Original Article

Impact of Yoga Intervention in Lower Limb Amputees following Trauma in Relation to Behavior and Quality of Life: A Randomized Controlled Trial

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Abstract

Background: Yoga is an emerging intervention causing improvement in physical, mental, and spiritual well-being. Its role in improving outcomes in patients with amputation was investigated. **Methodology:** Patients with traumatic lower limb amputation (n = 50) were enrolled and randomized to the Yoga group (n = 26) against control (n = 24). Sociodemographic details, quality of life (QOL) (World Health Organization QOL-BREF), Depression anxiety stress scale (DASS), Rosenberg self-esteem scale, and amputee body image score were applied at baseline, 6,–18 weeks of amputation. **Results:** Sociodemographic and clinical variables were comparable between groups. At 18 weeks, the Yoga group had better QOL (P = 0.005) than the control group. Symptoms of depression (0.02) and anxiety (<0.001) reduced, and self-image (P = 0.015) improved significantly at 6 weeks, while stress (P = 0.003) reduced at 18 weeks in the yoga group. Despite comparable body image scores, the prosthesis usage (hours/day) was more (P = 0.005) in the Yoga (6.9 ± 3.2) group against the control (12 ± 2.7). **Conclusion:** Yoga improves QOL and self-esteem and reduces depression, anxiety, and stress symptoms in patients with traumatic amputation.

Keywords: *Limb loss, quality of life, traumatic amputation, yoga*

Introduction

Amputation as a result of trauma is becoming a significant health challenge in medical care, as well as on families and society.[1] Amputation of a limb due to trauma is a profound, sudden, emotionally devastating, and irreversible act.[2] Due to several factors, such as the feeling of deprivation, self-stigma, and difficulty coping with the impairment, the person undergoing amputation may be at risk of developing psychiatric disorders.[3,4] Reduced job opportunities, job dissatisfaction, decreased social contact, interpersonal disputes with family members, decreased self-esteem, distorted body image, and increased dependence are only a few causes of psychological maladaptation.[5] Major depressive disorder, post-traumatic stress disorder (PTSD), generalized anxiety disorder, and panic disorder have all been commonly seen as psychiatric comorbidity after amputation.[6]

Depression is estimated to affect 28% of amputees, while 64% of amputees experience anxiety symptoms.[7] Higher levels of symptomatic distress and rates of suicidal behavior are identified when depression is accompanied by anxiety disorders, such as PTSD in amputees.[8]

Efficacious treatment to ease the suffering of amputees is still elusive. Yoga is a type of holistic medicine that incorporates mind-body techniques and has its origins in ancient India. Researchers are investigating the feasibility and success of yoga as a complementary and alternative therapy for uniting the body through mind and spirit to improve physical and mental wellness.[9] The triad of meditation, postures, and breathing exercises are part of yoga, which encourages body and mind harmony and relaxation.[10] Yoga provides amputees with the stability, power, and endurance needed, as well as physical, mental, and spiritual well-being, allowing them to thrive in life. A single-center study by Gunjiganvi *et al*. found that combining Yoga therapy with regular chest physiotherapy improves pulmonary function significantly during the early stages of hospitalization and, in turn, postinjury quality of life (QOL) in the chest trauma patient.[11]

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The ability to walk with a prosthesis is important since it avoids harmful consequences on a physical, psychological, and social basis, as well as leads to the reduction of comorbidities. Satisfaction with the prosthesis is critical for mobility rehabilitation, avoiding rejection, and increasing medical care compliance.

Methodology

Study design

The study was a prospective open-label randomized controlled trial (CTRI no-REF/2019/10/028767) carried out in the Trauma Surgery and Critical Care division of Level-I Trauma Center, catering to the national capital territory of Delhi with a footfall of 70,000 patients per annum. The sample size was calculated to be 50, keeping into consideration the total number of lower limb amputee patients during previous years with an α of 5% and power of 90%.

Selection criteria

Patients aged 18–65 who underwent lower limb amputation (included hemipelvectomy down to foot-level) related to trauma after being shifted to the ward within 48 h post surgery and were willing to participate were enrolled after obtaining informed consent. Patients with comorbidities based on history and clinical examination, such as cardiac condition, malignancies, coagulation, and bleeding disorders, on anti-epileptics and thyroid drugs, non-traumatic amputation, and pregnant women were excluded.

