Multicenter Analysis of Standard of Care versus Oxandrolone versus Testosterone in burn hypermetaboliSm (MASCOTS): First Interim Analysis

Parker M. Hannan, BS[1], Aaron Hong, MD[2,3], Anastasiya Ivanko, MS[1], Denise M. Danos, PhD[2], Alexandra DeWitt Davis, PharmD, BCCCP[3], Gina L. DeFelice, MD, MPH[3,4], Jonathan E. Schoen, MD, MPH, FABA[2,3], Jeffrey Carter, MD, FABA[2,3], M. Victoria P. Miles, MD, EMT-P[2,3]

Affiliations: Louisiana State University Health Sciences Center- School of Medicine[1] and Department of Surgery[2], University Medical Center – New Orleans[3], Tulane University School of Medicine[4]

Introduction

- Patients with major burn injuries experience a hypermetabolic response leading to extensive immunosuppression, inflammation, and muscle wasting.[1-3]
- Oxandrolone has been used to combat these deleterious effects in severely burned patients, but the FDA revoked its approval in June 2023 at the request of the manufacturer.[4]
- Other anabolic supplements like testosterone and Human Growth Factor have shown promise in blunting the hypermetabolic response but have not been compared to alternatives like oxandrolone.
- Testosterone most closely mimics the effects of oxandrolone but has a significantly higher risk of side effects, concerns for safety in female patients, and limited prior research data.[3, 5]
- This study aims to compare outcomes in patients receiving oxandrolone, testosterone, or the standard of care (SOC).

Methods

- Multicenter, retrospective, and prospective study currently reviewing patients >18 years with >20% TBSA thermal burns from 6/2022 to 9/2025; 13 centers are represented in this interim analysis.
- Patients taking hormonal modulators and non-thermal injuries were excluded. The primary outcome was inpatient weight loss > 5kg.
- Propensity score-matching was conducted between patients treated with oxandrolone or testosterone and SOC, controlling for age, sex, BMI, burn size and depth, concomitant trauma, inhalation injury, and burn center.
- Inpatient weight loss in the matched cohort was compared using logistic regression.
- Analysis was conducted in 9/2025 by the primary site.

Results

Table 1: Patient characteristics

	Oxandrolone (n=199)	Testosterone (n=59)	Standard of care (n=269)	p-value
Age, years, median (range)	44 (18-89)	41 (19-90)	46 (18-90)	0.1970
Sex, % (n)				0.0001
Male	77.4 (154)	100.0 (59)	75.1 (202)	
Female	22.6 (45)		24.9 (67)	
Total burn surface area, median (range)	34 (20-93.5)	29 (20-95)	27 (20-92)	<.0001
Full thickness burn, % (n)	94.5 (188)	88.1 (52)	87.7 (236)	0.0427
Concomitant trauma, % (n)	13.6 (27)	13.6 (8)	11.5 (31)	0.7784
Inhalation Injury, % (n)	19.6 (39)	35.6 (21)	15.2 (41)	0.0015
Amputation, % (n)	11.1 (22)	10.2 (6)	5.2 (14)	0.0557
Mechanism of Injury				
Scald, % (n)	4.5 (9)	6.8 (4)	10.0 (27)	0.0812
Flame, % (n)	83.4 (166)	69.5 (41)	70.3 (189)	0.0028
Electrical, % (n)	2.5 (5)	11.9 (7)	3.0 (8)	0.0026
Contact, % (n)	0.5 (1)	5.1 (3)	5.6 (15)	0.0117
Chemical, % (n)		1.7 (1)		0.0188
Flash, % (n)	10.6 (21)	11.9 (7)	17.8 (48)	0.0714
Length of stay, days, median (range)	36 (1-323)	36 (5-145)	25 (1-232)	<.0001
Inpatient weight change, kg, median (range)	-4.1 (-55.5-59.1)	-2.4 (-26-16.2)	-0.3 (-37.5-42)	0.0002
Inpatient weight loss > 5kg, % (n)	46.7 (93)	37.3 (22)	26.8 (72)	<.0001

Figure 1: Total burn surface area and absolute inpatient weight loss among those treated and standard of care before and after propensity score matching.

