Effects of Community-Based Exercise in Children with Severe Burns: A Randomized Trial

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Short title: Effects of Community-Based Exercise in Burned Children

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Abstract

Objective: To counteract long-lasting muscle break down, muscle weakness, and poor physical fitness resulting from severe burns, we recommend a 12-week in-hospital exercise training rehabilitation program. Unfortunately, this in-hospital training program requires time away from home, family, school or work). This study was undertaken to evaluate an alternative exercise rehabilitation strategy involving a 12-week community-based exercise training rehabilitation program (COMBEX) carried out at or near the patient and caretaker's home.

Study Design and Participants: Pediatric patients (7–18 years) with $\geq 30\%$ of the total body surface area (TBSA) burns were randomized to participate in COMBEX (N=12) or an outpatient exercise program (EX) at the hospital (N=22). Both programs were started after hospital discharge and consisted of 12 weeks of progressive resistive and aerobic exercise. COMBEX was performed in community fitness centers near the patients' home. Endpoints were assessed at discharge (pre-exercise) and after the 12-week program. Primary endpoints were lean body mass (dual energy x-ray absorptiometry), muscle strength (isokinetic dynamometry), and peak aerobic capacity (indirect calorimetry).

Results: Demographics, length of hospitalization, and TBSA burned were comparable between groups ($p > 0.05$). Both groups exhibited a significant ($p \leq 0.01$ for all) increase (mean $\pm$ SEM) in lean muscle mass (EX: $6.9 \pm 1.7\%$; COMBEX: $6.5 \pm 1.1\%$), muscle strength (EX: $67.1 \pm 7.0\%$; COMBEX: $49.9 \pm 6.8\%$), and peak aerobic capacity (EX: $35.5 \pm 4.0\%$; COMBEX: $46.9 \pm 7.7\%$). Furthermore, the magnitude of these increases were not different between groups ($P > 0.12$).

Conclusions: Both EX and COMBEX are efficacious in improving lean mass, strength, and cardiopulmonary capacity in severely burned children.

Keywords: community-based exercise program; exercise program; standard of care; lean body mass; muscle strength; peak aerobic capacity; rehabilitation

Abbreviations: community-based exercise program (COMBEX); total body surface area (TBSA); exercise program (EX)

INTRODUCTION

Burns covering significant portions of the total body surface area (TBSA) induce a physiological response characterized by a persistent and extensive catabolic state [1, 2]. Burn-induced catabolism lasts for up to 1 year and is exacerbated by physical inactivity [2]. This catabolic state decreases muscle mass, leading to weakness [2]. Due to these burn-induced responses, aerobic and resistive exercise activities have been recommended to counteract these outcomes.

We have previously shown that, in pediatric outpatients, a 12-week regimen of progressive resistive and aerobic exercise performed at the hospital attenuates muscle loss and weakness [3-5]. However, a drawback to this type of exercise program (EX) is that it requires significant financial resources and is a considerable time commitment, requiring patients and sometimes caregivers to be in the hospital rather than at school, work, or home. In cases in which the patient and family do not have the resources or need to be home due to family, work, or other issues, it is highly desirable to identify an approach aimed at improving muscle mass, strength, and improve cardiopulmonary fitness. Therefore, such activities or EXs, if carried out in or near the patient's home or community, would offer an alternative for in-hospital rehabilitation for burn victims. There are no studies currently published in patients with severe burns in reference to a community-based exercise program, however, there are numerous studies in other populations which have reported beneficial effects of such programs [6-10].

The objective of this study was to compare in children the efficacy of a 12-week community-based exercise program (COMBEX) relative to "in-hospital" EX program in improving lean mass, muscle strength, and aerobic capacity. There are no studies currently published in patients with severe burns in reference to a community-based exercise program,

however, there are numerous studies in other populations which have reported beneficial effects of such programs. Obtaining evidence that progressive resistive exercise and aerobic exercise offered through COMBEX provides superior or equivalent benefits to that offered by EX (the current standard of care) could lead to a much needed rehabilitation treatment alternative that allows for continued exercise rehabilitation without the obstacles that exist with “in-hospital”, outpatient EXs.