Assessment instruments

1. Sociodemographic and clinical data sheet: This included age, gender, education, marital status, socioeconomic status (SES) using the modified Kuppuswamy Scale, presentation of the patient, shock status, mechanism of injury, trauma scoring, comorbidity, site of amputation, number of extremities amputated, associated injury, number of physiotherapy and yoga sessions delivered to the patient, number of surgeries, hospital stay of the patient and history of past psychiatric illness or any psychotropic medication at the baseline. Lower- and upper-lower were combined in the category Lower SES, while lower middle and upper-middle were combined in the category middle SES. The trauma scoring system gives an accurate, dependable, and repeatable description of injuries as well as a predictor for morbidity and mortality. In our study, we have compared the Injury Severity Score, New Injury Severity Score, and Mangled Extremity Severity Score in an amputee, which were comparable in both groups
2. World Health Organization QOL-BREF (WHOQOL-BREF) contains a total of 26 questions and provides a broad and comprehensive assessment, and enables health professionals to assess changes in QOL over the course of treatment. There are four domains of this score: physical health, psychological, social relationships, and environment. WHOQOL-BREF is a sound, cross-culturally accurate measure of QOL, as evidenced by its four domains: physical, psychological, social, and environment[12]
3. Depression Anxiety Stress Scale (DASS) is a 42-item self-report instrument designed to measure the three-related negative emotional states of depression, anxiety, and tension/stress. The DASS-21 depression and anxiety subscales correlated well with the self-rating depression scale and the state-trait anxiety assessment. The psychometric qualities of the DASS-21 were found to be satisfactory, dependable, valid, and simple to use[13]
4. Rosenberg Self-esteem Scale (RSES) is a widely used self-report instrument for evaluating individual self-esteem. It is a 10-item scale that measures global self-worth by measuring both positive and negative feelings about the self. The RSES has adequate internal consistency, good test–retest reliability, and acceptable convergent validity.[14]

Intervention

Yoga practices were done by the patients under the supervision of a single yoga instructor for 18 weeks. A yoga booklet was given to all the enrolled patients so they could perform yoga practices with precision and keep a log of their exercises for unsupervised sessions. Regular physiotherapy sessions were given to both groups as a part of routine treatment, which also served as attention control. The yoga and physiotherapy sessions were selected considering the mobility limitations of such patients, and no modification was required for any patient. The details of the interventions are described in Figure 1. All the supervised sessions occurred during inpatient stay, and unsupervised sessions occurred during outpatient as well as inpatient stay. The length of each session was 30 min, and the frequency of sessions was daily for yoga. The length of each session was 30 min and the frequency of sessions was daily for physiotherapy. Compliance with unsupervised sessions was assessed using logbook and telephonic video consultation. No instruments or mats were provided to patients for this study.

Procedure

Ethical approval was obtained from the Institute's Ethics Committee. Screened participants were initially managed as per the Advanced Trauma Life Support protocol of the American College of Surgeons Committee on Trauma. Those meeting the eligibility criteria for the study were identified and approached after the patient was shifted to the ward post surgery. In case the intensive care unit stay was prolonged due to medical reasons, the assessment and intervention were started only after the patient returned to the ward. The purpose of the study was discussed and explained to the patient, and their relatives and consent was obtained. Randomization was done by block design by the

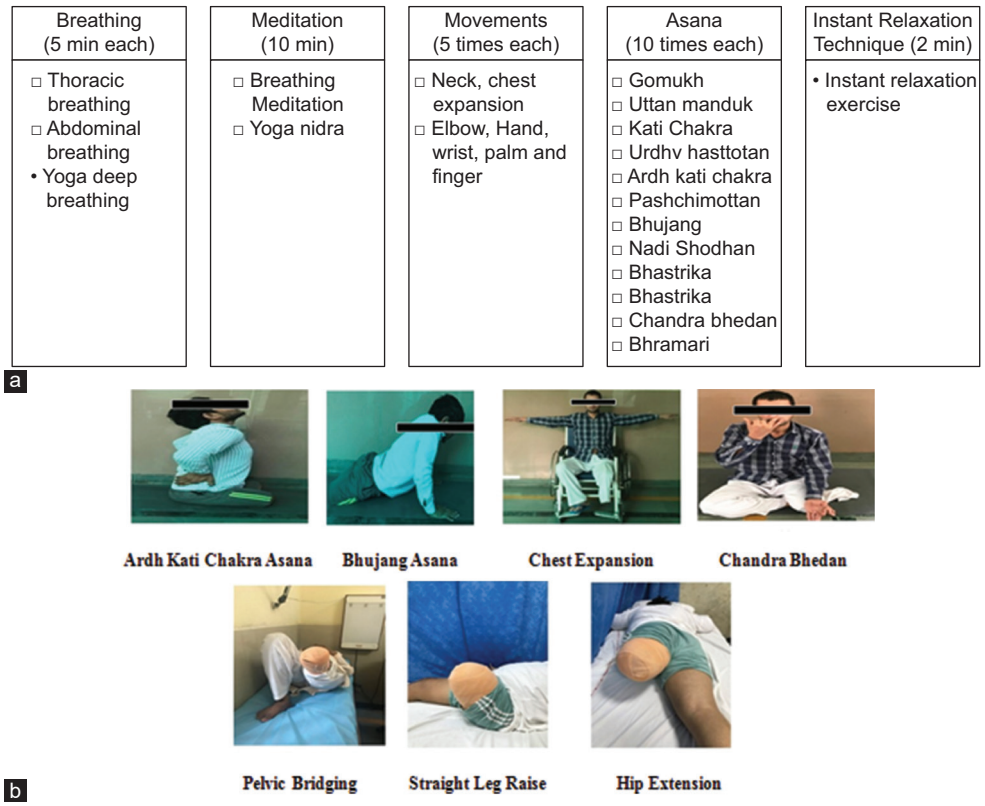

Figure 1: (a) List of Yoga Techniques prescribed for 18 weeks duration (b) Images of Yoga and Physiotherapy sessions