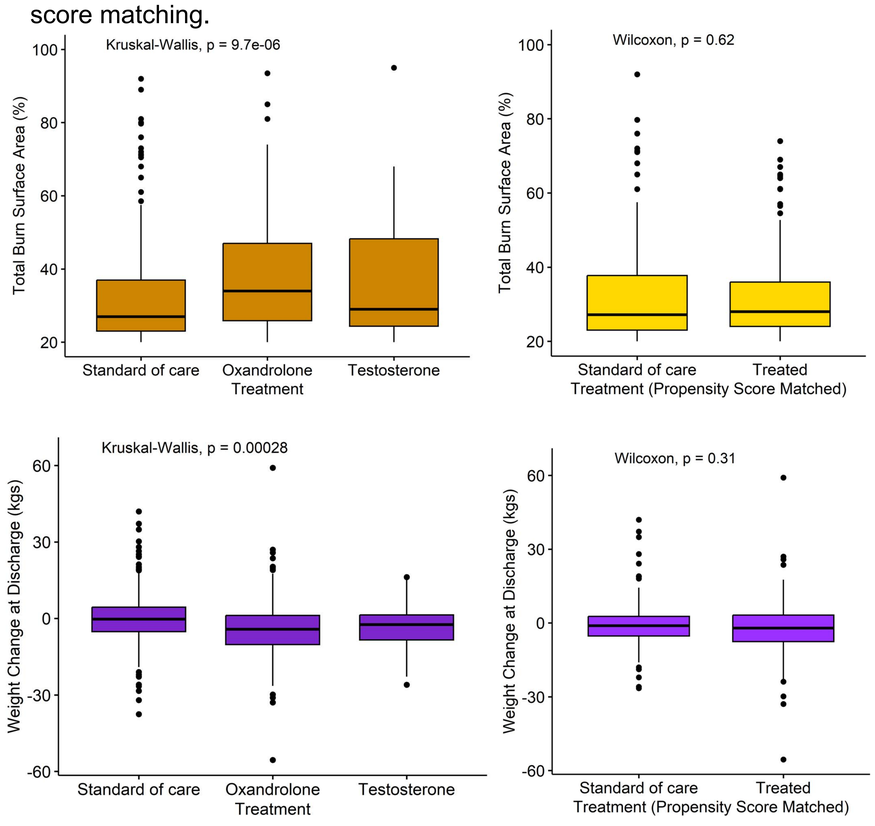
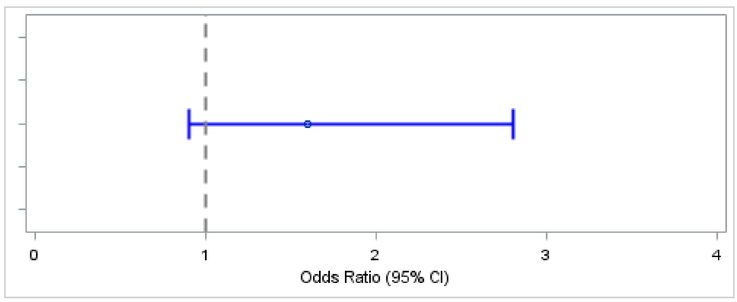


Figure 2: The odds of inpatient weight loss (>5kg) was not significantly different among treated compared to standard of care patients (110 treated : 110 control) [OR (95% CI) = 1.6 (0.9,2.8); p=0.1126].



- 527 patients met inclusion criteria, full-thickness burns were present in 90.3%, 19.2% had an inhalation injury, and 12.5% experienced concomitant trauma.
- Median length of stay was higher for patients in the anabolic treatment groups.
- Median absolute weight change from admission to discharge and the percentage of patients with weight loss >5kg were also higher for the anabolic treatment groups than the SOC group.
- TBSA was identified as a confounding variable.
- After propensity-score matching, no significant difference in the odds of inpatient weight loss was observed between groups.

Conclusions

- Unadjusted analyses suggested greater weight loss in treatment groups; this was not significant after controlling for injury severity and patient factors.
- This interim analysis highlights the importance of propensity score matching to minimize selection bias and improve data accuracy.
- As data collection continues, further analysis will explore the impact of anabolic agents on the hypermetabolic response and outcomes in burn patients.

Acknowledgments

We would like to thank the Spirit of Charity Foundation for funding this project. Additionally, we would like to thank the numerous clinical researchers, and site employees who collected data, and assisted in chart reviewing.

References

1. Herndon DN, Tompkins RG. Support of the metabolic response to burn injury. Lancet. 2004;363(9424):1895. PMID: 15183630
2. 2. Atiyeh BS, Gunn SW, Dibo SA. Metabolic implications of severe burn injuries and their management: a systematic review of the literature. World J Surg. 2008;32(8):1857. PMID: 18454355
3. 3. Gus EI, Shahrokhi S, Jeschke MG. Anabolic and anticatabolic agents used in burn care: what is known and what is yet to be learned. Burns. 2020;46(1):19–32.
4. Ferrando AA, Sheffield-Moore M, Wolf St, et al. Testosterone administration in severe burns ameliorates muscle catabolism. Crit Care Med. 2001;29(10):1936-1942.
5. Jeschke M. G. (2016). Postburn Hypermetabolism: Past, Present, and Future. Journal of burn care & research: official publication of the American Burn Association, 37(2), 86–96.