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TO COMPARE THE EFFECTIVENESS OF ADMINISTRATION OF ORAL ANABOLIC STEROIDS VERSUS CONVENTIONAL MANAGEMENT IN SECOND- AND THIRD-DEGREE BURNS: A PROSPECTIVE RANDOMIZED STUDY

Plastic Surgery

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ABSTRACT

Background : Second- and third-degree burn injuries with moderate total body surface area (TBSA) are associated with a sustained hypermetabolic and hypercatabolic response, leading to rapid loss of lean body mass, hypoalbuminemia, impaired wound healing, and prolonged hospitalization. Conventional burn management, including wound care and nutritional support, often fails to adequately counteract this metabolic derangement. Oxandrolone, an oral anabolic androgenic steroid with relatively low androgenic activity, has been proposed as an adjunct therapy to improve protein metabolism and preserve body mass in burn patients. **Objectives :** To compare the effectiveness of oral oxandrolone combined with conventional management versus conventional management alone in patients with second- and third-degree burns involving 10–50% TBSA, with respect to changes in body weight, serum albumin levels, total protein levels, and duration of hospital stay. **Methods :** This prospective, randomized comparative study was conducted at a tertiary care teaching hospital over a period of 24 months. A total of 42 patients with second- or third-degree burns involving 10–50% TBSA were enrolled and randomized into two groups. Group A (control) received conventional burn management, while Group B (test) received conventional management along with oral oxandrolone (10 mg twice daily for adults, with appropriate dose adjustments for age) administered for two weeks and tapered over one week. Baseline and follow-up assessments included body weight, serum albumin, and total protein levels, recorded at predefined intervals up to three weeks. Duration of hospital stay was also documented. Statistical analysis was performed using appropriate parametric and non-parametric tests, with a p-value <0.05 considered statistically significant.**Results :** Complete data were available for 39 patients (21 in the control group and 18 in the test group), who were included in the final analysis. The test group demonstrated significantly less weight loss compared to the control group from the first week onward. At three weeks, the mean percent weight change was $-0.94 \pm 3.2\%$ in the test group versus $-8.45 \pm 6.7\%$ in the control group ($p < 0.001$). Serum albumin and total protein levels at three weeks were significantly higher in the test group (3.65 ± 0.53 g/dL and 5.65 ± 0.92 g/dL, respectively) compared to the control group (2.83 ± 0.84 g/dL and 4.52 ± 0.71 g/dL; $p < 0.001$ for both). The mean duration of hospital stay was significantly shorter in the test group (10.94 ± 4.7 days) compared to the control group (15.85 ± 9.4 days; $p = 0.04$). Three patients in the test group required discontinuation of oxandrolone due to adverse events, including transient elevation of liver enzymes and persistent high-grade fever, raising concern of possible immunosuppression. **Conclusion :** The addition of oral oxandrolone to conventional burn management significantly improves weight preservation, maintains serum protein levels, and reduces duration of hospital stay in patients with second- and third-degree burns involving 10–50% TBSA. These findings support the role of oxandrolone as an effective adjunct in mitigating burn-induced hypercatabolism and enhancing clinical recovery. However, careful monitoring for potential adverse effects is essential during therapy.

KEYWORDS

Burns; Oxandrolone; Anabolic steroids; Hypercatabolism; Serum albumin; Total protein; Weight change; Hospital stay

INTRODUCTION

Burn injuries continue to represent a significant clinical and public health challenge, particularly in developing countries where the burden of morbidity, prolonged hospitalization, and resource constraints remains substantial. Second- and third-degree burns involving moderate to large total body surface area (TBSA) are not only associated with local tissue destruction but also with profound systemic metabolic disturbances [1]. Among these, the development of a sustained hypermetabolic and hypercatabolic state is one of the most critical determinants of patient outcomes.

The metabolic response to burn injury is characterized by markedly increased energy expenditure, accelerated protein breakdown, loss of lean body mass, and negative nitrogen balance. This response is mediated by elevated levels of catecholamines, cortisol, and pro-inflammatory cytokines, which collectively drive persistent catabolism [2]. In addition, increased capillary permeability and hepatic reprioritization of protein synthesis contribute to a decline in circulating proteins such as serum albumin and total protein. These changes result in muscle wasting, impaired wound healing, increased susceptibility to infections, and prolonged recovery, thereby significantly impacting morbidity and mortality [3].