allocator. Patients were randomized into two groups, and the sequence was concealed till analysis of the data was done. Group A received the conventional line of treatment was given (control group), and in Group B, patients were made to do yoga practices along with the conventional line of treatment (intervention group). Baseline measurement of psychological scales was done by a trained Clinical Psychologist, which included WHOQOL-Bref, DASS, and RSES, who was blinded to the group allotment. Serial assessments were done for all the scales at the 6th week and 18th week. In a few patients (n = 5), a follow-up assessment was done telephonically due to the outbreak of the Covid-19 pandemic and subsequent nationwide lockdown. Both groups were assessed for any adverse events that could potentially be related to these interventions, like falls during yoga maneuvers, episodes of dizziness or lightheadedness, or requirements for additional pain medication before or after yoga instruction sessions, etc., The statistical analysis was done at the end of the study. The analyst was blinded to the group allotment, and the allocation of groups was revealed after the analysis was complete.

Results

A total of 250 patients were screened for lower limb amputation, of which 50 were recruited for the study, 24 patients in the control group and 26 patients in the intervention group [Figure 2]. Three patients (Group A: 1 and Group B: 2) died during the hospital course out of complications developed due to associated injuries The data of these three patients were incomplete and thus not analyzed. There was 100% follow-up at 6–18 week follow up. All patients logged their sessions more than 90% of the total unsupervised sessions during the study duration. None of the patients reported any adverse events related to the intervention.

Table 1 depicts the sociodemographic variables of the two groups. The majority of the patients in both groups were young married males following the Hindu faith, living in a nuclear family, and from Low SES [Table 1]. The demographic variables did not differ between the two groups significantly.

A comparison of the clinical variables of the two groups can be seen in Table 2. There was no significant difference between referral status, shock at presentation, mechanism of injury, trauma scores, medical or surgical comorbidity, type of amputation, number of surgeries, associated injuries, physiotherapy sessions, psychiatric history, and duration of admission, follow-up status, stump status, and prosthesis status. Road traffic injury was found to be the major reason for lower limb amputation in both groups (50% vs. 81%), followed by railway track injuries, which was the mechanism of injury (38% vs. 19%). The majority of the patients in both groups were amputated in their index surgery. Above-knee amputation was performed in the majority of the patients, followed by below-knee