METHODS

This prospective, randomized study, with an intended allocation of 1:1, was conducted according to a study protocol approved by the Institutional Review Board (IRB) at the University of Texas Medical Branch (Galveston, Texas). Legal guardians agreed to their child’s study participation by signing an informed consent form approved by the IRB. Children older than 7 years of age agreed to study participation by signing an IRB-approved assent. After consent/assent was obtained by the clinical research staff, children were randomized to EX (N=23) or COMBEX (N=23) in sequentially numbered, alternating containers (EX versus COMBEX). A total of 34 children aged ≥ 7 to < 18 years and with burns covering $\geq 30\%$ of their TBSA completed this study. Children in both groups received standard burn care and comparable treatments from emergency admission until acute care and hospital discharge. Three primary variables were assessed in this study: lean mass, muscle strength, and cardiopulmonary fitness (VO_2 peak). Assessments were made at hospital discharge and at completion of the 12-week COMBEX and EX.

Lean Body Mass

Dual energy X-ray absorptiometry (Hologic Inc., Bedford, MA) was performed while patients were supine. Total lean mass was expressed in kilograms of body weight and corrected for height. The methodology used is detailed in previous studies by our group [3, 11].

Muscle Strength

Peak torque was measured using an isokinetic dynamometer (Biodex System 3, Shirley, NY). Peak torque is the highest muscular force output and is similar to a one repetition maximum effort in an isokinetic contraction (Biodex Advantage Software Operations Manual. Shirley, NY, 2001). Dominant leg extensors were tested at 150 degrees per second while patients were seated and secured in this position with a strap fastened over the midthigh and pelvis. Dominant leg was determined by asking patient which leg was used when kicking a ball, as well as having patient simulate the act of kicking a ball. Patients were told what to expect throughout testing and were then allowed to complete one practice session of 10 repetitions at a speed of 150 degrees per second. After the practice session, the patient underwent testing by performing 10 repetitions at 150 degrees per second at a maximal volitional effort. Verbal encouragement was given throughout the test in an attempt to elicit a maximal volitional effort. Similar wording was used for encouragement in all patients.

Cardiopulmonary Fitness

Patients underwent maximal exercise testing according to a modified Bruce protocol [12]. The test consisted of changing the incline and/or speed every 3 minutes, with the incline being started at an angle of zero and the speed being started at 1.7 miles/hour [12]. Exercise intensity was progressively increased (i.e., a graded exercise test) and lasted until the patient could not maintain the required workload (volitional fatigue). A Respiratory Quotient exceeding 1.10 and a

Borg's Rated Perceived Exertion level (RPE; CR-10) of 9-10 also served as indicators that a maximal or peak value had been attained [3, 5]. Heart rate and VO₂ peak (mL O₂ consumed/kg body weight/minute) were measured and analyzed as described elsewhere [12]. We used VO₂ peak and peak heart rate to guide the intensity of training of aerobic exercise in the COMBEX and EX programs.

Exercise Program (EX) Group

After discharge, patients were housed at a hotel or home within or near the hospital. Housing accommodations were provided for burned children and families by the hospital. Children remained as outpatients, living in these facilities for 12 weeks before they returned to their permanent homes or place of living. Throughout these 12 weeks, patients visited the hospital daily (on weekdays) for clinical appointments (tub room, medical management, occupational therapy management, physical therapy management) and for the supervised EX sessions. Physical Therapy and Occupational Therapy daily sessions are both Standard of Care for all burn patients at our hospital, thus the EX group received approximately one hour to two hours per day, 5 days per week of PT/OT. Once the EX ended, patients were given a prescription with instructions for physical and occupational therapy to be done at home. The instructions included information on positioning and splinting, range of motion exercises, strengthening, and scar management [13].

