of patients with MLLA, Davie-Smith et al. found that working, helping at home, and being able to walk with a prosthesis after MLLA had a positive impact on patients QoL after discharge[5]. Furthermore, Sinha et al. found that having a job and better adaptation to functional limitation after LLA were positively associated with better PCS of QoL[16]. In a systematic review conducted by Christensen et al, physical activity level and sports exercise had a positive impact on physical QoL[43]. In our study, employment prospects were more limited because of a lack of training and academic qualification (50% of the study population was illiterate). Opting for a job that requires less physical effort poses a challenge for patients with MLLA. In the field of mental health, the factors that influenced positively the MCS of QoL were informing the patient before the amputation procedure, explaining the amputation procedure and its health consequences to the patient, the stay before amputation, and the fitting of a temporary prosthesis.

Limitations

The present study has some limitations. Firstly, the QoL was not assessed with a specific scale for limb amputation but with a generic QoL scale. Secondly, the role of the partner in the limitations experienced by the amputee in the different health domains was not assessed. Thirdly, no patient recruitment for the control group. Finally, prospective studies including a large number of patients with long follow-ups are needed to definitively characterize QoL in patients with MLLA.

Conclusion

The QoL is generally impaired in Moroccan population with MLLAs at three months. Advanced age, limitation of mobility, general anesthesia, and a long hospital stay negatively impacted physical health in the immediate postoperative period, while reamputation and stump pain negatively impacted physical health three months after hospital discharge. Peripheral nerve block and limited mobility reduced the mental health score in the immediate postoperative period, while cardiovascular disease and limited mobility had a negative effect on the patient's mental health.

Informing the patient about the act of amputation and its consequences, adequate and early management, and a physical rehabilitation program with stump fitting will facilitate the return of these patients to a normal life. The results of this study underline the importance of paying particular attention to the different dimensions of the health of patients who have undergone a MLLA. Hence, the interest in the intervention of a multidisciplinary team consisting of the surgeon, psychologist, anesthetist, orthopaedist, and physiotherapist to improve the physical and mental QoL of the patient.

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Ethics approval and consent to participate:
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