Conventional burn management strategies, including early wound care, infection control, fluid resuscitation, and nutritional support, are essential components of treatment. However, despite optimal supportive care, these measures are often insufficient to fully counteract the intense and prolonged catabolic response observed in burn patients [4]. As a result, there has been increasing interest in pharmacological interventions aimed at modulating the metabolic response and improving clinical outcomes.

Anabolic agents have emerged as a promising therapeutic option in this context due to their ability to enhance protein synthesis, promote nitrogen retention, and preserve lean body mass [5]. Oxandrolone, a synthetic anabolic androgenic steroid derived from testosterone, has gained particular attention because of its high oral bioavailability and relatively low androgenic activity. It has been shown to improve net protein balance, attenuate muscle wasting, and support metabolic recovery in patients subjected to severe physiological stress, including burn injury [6].

Several clinical studies have reported that oxandrolone administration in burn patients is associated with improved weight maintenance, better preservation of serum protein levels, enhanced lean body mass, and reduced duration of hospital stay. These effects are especially relevant in patients with moderate to severe burns, in whom prolonged catabolism and nutritional depletion significantly influence recovery

and overall outcomes. However, despite growing evidence, the routine use of oxandrolone in burn management remains variable, particularly in resource-limited settings, where data on its effectiveness and safety are still evolving [7].

In this context, the present prospective randomized study was undertaken to compare the effectiveness of oral oxandrolone combined with conventional management versus conventional management alone in patients with second- and third-degree burns involving 10–50% TBSA. The study specifically aimed to evaluate changes in body weight, serum albumin levels, total protein levels, and duration of hospital stay, while also assessing the clinical utility and tolerability of oxandrolone as an adjunct in the metabolic management of burn patients.

MATERIALS AND METHODS

Study Design and Setting

This study was designed as a prospective, randomized, comparative clinical study conducted at JSS Hospital, Mysuru, over a period of 24 months. The objective was to compare the effectiveness of oral oxandrolone in addition to conventional burn management versus conventional management alone in patients with second- and third-degree burns involving 10–50% total body surface area (TBSA).

Study Population

Patients presenting with second- or third-degree burns involving 10–50% TBSA and fulfilling the eligibility criteria were screened for inclusion. Both adult and pediatric patients were considered as per the predefined protocol. Written informed consent was obtained from all participants or their legal guardians prior to enrollment.

Inclusion Criteria

1. Patients with second- or third-degree burns involving 10–50% TBSA.
2. Age greater than 1 year.
3. Patients willing to participate in the study and provide informed consent.

Exclusion Criteria

1. Patients with burns involving more than 50% TBSA.
2. Patients aged less than 1 year.
3. Pregnant women.
4. Patients with abnormal liver function tests or abnormal lipid profiles at baseline.
5. Patients with known contraindications to anabolic steroid therapy.

Sample Size Estimation

The sample size was calculated using the formula:

$$n = (Z\alpha + Z\beta)^2 \times \sigma^2 / d^2$$

Where $Z\alpha = 1.96$ for a 5% level of significance, $Z\beta = 0.84$ for 80% power, σ (standard deviation) = 4.9, and d (clinically significant difference) = 3. Based on this calculation, the estimated sample size was 42 patients. Accordingly, 42 patients were enrolled in the study.

Randomization and Group Allocation

Patients were randomized into two groups using computer-generated randomization:

- **Group A (Control group):** Received conventional burn management, including wound debridement, appropriate dressings, infection control measures, and nutritional support.
- **Group B (Test group):** Received conventional burn management along with oral oxandrolone.

Intervention Protocol

Patients in the test group received oral oxandrolone in addition to conventional treatment. The dosage regimen was as follows:

- Adults: 10 mg orally twice daily
- Elderly patients (>65 years): 5 mg twice daily
- Pediatric patients: 0.1 mg/kg/dose twice daily

Oxandrolone (above mentioned dose) was administered for two weeks and subsequently tapered over one week as per the study protocol. The control group did not receive oxandrolone.