EX training consisted of 12 weeks of in-hospital progressive resistive and aerobic exercise. Training consisted of cardiovascular workouts adhering to American College of Sports Medicine (ACSM) training guidelines [14]. The aerobic workout has been previously described by our group [3, 5, 15].

The aerobic training protocol consisted of a warm-up phase, the actual exercise training phase, and a cool-down phase. The duration of the exercise training phase ranged from 20 to 40 minutes as tolerated. Physical activity was performed using a treadmill, cycle ergometer, rowing machine, or elliptical. The warm-up phase lasted 5 minutes with an activity that yielded an RPE of 4 or lower (reflective of a mild to light effort). Thereafter, patients exercised for at least 20 minutes at a workload eliciting 60% to 85% of peak heart rate (obtained during the peak exercise treadmill test) and an RPE of 6 to 8 (Borg Scale of 1-10, reflective of a somewhat hard to hard effort). Finally, the exercise intensity was decreased so that the RPE was less than 4 and continued for 5 minutes. The aerobic sessions were done 5 days a week and were supervised by an ACSM-certified personal trainer.

Resistance training was performed 3 days a week. Activities consisted of the following seven exercises: bench press, biceps curls, triceps curls, lateral pull down, knee extension exercises, hamstring curls, and abdominal curls. Three sets of eight to fifteen repetitions were done of each exercise with the exception of abdominal curls, which were done to tolerance.

Community-Based Exercise Program (COMBEX)

Children in the COMBEX group underwent what is typical or current standard of care in the physical rehabilitation of burn patients; that is, they were discharged with prescribed written activities involving physical therapy and occupational therapy [4, 13]. Unlike the EX group, children in the COMBEX group did not receive the 12 weeks of exercise, tub room, occupational therapy management, and physical therapy management at our hospital. Children in the COMBEX were not given orders to receive medical management related to their burns during exercise training. The COMBEX group received SOC as prescribed to them by our hospital PT/OT Department, and were instructed to do this at home daily. However, if they needed and

had access (insurance, affordability, or access), they were free to seek and receive burn-related medical management, but not as part of SOC guidelines. In addition, children in the COMBEX group were discharged with arrangements for 12-week exercise training program in a community-based exercise facility. These arrangements included a 3-month gym membership and 36 sessions with a personal trainer. The COMBEX participants exercised at least three times a week under the supervision and guidance of a personal trainer.

A prescription for aerobic and resistive exercise was given to the personal trainer at the gym. The prescription provided a recommendation that three days per week of aerobic exercise sessions consist of a warm-up phase, an exercise training phase, and a cool-down phase, with exercise being performed on a treadmill, a cycle ergometer, a rower, or an elliptical. Exercise was performed for 20-40 minutes per day at an intensity eliciting 60–85% of the patient's peak heart rate or an RPE of 6-8, similar to that of the EX group. The prescription also provided a directive for resistive exercise using variable resistance machines and free weights. Resistive exercise was to be performed 3 days a week for approximately 30 minutes of 3 sets of 8-15 repetitions (8-15 RM). Patients were not limited to exercising only with personal trainer and were allowed to go to the gym as desired within the 3-month membership.

A final attendance report prepared by the hospital exercise staff and the legal guardian/patient was completed during the post-intervention visit.

Statistical Analyses

For each subject in each group, the percent change in measured outcomes due to exercise was determined as $100 \times (\text{Post 12-week value} - \text{Pre 12-week value}) / \text{Pre 12-week value}$; we utilized the percentage change as a way of normalizing the outcomes to the patient's initial baseline condition. Outcomes included lean body mass normalized to height (kilograms of lean

body mass/height in meters²), muscle strength normalized to body weight (peak torque in Newton-meters/body weight in kilograms), peak aerobic capacity normalized to body weight (peak VO₂ in milliliters per kilogram of body weight per minute). Normality of the data was confirmed in both groups. Differences between the groups for the relative changes were analyzed with a two-sample t-test. Values are means $\pm$ SEM. Significance was set at a $p < 0.05$.