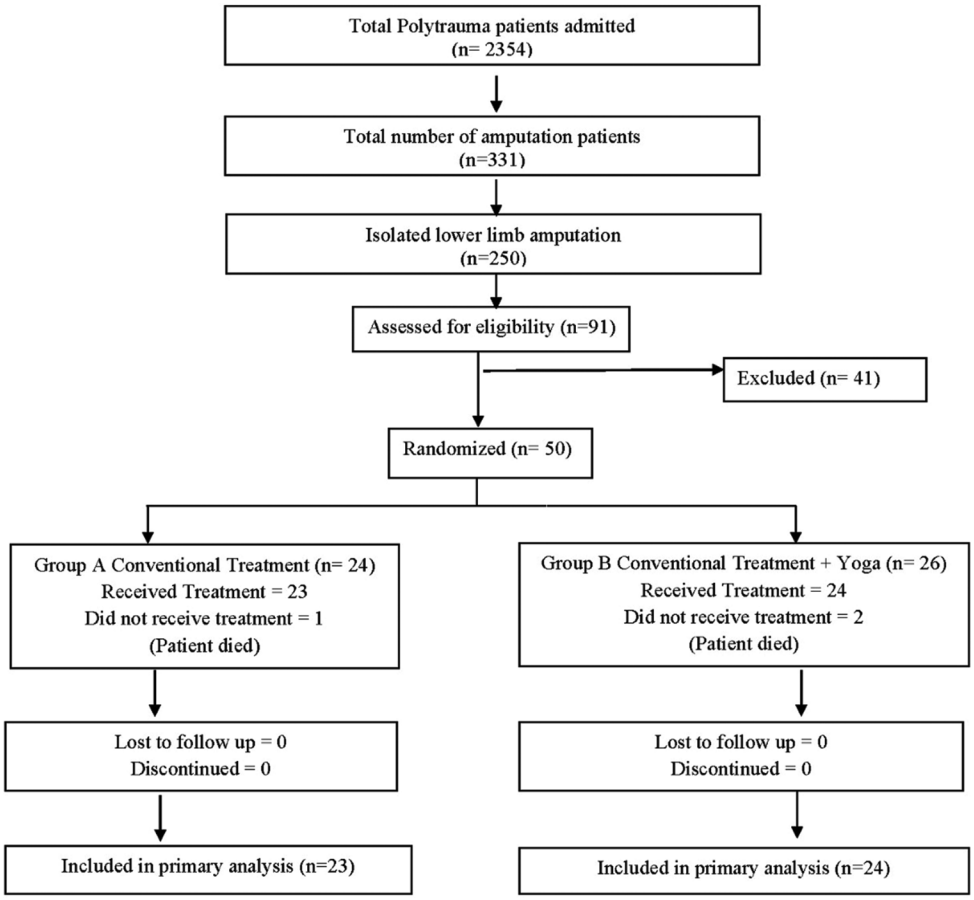

Figure 2: Consort diagram

Table 1: Sociodemographic variables

Parameters	Frequency (%)		χ^2/Mann–Whitney *U* (*P*)
	Control (*n*=23)	Yoga (*n*=24)	
Age, mean±SD	31.2±9.3	30.3±10.8	249 (0.565)
Gender			
Female	4 (17.4)	2 (8.3)	0.86 (0.416)[@]
Male	19 (82.6)	22 (91.7)	
Religion			
Hindu	20 (87)	19 (79.2)	0.50 (0.701)[@]
Others	3 (13)	5 (20.8)	
Education			
≤5 i.e., literate	8 (34.8)	7 (29.2)	0.17 (0.68)
>5 i.e., illiterate	15 (65.2)	17 (70.8)	
Income			
Category 1 or 2	18 (78.3)	18 (75)	0.07 (0.792)
Category 3, 4 or 5	5 (21.7)	6 (25)	
Kuppuswamy score			
Low SES	16 (69.6)	15 (62.5)	0.26 (0.609)
Middle SES	7 (30.4)	9 (37.5)	

[@]Fisher's exact value. SD: Standard deviation,
SES: Socioeconomic status

amputation. Majority of the patients presented with no comorbidities (96% vs. 92%). Skin grafting, also known as split-thickness skin grafting (STSG), is the most commonly performed procedure to close defects unable to be closed with the simple approximation of the wound edges. The majority of the patients in both groups (65% vs. 79%) did not require STSG. In Group A, 22% of patients and Group B, 17% of patients reported a history of past psychiatric illness.

Table 3 compares WHOQol Bref, DASS scores, and RSES scores between the groups over different time points. There was no difference between the two groups in these measures at baseline. Over the course of time, in both groups, there was a significant improvement in all the domains of QOL. At 6 weeks, yoga group had a significantly better WHOQoL total score (75.8 vs. 71.1, $P = 0.027$) and environmental domain (23.3 vs. 20.9, $P = 0.023$). While at the end of 18 weeks of post assessment yoga group had better scores as compared to the control on the physical domain (30.8 vs. 28.7; $P = 0.008$), psychological domain (26.3 vs. 24.1; $P = 0.016$), and environmental domain (35.5 vs. 32.2; $P = 0.003$). On the Depression, Anxiety Stress Scale, improvement was seen in all domains in both groups over time. The improvement in depressive (9.6 vs. 11.7; $P = 0.02$) and anxiety symptoms (6.8 vs. 11.1; $P < 0.001$) was significantly more in the Yoga group than in the control group in the first follow-up, i.e. at 6 weeks. In comparison, the stress symptoms (6.6 vs. 8.3; $P = 0.003$)

Table 2: Clinical variables

Parameters	Frequency (%)		χ^2/Mann–Whitney *U* (*P*)
	Control (*n*=23)	Yoga (*n*=24)	
Presentation			
Primary	12 (52.17)	10 (41.66)	0.521 (0.47)
Referred	11 (47.82)	14 (58.33)	
Status of shock at presentation			
Yes	7 (30.4)	4 (16.7)	1.24 (0.318)@
No	16 (69.6)	20 (83.3)	
Mechanism of injury			
Road traffic injuries	12 (50)	21 (80.77)	6.25 (0.06)
Train associated injury	9 (37.50)	5 (19.23)	df=4
Machine cut	1 (4.17)	0	
Bomb blast	1 (4.17)	0	
Cylinder blast	1 (4.17)	0	
Trauma scoring, mean±SD			
ISS	10.7±4.1	12.5±3.9	218.5 (0.216)
NISS	14±5.4	16.8±7.7	216.5 (0.204)
MESS	6.2±2.4	4.8±3.6	243.5 (0.48)
Comorbidity			
No	22 (95.7)	22 (91.7)	0.31 (1)@
Yes	1 (4.3)	2 (8.3)	
Amputation on arrival			
Index	18 (78.3)	22 (91.7)	1.66 (0.245)@
Secondary	5 (21.7)	2 (8.3)	
Site of amputation			
Hemipelvectomy	0	1 (3.85)	6.3 (0.69)
Hip disarticulation	3 (12.50)	2 (7.69)	df=6
Above knee	10 (41.67)	11 (42.31)	
Knee disarticulation	0	3 (11.54)	
Below knee	7 (29.17)	6 (23.08)	
Ankle and foot	1 (4.17)	1 (3.85)	
More than one site	3 (12.50)	2 (7.69)	
Side of amputation			
Right	7 (30.4)	16 (66.7)	3.31 (0.069)@
Left	11 (47.8)	4 (16.7)	df=2
Bilateral	5 (21.7)	4 (16.7)	
Associated injury at any other site than amputation			
Yes	13 (56.5)	7 (29.2)	3.59 (0.058)
No	10 (43.5)	17 (70.8)	
STSG			
Yes	8 (34.8)	5 (20.8)	1.14 (0.285)
No	15 (65.2)	19 (79.2)	
Number of physiotherapy sessions			
≤10	10 (43.5)	16 (66.7)	2.55 (0.11)
≥11	13 (56.5)	8 (33.3)	
Number of supervised yoga sessions, mean±SD		19±10.7	-
Past psychiatric illness			
Absent	18 (78.3)	20 (83.3)	0.19 (0.724)@
Present	5 (21.7)	4 (16.7)	
Psychotropic medication (at baseline)			
No	11 (47.8)	11 (45.8)	0.01 (0.891)
Yes	12 (52.2)	13 (54.2)	
Number of surgery			
2 or less	10 (43.5)	16 (66.7)	2.55 (0.11)
3 or more	13 (56.5)	8 (33.3)	