Clinical and Laboratory Assessment

Baseline evaluation included detailed clinical examination and documentation of demographic data, extent and degree of burns, and nutritional status. TBSA was calculated using Wallace's rule of nine for adults and the Lund and Browder chart for children.

Baseline laboratory investigations included:

- Complete blood count
- Liver function tests
- Renal function tests
- Lipid profile
- Serum albumin
- Total protein

Follow-up assessments were performed at predefined intervals and included:

- Body weight measurement
- Serum albumin levels
- Total protein levels

These parameters were recorded at baseline, on post burn day 3, day 7 and subsequently weekly upto 3 weeks post burn after enrollment. Duration of hospital stay was calculated from admission to discharge.

Monitoring and Safety Assessment

Patients receiving oxandrolone were monitored clinically and biochemically during the study period. Liver function tests were periodically assessed to detect potential hepatotoxicity. Any adverse events, including abnormal laboratory parameters or clinical deterioration, were documented.

In cases of suspected drug-related adverse effects, oxandrolone therapy was discontinued based on clinical judgment. Patients who discontinued therapy were excluded from final analysis if complete follow-up data were not available.

Data Collection

All clinical and laboratory data were recorded in a predesigned proforma. The master chart was used to compile and organize the data systematically. Only patients with complete follow-up data were included in the final analysis, resulting in a total of 39 patients (21 in the control group and 18 in the test group; 3 patients discontinued in test group).

Statistical Analysis

Data were analyzed using SPSS version 28.0. Continuous variables were expressed as mean ± standard deviation, and categorical variables were expressed as frequencies and percentages.

Normality of data distribution was assessed using the Shapiro–Wilk test.

- Within-group comparisons were performed using paired t-test or Friedman test for non-parametric data.
- Between-group comparisons were carried out using independent t-test or Mann–Whitney U test as appropriate.
- Duration of hospital stay was analyzed using the Mann–Whitney U test.

A p-value of less than 0.05 was considered statistically significant.

RESULTS

Results Overview

A total of 42 patients were enrolled in the study, of whom complete follow-up data were available for 39 patients (21 in the control group and 18 in the test group). These patients were included in the final analysis. Both groups were comparable at baseline with respect to blood investigations as mentioned prior, ensuring validity of subsequent comparisons.

The analysis demonstrated a clear divergence in metabolic outcomes between the two groups. Patients receiving conventional management alone exhibited progressive weight loss and decline in serum protein parameters over the study period, reflecting ongoing hypercatabolism following burn injury. In contrast, patients receiving oxandrolone in addition to conventional therapy showed significantly better preservation of body weight and higher serum albumin and total protein levels.

The beneficial effects of oxandrolone became evident early, with statistically significant differences in weight change observed from the

first week onward. Biochemical parameters, including serum albumin and total protein, showed significant differences at three weeks. Additionally, the duration of hospital stay was significantly shorter in the test group, indicating improved clinical recovery.

Adverse Events and Drug Discontinuation

Among patients in the test group, oxandrolone therapy was discontinued in 3 cases due to adverse events. One patient developed a transient elevation in liver function tests during the first week of therapy. Two patients developed persistent high-grade fever, raising concern for possible immunosuppression, leading to discontinuation of the drug as a precautionary measure.

These patients were excluded from the final analysis due to incomplete follow-up data. No mortality was reported during the study period.

Table 1: Baseline biochemical characteristics of study participants

Table 1 shows that both groups were comparable at baseline with no statistically significant differences.

Parameter	Control group (n = 21)	Test group (n = 18)	p-value
Serum albumin (g/dL)	4.38 ± 0.54	4.12 ± 0.61	0.56
Total protein (g/dL)	6.49 ± 0.58	6.29 ± 0.81	0.85

Table 2: Mean percent weight change from baseline over time

Table 2 shows comparison of percent weight change between groups at different time points.