RESULTS

Physical characteristics such as age, height, TBSA burned, and TBSA with third-degree burns, as well as LOS were similar in both groups ($p > 0.05$; Table 1). In addition, Figure 1 shows participant flow (consort diagram) for the study. A total of 46 children were randomized to EX or COMBEX, with fewer children included in the COMBEX arm for data analyses due to five children deciding not to participate after giving consent, and six children not being compliant with assessment schedule. Therefore, a total of 12 children in the COMBEX group were analyzed compared to 22 children in the EX group. The length of hospitalization (inpatient) was 30.0 ± 3.6 days in the EX group and 23.8 ± 4.5 days in the COMBEX group ($p = 0.31$). Compliance for patients in the EX group was $87.0 \pm 7.9\%$ (range, 88%-100%); which reflected an average of 52 days of attendance (range 43 to 60 days) of a possible maximal total of 60 days for a frequency of training of 5 days per week. Self-reported compliance for patients in the COMBEX group was $73.0 \pm 12.3\%$ (range, 61%-100%); which reflected an average of 26 days of attendance (range 22 to 36 days) of a possible maximal total of 36 days for a frequency of training of 3 days per week.

Body weight, lean body mass, muscle strength, and cardiorespiratory fitness measured before and after intervention are presented in Table 2. The percent changes in subject's outcomes

were normally distributed over the sampled range. Between group comparison showed significant and similar improvements in lean mass, muscle strength, and VO₂ peak (Figure 2). After 12 weeks of exercise, the increase in lean body mass improved $6.9 \pm 1.7\%$ in the EX group and $6.5 \pm 1.1\%$ in the COMBEX group. The relative improvements in lean body mass were similar between groups ($p = 0.87$). Similarly, leg extension strength (EX: $67.1 \pm 7.0\%$; vs. COMBEX: $49.9 \pm 6.8\%$) and VO₂ peak increased (EX: $35.5 \pm 4.0\%$; vs. COMBEX: $46.9 \pm 7.7\%$) after exercise training, however, no significant differences were detected between the groups in the magnitude of these increases ($P > 0.12$).

DISCUSSION

The results from this study support previous studies showing that in-hospital, outpatient EXs are beneficial to burned children [3-5, 15]. Moreover, they show that EX and COMBEX are efficacious, with these exercise training programs providing similar improvements in lean mass, muscle strength, and cardiopulmonary capacity. In previous studies, we have conclusively shown that burned children who do not undergo 12 weeks of exercise training show non-significant improvements in lean mass, muscle strength and peak VO₂ [3, 5, 15]. For this reason, our hospital has adopted exercise as standard of care, and we offer exercise rehabilitation to all patients aged 7 years and older. The present findings are consistent with the hypothesis that EX, as well as COMBEX, produces better outcomes than those seen in non-exercising burned children [14, 15].

It is important to note that although the two programs were different in terms of frequency and duration of exercise sessions, these differences did not prevent beneficial effects of COMBEX. Aerobic exercise was carried out 5 days every week in the EX group and 3 days every week in the COMBEX group (resistance exercise was performed 3 days every week for

both). It would have been ideal to have the both groups participate with equal frequency. However, the selected frequency for the COMBEX group was selected to aid compliance so that the program would more feasible for parents and children. As COMBEX did confer benefits to these burned children, we are confident that this approach is a viable, effective, and feasible program for both children and parents.

Another difference between the EX and COMBEX groups was the experience that personal exercise trainers had with burned individuals. Clearly, the hospital-based trainers had more experience working with burned patients. These trainers assess each situation individually and carefully consider the patient's goals. They create a customized and unique EX (following American College of Sports Medicine guidelines), enabling them to improve each patient's fitness level and range of motion. In contrast, the trainers employed in the COMBEX limb were unlikely to have the same level of experience with burned patients. Nevertheless, we do not think that the level of expertise of the respective trainers affected the outcome of the project.