Contd...

Table 2: Contd...

Parameters	Frequency (%)		χ^2/Mann–Whitney *U* (*P*)
	Control (*n*=23)	Yoga (*n*=24)	
Hospitalised days			
Less than a week	8 (34.78)	9 (37.5)	0.038 (0.846)
8 days or more	15 (65.22)	15 (62.5)	
Number of follow-up in amputation clinic, mean±SD	5.3±3.3	6.1±2.7	227 (0.294)
Stump ready status (weeks), mean±SD	6.6±3.1	6.3±2.6	275 (0.983)
Prosthesis application Yes/No			
Yes	7 (30.4)	10 (41.7)	0.64 (0.423)
No	16 (69.6)	14 (58.3)	

[@]Fisher's exact value. SD: Standard deviation, STSG: Split thickness skin grafting, ISS: Injury severity score, NISS: New ISS, MESS: Mangled extremity severity score

Table 3: Comparisons of World Health Organization quality of life between groups at different time points

Domains	Baseline, mean±SD			6 weeks, mean±SD			18 weeks, mean±SD		
	Control (*n*=23)	Yoga (*n*=24)	Mann–Whitney *U* (*P*)	Control (*n*=23)	Yoga (*n*=24)	Mann–Whitney *U* (*P*)	Control (*n*=23)	Yoga (*n*=24)	Mann–Whitney *U* (*P*)
WHOQoL-Bref									
Physical	10.4±1.8	9.9±1.2	200.5 (0.099)	19.8±4.1	21±3.5	217 (0.206)	28.7±2.8	30.8±2.6	153 (0.008)**
Psychological	8.9±1.7	9.1±1.5	242 (0.458)	15.9±2.7	17.3±2.7	195.5 (0.084)	24.1±3.4	26.3±2.3	164 (0.016)**
Social	4.3±0.8	4.1±1.1	221 (0.216)	9.8±1.7	9±2.5	205 (0.126)	12.7±1.7	13±1	235 (0.368)
Environmental	11.4±2.3	12±2.4	232 (0.344)	20.9±3.5	23.3±2.8	169.5 (0.023)*	32.2±3.9	35.5±2.8	135.5 (0.003)**
Total score	37.7±4	37.9±3.8	263.5 (0.789)	71.1±7.7	75.8±6.4	172.5 (0.027)*	105.8±10.2	114.3±6.8	144 (0.005)**
DASS									
Depression	17±3.7	16.5±4.7	247.5 (0.542)	11.7±2.9	9.6±2.9	168 (0.02)*	7.4±2.2	7±2.4	216.5 (0.2)
Anxiety	15.3±3.9	14.6±3.2	231.5 (0.341)	11.1±2.6	6.8±2.2	54.5 (<0.001)***	5±1.8	5.1±1.1	252.5 (0.607)
Stress	24.3±5.5	25±5.7	251.5 (0.597)	14.4±3.8	12.9±2	190.5 (0.067)	8.3±1.8	6.6±1.7	136.5 (0.003)**
Total score	56.7±9.5	56.1±9	258 (0.701)	37.3±6.2	29.3±4.2	76 (<0.001)***	20.7±4.3	18.7±3.3	168 (0.021)*
RSES									
RSES total score	13.5±1.5	14.1±1.8	220.5 (0.223)	21.9±3.3	24.8±4.2	162.5 (0.015)*	33±2.4	32.9±3.2	271 (0.915)

*P<0.05, **P<0.01, ***P<0.001. SD: Standard deviation, DASS: Depression anxiety stress scale, RSES: Rosenberg Self Esteem Scale, WHOQoL: World Health Organization Quality of Life

were significantly lower in the Yoga group compared to the Control group at 18 weeks. Compared to the Control group, the total DASS scores were lower in the Yoga group at both follow-ups. The self-esteem measures improved in both groups over time, but they were significantly better at the first follow-up in the Yoga Group compared to the control (24.8 vs. 21.9; P = 0.015). The trends of these scales are depicted in Figure 3a-c.