Time point	Control group (n = 21)	Test group (n = 18)	p-value
PBD 3	0.45 ± 2.1%	0.76 ± 1.8%	0.12
1 week	−4.25 ± 4.3%	−2.18 ± 3.1%	0.008
2 weeks	−7.65 ± 5.8%	−1.76 ± 3.0%	0.001
3 weeks	−8.45 ± 6.7%	−0.94 ± 3.2%	< 0.001

Table 2 shows a progressive decline in body weight in the control group from PBD 3 (0.45 ± 2.1%) to 3 weeks (−8.45 ± 6.7%), reflecting sustained hypercatabolism despite conventional management.

Table 2 demonstrates that the test group maintained relatively stable body weight, with minimal reduction from PBD 3 (0.76 ± 1.8%) to 3 weeks (−0.94 ± 3.2%), indicating effective attenuation of catabolic processes.

Table 3: Comparison of serum albumin levels between groups

Table 3 shows significant preservation of serum albumin in the test group at three weeks.

Time point	Control group (n = 21)	Test group (n = 18)	p-value
Baseline	4.38 ± 0.54	4.12 ± 0.61	0.56
3 weeks	2.83 ± 0.84	3.65 ± 0.53	< 0.001

Table 4: Comparison of total protein levels between groups

Table 6 shows better preservation of total protein levels in the test group.

Time point	Control group (n = 21)	Test group (n = 18)	p-value
Baseline	6.49 ± 0.58	6.29 ± 0.81	0.85
3 weeks	4.52 ± 0.71	5.65 ± 0.92	< 0.001

Table 5: Duration of hospital stay

Table 5 shows significantly shorter hospital stay in the test group.

Group	Mean ± SD (days)
Control (n = 21)	15.85 ± 9.4
Test (n = 18)	10.94 ± 4.7
p-value	0.04

Table 1 demonstrates that the control group (serum albumin 4.38 ± 0.54 g/dL; total protein 6.49 ± 0.58 g/dL) and test group (serum albumin 4.12 ± 0.61 g/dL; total protein 6.29 ± 0.81 g/dL) were comparable at baseline with no statistically significant difference (p = 0.56 and 0.85 respectively), confirming appropriate baseline matching.

Table 2 shows that at PBD 3, the difference in weight change between the control group (0.45 ± 2.1%) and test group (0.76 ± 1.8%) was not statistically significant (p = 0.12). However, from 1 week onward, the control group demonstrated significantly greater weight loss (−4.25 ± 4.3% vs −2.18 ± 3.1%; p = 0.008), which further widened at 2 weeks (−7.65 ± 5.8% vs −1.76 ± 3.0%; p = 0.001) and at 3 weeks (−8.45 ± 6.7% vs −0.94 ± 3.2%; p < 0.001), indicating a strong protective effect of oxandrolone against burn-induced catabolism.

Table 3 shows that while serum albumin levels were comparable at baseline (p = 0.56), a significant difference was observed at 3 weeks, with the control group declining to 2.83 ± 0.84 g/dL compared to 3.65 ± 0.53 g/dL in the test group (p < 0.001), suggesting better preservation of protein status with oxandrolone.

Table 4 demonstrates a similar trend for total protein levels, with baseline comparability (p = 0.85), but significant decline in the control group (4.52 ± 0.71 g/dL) compared to the test group (5.65 ± 0.92 g/dL) at 3 weeks (p < 0.001), reinforcing the anabolic and protein-sparing effects of oxandrolone.

Table 5 shows that the mean duration of hospital stay was significantly longer in the control group (15.85 ± 9.4 days) compared to the test group (10.94 ± 4.7 days), with statistical significance (p = 0.04), indicating faster clinical recovery in patients receiving oxandrolone.

Overall, the findings demonstrate that oxandrolone significantly attenuates weight loss, preserves serum protein levels, and reduces hospital stay, thereby improving both metabolic and clinical outcomes in burn patients.

INTERPRETATION

1. **Weight Change:** Patients in the test group receiving oxandrolone in addition to conventional management exhibited significantly less weight loss at 1 week, 2 weeks, and 3 weeks post-burn compared to the control group. The progressive divergence in weight trends between the two groups indicates that oxandrolone effectively attenuates the hypercatabolic response associated with burn injury. The near preservation of baseline body weight in the test group at three weeks suggests improved maintenance of lean body mass, which is critical for recovery, immune function, and overall clinical outcome.