Our study demonstrated that structured aerobic exercise 3 days per week is as efficacious as structured aerobic exercise 5 days per week. Based on this finding, it seems that we could recommend that exercise programs for individuals with burn injury be not limited to three days per week, but can range from 3 to 5 days per week. Obviously, a future study could be completed where frequency of training other than 3 to 5 days per week is evaluated (i.e., 1 day per week). However, based on our results, the recommendation is to be physically active, and an exercise program of 3 to 5 days per week is beneficial. In addition, one must consider the practicality of going to the exercise facility 5 days per week, given the most probable busy schedule of work for the parents and school for the child. Parents of children in the EX group did not have to deal with going to their jobs and schooling was offered in the hospital.

One shortcoming of this study includes the possibility of type II error. That is, we cannot exclude the possibility that a difference was not detected between the EX and COMBEX programs because of a small sample size. However, even if the results of this study reflect non-statistical significant differences, they also reflect that both exercise training programs were physiologically beneficial, though each has inherent advantages and disadvantages.

Limitations

Our study does not include a group of non-exercising children. We have reported that non-exercising children with severe burns do not exhibit the significant improvements in lean mass, muscle strength, or cardiopulmonary fitness seen in those that do exercise [3, 5, 15]. Therefore, the benefits of exercise, coupled with our prior findings, make inclusion of a non-exercise control group inappropriate, unethical, and unacceptable.

Compliance in the EX group was documented by the hospital exercise staff. However, for the COMBEX group, a final self-report on attendance was obtained from the legal guardian/patient after the 12-week program had been completed. While all patients provided this self-report, attendance logs requested from the personal trainers or community-based gyms were for the most part not provided. We attempted to communicate with the personal trainers biweekly, but these communications mostly went unanswered. Thus, compliance for the COMBEX limb was essentially limited to a self-report at the end of the study. For this reason, future COMBEX studies or programs should include methods for improved level of communication and of periodic progress reports by the personal trainers.

Many study participants were taking research drugs as well as placebo. Nevertheless, both groups had patients receiving these drugs, and both groups were relatively equally matched in this regard. In the EX group, 13 patients received placebo, 4 received propranolol, 1 received

oxandrolone, 1 received metformin, and 3 received oxandrolone in combination with propranolol. In the COMBEX group, 4 patients received placebo, 3 received propranolol, 1 received oxandrolone, 1 received metformin, and 3 received oxandrolone in combination with propranolol. The finding that both groups benefited from each intervention suggests that a potent drug-exercise effect was not present and that the combination of exercise with other burn care research-related drugs is beneficial.

Finally, we note that there are limitations/challenges for both the EX program and the COMBEX program. Children in the EX program must live near the hospital and be away from home, work and school. The EX program is more costly, if you consider the burn-specialized staff that is required. On the other hand, children and families in the COMBEX program face the challenge of access to an appropriate exercise center, the variability in personal trainer skill level and the cost of gym membership, as well as the cost of a personal trainer. One major problem encountered in the COMBEX arm is that a greater number of children were unable or could not return to the hospital for final assessments. Thus, attention to compliance with evaluations or assessments is an area that will need attention for COMBEX programs to be beneficial or implementable. Fortunately, in this study access to an appropriate and interested exercise center was not a problem. It may be that implementation or merging of both EX and COMBEX programs will yield the most benefits and be a better strategy for the rehabilitation of burned children. That is, to implement EX for one month after hospital discharge, or until the child/parents are familiar with the exercise routine. Thereafter, the patient would then transition to COMBEX for two more months under a personal trainer; that is, if all other medical needs were met. Our results provide evidence that both programs are effective. Perhaps a “merge

model” or “transition model” as discussed above could be more appropriate, rather than a one versus the other model. However, this will need to be studied.