Of those who used prosthesis, a comparison of the use of prosthesis and body image is shown in Table 4. The total duration of application of prosthesis (in months) was comparable in both groups. The mean Amputee body image score did not differ significantly between the groups. However, it was seen that those in the Yoga group were wearing the prosthesis significantly more than the control group (12 h vs. 7 h; P = 0.005).

Since the sample size was small, so nonparametric tests were used instead of repeated analysis of variance. We have used the Friedman test, Wilcoxon-signed rank test, and Generalizing estimating equation. The results of the Friedman test revealed a significant difference in both the treatment as usual (TAU) group (χ^2 = 46, P < 0.001) and the Yoga group (χ^2 = 48, P < 0.001) for WHOQol Bref Total Scores, indicating that the QOL in participants significantly varied across different time points within each group. Similarly, for the Depression Anxiety Stress Scale (DASS), both the TAU group (χ^2 = 46, P < 0.001) and the Yoga group (χ^2 = 48, P < 0.001) exhibited significant differences. In addition, for the RSES, significant differences were observed in both the TAU group (χ^2 = 43.7, P < 0.001) and the Yoga group (χ^2 = 45.6, P < 0.001). Overall, the results indicate that both the TAU and Yoga interventions had a notable improvement in the QOL, psychological well-being, and self-esteem of participants. The sub-analysis was performed using the Wilcoxon Signed-rank test for baseline (Point 0) to 6 weeks (Point 1), 6 weeks (Point 1) to 12 weeks (Point 2), and baseline (Point 0) to 12 weeks (Point 2). In both the TAU and Yoga groups, significant improvements were observed across all assessed variables. The revealed highly significant P < 0.001 for all within-group comparisons, including total QOL, mental health, and self-esteem from baseline to intermediate time points, and from baseline to

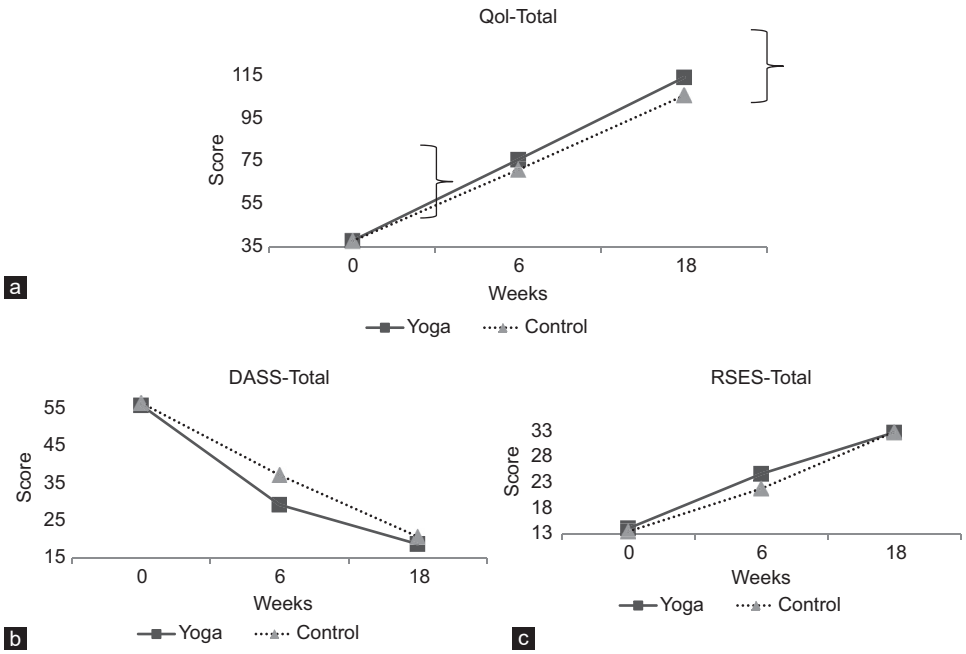

Figure 3: (a-c) Graphical representation of scales

Table 4: Comparison of patients with prosthesis

	Mean±SD		Mann–Whitney *U* (*P*)
	Control (*n*=7)	Yoga (*n*=10)	
Duration of application of prosthesis (months)	3.86±0.38	3.3±0.95	255.5 (0.608)
ABIS	45.57±8.71	42.4±11.29	28 (0.536)
Number of hours patient wears prosthesis per day	6.86±3.23	12±2.66	7.5 (0.005)**