2. **Serum Albumin and Total Protein:** The test group demonstrated significantly higher serum albumin and total protein levels at three weeks compared to the control group, despite comparable baseline values. This indicates better preservation of protein reserves and improved nitrogen balance in patients receiving oxandrolone. The decline observed in the control group reflects ongoing protein catabolism and metabolic stress, whereas the relatively stable levels in the test group highlight the anabolic and protein-sparing effects of oxandrolone in the post-burn period.

3. **Metabolic Response and Catabolic Attenuation:** The combined improvement in weight preservation and serum protein levels in the test group suggests that oxandrolone plays a key role in modulating the burn-induced hypermetabolic state. By enhancing protein synthesis and reducing proteolysis, oxandrolone contributes to improved metabolic stability. This effect is particularly important in moderate to severe burns, where prolonged catabolism significantly delays recovery and increases complication risk.

4. **Clinical Recovery and Hospital Stay:** The significantly shorter duration of hospital stay observed in the test group reflects faster overall clinical recovery. Although direct parameters of wound healing were not measured, hospital stay serves as a practical surrogate indicator, as discharge was based on satisfactory wound healing and clinical stability. The reduced length of hospitalization suggests that improved metabolic status translated into better clinical outcomes.

5. **Safety and Tolerability:** Oxandrolone was generally well tolerated; however, discontinuation in three patients due to elevated liver enzymes and persistent fever highlights the need for careful monitoring. These findings indicate that while oxandrolone is effective, its use should be accompanied by periodic clinical and biochemical surveillance to detect potential adverse effects early.

DISCUSSION

Burn injury induces a profound and sustained hypermetabolic and hypercatabolic response that leads to rapid loss of lean body mass, depletion of circulating proteins, and delayed clinical recovery [8]. The present prospective randomized study evaluated the effect of adding oral oxandrolone to conventional burn management in patients with second- and third-degree burns involving 10–50% TBSA. The findings demonstrate that oxandrolone provides significant metabolic and clinical

benefits, particularly in terms of weight preservation, maintenance of serum protein levels, and reduction in duration of hospital stay [9].

One of the most consistent and clinically relevant findings in this study was the significant attenuation of weight loss in patients receiving oxandrolone. Burn patients managed with conventional therapy alone showed a progressive decline in body weight over the study period, reflecting ongoing hypercatabolism. In contrast, patients receiving oxandrolone exhibited minimal weight loss, with near preservation of baseline body weight by the third week. This early and sustained divergence in weight trends indicates that oxandrolone effectively counteracts protein breakdown and muscle wasting associated with burn injury [10]. Preservation of lean body mass is crucial not only for physical recovery but also for maintaining immune competence and reducing the risk of complications in burn patients [11].

The beneficial effects of oxandrolone were further supported by biochemical parameters. Serum albumin and total protein levels, which are key indicators of nutritional and metabolic status, declined significantly in the control group, consistent with the known effects of burn-induced inflammation, increased vascular permeability, and hepatic reprioritization of protein synthesis. In contrast, these parameters were significantly better preserved in the oxandrolone group at three weeks, indicating improved nitrogen balance and reduced protein catabolism [12]. Maintenance of serum albumin is particularly important in burn patients, as hypoalbuminemia is associated with edema, impaired wound healing, increased susceptibility to infection, and higher morbidity [13].

An important clinical implication of these metabolic benefits was the significantly shorter duration of hospital stay observed in patients receiving oxandrolone. Although direct measures of wound healing were not included in this study, the reduced length of hospitalization suggests faster overall recovery and improved clinical progress. This finding is consistent with the concept that improved metabolic stability facilitates wound healing, reduces complications, and accelerates rehabilitation in burn patients [14].

The observed benefits of oxandrolone can be explained by its pharmacological action as an anabolic agent. Oxandrolone enhances protein synthesis, promotes nitrogen retention, and reduces muscle protein breakdown, thereby improving net protein balance in the body. It acts as a metabolic modulator rather than a direct wound-healing agent, creating a physiological environment that supports tissue repair and recovery. These mechanisms are consistent with previous experimental and clinical observations demonstrating improved lean body mass, enhanced metabolic efficiency, and favorable gene expression changes in burn patients treated with anabolic agents [15].