Conclusion

No adverse events were associated with activities related to EX or COMBEX. Both exercise interventions are viable and efficacious in improving lean mass, strength, and cardiopulmonary capacity. These programs should be implemented into standard burn care rehabilitation practices depending on each patient and their family situation.

Acknowledgements

The authors would like to acknowledge Dr. Tabatha Elliott, Ph.D., Clark R. Andersen, MS, Heather Suhey (Research Associate), and all clinical and scientific staff at Shriners Hospitals for Children—Galveston for their patient guidance, enthusiastic encouragement, and useful critiques in conducting this study. In addition, we thank Dr. Kasie Cole-Edwards for editing support.

This study is registered with ClinTrials.gov under the name “Assessment of the Treatment of Severely Burned with Anabolic Agents on Clinical Outcomes, Recovery and Rehabilitation” and has a ClinicalTrials.gov Identifier: NCT00675714.

This study was partially funded by grants from the following sources: NIH (P50-GM060388, R01-HD049471, R01-HD049471-08S1), NIDRR (H133A120091), Department of Defense/American Burn Association (W81XWH-09-2-0194), and Shriners Hospitals for Children (71006, 71008, 71009, 84080).

Authors’ contributions

Drs. Suman, Crandall, Wolf, and Herndon are responsible for conception and design of the study; Drs. Pena and Ramirez with the help of the statistician Clark Andersen analyzed the data; all authors contributed to the interpretation of the results of the experiments. All authors were involved in drafting the manuscript; Drs. Pena, Ramirez, and Suman prepared the figures. Drs. Pena, Crandall, and revised the manuscript. All authors approved the final version of the manuscript.

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Figure Legends

Figure 1. Participant flow diagram (consort) showing the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome.

Figure 2. Mean ($\pm$ SEM) percentage change in lean body mass (LBM), peak torque normalized to bodyweight (PT/BW), and peak volume of oxygen consumption (VO_2) in the EX (exercise program) group (n=22) and COMBEX (community-based exercise program) group (n=12).

Table 1. Demographic and baseline characteristics.

Characteristic	Group		
	EX	COMBEX	P Value
N	22	12	
Gender distribution	17 male/5 female	10 male/2 female	
Age (yr)	14.0 $\pm$ 0.7	13.7 $\pm$ 1.0	0.80
Height (m)	1.53 $\pm$ 0.03	1.59 $\pm$ 0.04	0.78
TBSA burned (%)	55% $\pm$ 2%	52% $\pm$ 6%	0.58
TBSA burned, 3 rd -Degree (%)	37% $\pm$ 4%	29% $\pm$ 6%	0.23
LOS (days)	30.0 $\pm$ 3.6	23.8 $\pm$ 4.5	0.31

Values are mean $\pm$ SEM. TBSA (total body surface area), LOS (length of hospital stay), COMBEX (community-based exercise program), EX (exercise program).

Table 2. Normalized values of lean mass, strength, and cardiopulmonary capacity in EX and COMBEX patients.

	EX (n=22)		COMBEX (n=12)	
	Pre-Test	Post-Test	Pre-Test	Post-Test
Weight (kg)	46.8 ± 2.8	50.4 ± 3.2	56.3 ± 5.4	61.1 ± 6.3
Lean Body Mass (kg/m ²)	13.8 ± 0.27	14.7 ± 0.39	15.2 ± 0.78	16.2 ± 0.81
Peak torque/Body Weight (Nm/kg)	87.2 ± 5.9	141.0 ± 7.8	112.3 ± 14.1	159.3 ± 14.7
VO ₂ peak (ml/kg/min)	24.0 ± 1.0	32.2 ± 1.1	25.4 ± 2.0	36.3 ± 2.1

Values are mean ± SEM. COMBEX (community-based exercise program); EX (exercise program).