***P*<0.001. SD: Standard deviation, ABIS: Amputee body image score

the final time point. These findings indicate that both TAU and Yoga interventions led to significant positive changes in QOL, mental health, and self-esteem over the course of the study. Further, the generalized estimating equation (GEE) analysis was conducted to explore the impact of group assignment (Group), time of assessment (Time), and their interaction (Group * Time) on various outcome measures. For the WHOQoL Bref total score, the GEE model revealed highly significant effects for both time (Wald χ^2 = 3151.159, df = 2, P < 0.001) and the interaction between group and time (Wald χ^2 = 11.026, df = 2, P = 0.004). This indicates that over time, there was a significant change in the QOL scores, and the impact of time on these scores varied depending on the group. Additionally, the group effect was significant (Wald χ^2 = 16.211, df = 1, P < 0.001), indicating that there were differences in WHOQoL Bref total scores between the two groups. Similarly, for the Depression Anxiety Stress Scale (DASS), time (Wald χ^2 = 716.596, df = 2, P < 0.001) and the interaction between group and time (Wald χ^2 = 16.134, df = 2, P < 0.001) exhibited significant effects, suggesting that changes in depression, anxiety, and stress levels occurred over time, with differential effects in the intervention and control groups. Furthermore, the group effect was significant (Wald χ^2 = 7.819, df = 1, P = 0.005), indicating differences in DASS scores between groups. For the RSES, while the time effect (Wald χ^2 = 1657.572, df = 2, P < 0.001) was highly significant, suggesting changes in self-esteem scores over time, the interaction between group and time (Wald χ^2 = 4.911, df = 2, P = 0.086) showed a trend toward significance. I addition, the group effect was significant (χ^2 = 6.1, df = 1, P = 0.013), suggesting that there were differences in self-esteem scores between the intervention and control groups [Table 5].

For the Mann–Whitney *U* test, which examines group differences, we observed varying effect sizes for the WHOQoL Bref, DASS, and RSES scales. Specifically, for the WHOQoL Bref scale, the effect sizes were small at baseline (Cohen's d = 0.078) but became notably larger at 6 weeks (Cohen's d = 0.679) and 18 weeks (Cohen's d = 0.898). These findings suggest that the yoga intervention had a progressively more substantial impact on improving the QOL in lower limb amputees as the study duration increased. Similarly, for the DASS scale, a moderate effect size was evident at 6 weeks (Cohen's d = 1), indicating a significant reduction in depression, anxiety, and stress levels in the yoga group compared to the control group. On the RSES scale, the effect sizes ranged from moderate at baseline (Cohen's d = 0.35) and 6 weeks (Cohen's d = 0.753) to smaller at 18 weeks (Cohen's d = 0.031), indicating a positive influence of the yoga intervention on self-esteem, particularly in the earlier phases of the study.

In addition, the calculations of Kendall's W for the Friedman test, which assesses the effect of time on

Table 5: Comparisons of output parameters between groups over time and generalized estimating equation model for effect over time

Variables	Friedman test, χ^2 (df) (*P*)		Wilcoxon signed-rank test[#] (*P*)		
	TAU	Yoga	Sub-group analysis	TAU	Yoga
WHOQoL Bref	46 (2) (<0.001***)	48 (2) (<0.001***)	Total 1 - total 0	<0.001***	<0.001***
			Total 2 - total 1	<0.001***	<0.001***
			Total 2 - total 0	<0.001***	<0.001***
DASS	46 (2) (<0.001***)	48 (2) (<0.001***)	DASS total 1 - DASS total 0	<0.001***	<0.001***
			DASS total 2 - DASS total 1	<0.001***	<0.001***
			DASS total 2 - DASS total 0	<0.001***	<0.001***
RSES	43.7 (2) (<0.001***)	45.6 (2) (<0.001***)	RSES 1 - RSES 0	<0.001***	<0.001***
			RSES 2 - RSES 1	<0.001***	<0.001***
			RSES 2 - RSES 0	<0.001***	<0.001***

Variables	Generalized estimating equation											
	Intercept			Group			Time			Group × time		
	Wald χ^2	df	*P*	Wald χ^2	df	*P*	Wald χ^2	df	*P*	Wald χ^2	df	*P*
WHOQoL Bref total	17,720	1	<0.001***	16.2	1	<0.001***	3151	2	<0.001***	11	2	0.004**
DASS total	3269	1	<0.001***	7.8	1	0.005**	716	2	<0.001***	16	2	<0.001***
RSES score	10,256	1	<0.001***	6.1	1	0.013*	1657	2	<0.001***	5	2	0.086

*P<0.05, **P<0.01, ***P<0.001. DASS: Depression anxiety stress scale, RSES: Rosenberg Self-Esteem scale, TAU: Treatment as usual, WHOQoL: World Health Organization Quality of Life

outcome measures within and between groups, revealed consistently high effect sizes across all measures and in both the TAU (control) and Yoga groups. Specifically, for the WHOQoL Bref, Kendall's W values were 0.949 for the TAU group and 0.951 for the Yoga group. For the DASS scale, both groups exhibited Kendall's W values of 1, indicating a substantial impact of time on depression, anxiety, and stress levels. The RSES scale also showed high Kendall's W values of 0.949 for the TAU group and 0.951 for the Yoga group, emphasizing the significant influence of time on self-esteem measures.