Despite these advantages, the study also highlights important considerations regarding safety. In the present study, oxandrolone therapy was discontinued in three patients due to adverse events, including transient elevation of liver enzymes and persistent febrile episodes. Although these events were limited and reversible, they underscore the need for careful patient selection and regular monitoring during therapy. Hepatic function surveillance is particularly important given the known potential of anabolic steroids to affect liver enzymes, even though oxandrolone is considered to have a relatively favorable safety profile compared to other agents.

From a practical perspective, the use of oxandrolone as an adjunct to conventional burn management appears especially valuable in resource-limited settings, where advanced nutritional and metabolic support strategies may not be readily available. Its oral route of administration, ease of use, and demonstrated metabolic benefits make it a feasible and effective option for improving outcomes in patients with moderate to severe burns.

However, certain limitations must be acknowledged. The sample size was relatively small, and complete data were available for 39 patients, which may limit the generalizability of the findings. The study also did not include direct objective measures of wound healing or long-term functional outcomes. Additionally, detailed biochemical monitoring of adverse effects was not incorporated as a primary endpoint. Future studies with larger sample sizes, extended follow-up, and inclusion of objective wound healing parameters and safety endpoints would provide a more comprehensive evaluation of the role of oxandrolone in burn care.

Overall, the present study reinforces the concept that pharmacological modulation of the metabolic response to burn injury can significantly improve clinical outcomes. The consistent improvements observed in weight preservation, serum protein levels, and duration of hospital stay support the incorporation of oxandrolone as an effective adjunct to conventional burn management in appropriately selected patients.

CONCLUSION

This prospective randomized study demonstrates that the addition of oral oxandrolone to conventional burn management provides significant metabolic and clinical benefits in patients with second- and third-degree burns involving 10–50% total body surface area. Patients receiving oxandrolone showed markedly reduced weight loss, better preservation of serum albumin and total protein levels, and a significantly shorter duration of hospital stay compared to those receiving conventional management alone.

These findings indicate that oxandrolone effectively attenuates the hypermetabolic and hypercatabolic response following burn injury, thereby helping to preserve lean body mass and maintain protein homeostasis during the critical recovery period. The improvement in metabolic parameters appears to translate into enhanced clinical recovery, as reflected by reduced hospitalization duration.

In clinical practice, particularly in resource-limited settings, oxandrolone represents a practical and effective adjunct to standard burn care. Its ease of administration and ability to improve metabolic stability make it a valuable therapeutic option in appropriately selected patients. However, its use should be accompanied by careful clinical and biochemical monitoring to ensure safety.

LIMITATIONS

The present study has certain limitations that should be considered while interpreting the findings. The sample size was relatively small, and complete follow-up data were available for only 39 patients, which may limit the generalizability of the results. Additionally, the study was conducted at a single center, which may not fully represent broader patient populations with varying clinical and nutritional profiles.

Direct objective parameters of wound healing were not assessed, and hospital stay was used as a surrogate indicator of clinical recovery. Long-term outcomes, including functional recovery and quality of life, were also not evaluated.

Although oxandrolone demonstrated clear metabolic benefits, three patients required discontinuation of therapy due to adverse events, including transient elevation of liver enzymes and persistent febrile episodes. Detailed biochemical monitoring of potential drug-related adverse effects was not included as a primary endpoint, which limits comprehensive assessment of the safety profile.

Future studies with larger sample sizes, multicentric design, longer follow-up duration, and inclusion of objective wound healing parameters and safety outcomes are required to further validate these findings and define the optimal role of oxandrolone in burn management.

Ethical Considerations

The study was conducted after obtaining approval from the Institutional Ethics Committee. Written informed consent was obtained from all participants or their legal guardians. Patient confidentiality was maintained throughout the study.

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This study did not receive any external funding and was conducted using institutional resources.

Conflict Of Interest

The authors declare no conflict of interest.

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