Discussion

Traumatic amputation is both a life-saving and life-changing surgery that affects a person's physical activity, social involvement, confidence, psychological issues, and career options. The first responses after amputation of a limb are varied and complicated. The current study is a randomized controlled trial and is one of its kind to incorporate yoga techniques into the treatment of traumatic lower limb amputation patients irrespective of the level of amputation and it being unilateral or bilateral lower limbs.

A substantial number of working-age amputees reported being forced to retire owing to disability, limiting their output, especially during their prime years.[15] The average age of the participants in this study matches with other studies from this part of the globe, thus reiterating the fact that trauma is a disease of the young.[16] The functional competence of a big proportion of the population in their 20s and 30s was lowered in either daily or social activities, potentially increasing the economic burden of the state.[15,16] Majority of the patients were males in the present study, like in previous studies done elsewhere.[17,18] The male population in developing nations bears the brunt of the injury load as they are more likely to work in the field and so are more exposed to the risk of an accident as quoted in previous studies too.[16] SES is among the important indicators used in evaluating the health and nutritional status of a family. Some individuals have functional, social, and psychological problems as a result of amputation, while others adjust and function normally after a duration of amputation with the prosthetic leg.[1] In the present study, the most common mechanism of injury was road traffic injuries, followed by train associated injury. The majority of the patients in both groups were amputated at their index surgeries, and the most common site of amputation in both groups was above-knee amputation, which is in concordance with the study done by Pohjolainen *et al*.[19] in 1989 and Mir *et al*.[20]

In the current study, the overall QOL was significantly improved in patients receiving yoga therapy as well as in all the physical, psychological, and environmental domains. This difference was stable over time. Similar results have been observed in other studies by Woodyard[9] in 2011 and Reddy *et al*.[21] in 2014, in which yoga is supposed to improve well-being, relaxation, self-confidence, and body image, as well as increase efficiency, interpersonal interaction, attentiveness, reduce irritation, and encourage a positive attitude toward life. It is important to note that determining a patient's QOL before a traumatic incident is impossible, and there is always a bias of the current traumatic event obscuring genuine QOL.

The present study showed that yoga as a regular practice proved to improve depression and anxiety in as early as 6 weeks when compared to the control group. The stress

domain also significantly improved in the later follow-ups with continued yoga, which was not there at 6 weeks. Similar results of yoga benefits in improving depression, anxiety, and stress scores were evident in studies conducted by Shohani *et al*.[22] and Büssing *et al*.[23] A study conducted by Gunjiganvi *et al*.[11] also suggests the benefits of yoga in trauma patients.

Self-esteem is a measure of own worth or worthiness. Lower-limb amputations have a considerable impact on patients' body image and QOL and have a substantial impact on self-esteem.[24] Self-esteem also has a role in the treatment outcome of surgery.[25-27] In the current study, yoga had an early improvement in self-esteem. This is probably associated with the increased use of prosthesis per day despite having similar scores on body image and overall duration of prosthesis use.

The main strength of the study was that it is a randomized controlled trial in which the psychological state of the traumatic lower limb amputation patients was deeply studied, which were deciding factors for one's mood, anxiety, stress, low esteem, etc., The selection criteria were stringent, and the assessment was detailed. In addition, due to randomization, the sociodemographic details and clinical variables (patient-related and trauma-related) were comparable in the two groups. These changes were observed over a longitudinal course. Yoga practices were incorporated into patients, and their benefits were studied. The GEE analysis further elucidates the temporal dynamics of these outcomes. The significant interaction between group assignment and time for both QoL and mental health outcomes implies that the impact of yoga intervention evolves over the course of treatment. This underscores the importance of considering the duration and consistency of yoga practice in clinical settings.

The present study has certain limitations in the form of a small sample size and loss of follow-up of patients due to the outbreak of the COVID-19 pandemic. Telephonic assessment of psychological scales was done in patients who could not come for follow-up due to the nationwide lockdown. Another limitation was non inclusion of pain assessments score in the study, which is important in all the outcome variables. It was conducted at a tertiary center, thus a cause of bias. Thus, future studies could be planned by making a multi-centric design with the inclusion of different levels of trauma centers.

Conclusion

We conducted a randomized trial evaluating the impact on self-reported QOL, depression and anxiety, and self-esteem of an 18-session yoga regimen compared to standard care in 50 patients with trauma-related lower limb amputation. The intervention consisted of supervised yoga instruction. The addition of yoga to standard physiotherapy as part of recovery after lower-limb amputation led to improved QOL, reduced depression/anxiety, improved self-esteem, and increased average prosthesis use. This study identifies a readily deployable, low-cost addition to standard therapy that may provide much-needed mental and physical health benefits for patients undergoing trauma-related lower extremity amputation.

Ethical statement

Ethical approval was obtained from the Institute's ethics committee of All India Institute of Medical Sciences, New Delhi with approval number IEC-494/07.10.2016,RP-53/2017.

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Conflicts of interest

There are no conflicts of interest.

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