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Prototype Hybrid Systems for Neonatal Warming: In Vitro Comparisons to Standard of Care Devices

Terrence L. Hubert, BS,
is pursuing his PhD in the Department of Physiology at Temple University in Philadelphia, PA.

Rolf Lindemann, MD, PhD,
is a professor of pediatrics, neonatologist, and director of the Neonatal Care Unit at Ulleval University Hospital in Oslo, Norway.

Jichuan Wu, MD, PhD,
is a senior scientist and clinical neonatal and pediatric intensivist, working in pre-clinical studies at Temple University.

Catherine Agnew, BS,
is pursuing her degree as a physician's assistant at Arcadia University.

Thomas H. Shaffer, MSE, PhD, and
is a Temple professor of physiology and pediatrics, mechanical engineer, and physiologist

Marla R. Wolfson, MS, PhD
is a Temple professor of physiology, pediatrics, and medicine; physiologist; and developmental physical therapist. marla.wolfson@temple.edu

Abstract

Preterm infants lack necessary thermoregulation. An ideal incubator should maintain a uniform and constant thermal environment. We compared the effectiveness of a supplemental heating blanket to improve the heating characteristics of two different incubator warming devices using assessment of their respective function alone as controls. Device A and device B, with and without a heating blanket (Harvard Apparatus), were instrumented with a distribution matrix of multiple temperature ($n = 11$) and humidity probes. These data were serially measured during warm up to 37.5 °C and through a series of open-door perturbations. The time constant, temperature variation, and change in air temperature were calculated. Data were analyzed for significance by 2-factor ANOVA for each respective incubator either turned on or off with either the heating blanket turned on or off. Device A warms faster (33.87% ; $p < 0.05$) than device B, but has a greater (37.27% ; $p < 0.05$) temperature variation during warmup. The heating blanket enhances the thermal response of device A during warmup, but does not alter those of device B. With the side door open, device A shows a smaller (−16.5% ; $p < 0.05$) temperature variation than device B; the heating blanket attenuates the temperature change in both devices. These results demonstrate that the use of a supplemental heating blanket, as well as device-related differences, may impact clinical control of a thermal environment.

Introduction

Premature infants are born with an underdeveloped ability to produce and maintain their body heat.[1,2,3] With a large surface-area-to-volume ratio, low adipose tissue—among other deficiencies—they require supplemental heating. Radiant warmers,[1] incubators, radiant warmer/incubator hybrids,[4] and a heating mattress[5,6,7] are all used to combat heat loss.

The use of incubators for premature neonates was first developed in France in the 1880s[8] and highly publicized in the United States through public expositions.[2] Since then, incubators have evolved into modern devices with increased capabilities, such as heliox[9] and computerized environmental control. Despite the improvements in design and technology of incubators, opening a side access door or handports can lead to heat and humidity loss. The change in environment is potentially detrimental to the infant, but the rebound and potential overshooting of the temperature and humidity set point can also be harmful.

In this study, we assessed the impact of an experimental heating blanket used in conjunction with two incubator warming devices and evaluated this setup against the performance of each incubator warming device alone as control, through a series of comparable conditions including warm-up time and clinical perturbations. We hypothesized that use of the auxiliary heating blanket will augment the function of both incubator warming devices. We also hypothesized that device A will reach the set point faster and maintain a steady state environment more effectively than device B based on differences in heater output wattage between devices.

Methods

Instrumentation

We evaluated device A and device B with and without the Harvard Apparatus homoeothermic blanket system (HB). Device A has an air heater output of 500W with an approximate internal volume of $0.14m^3$ and bed surface area of $3152.5cm^2$. Device A has an access door opening of $1518cm^2$ and a handport opening of $345cm^2$; the ratio of air heater output to volume is $3571W/m^3$. Device B has an air heater output of 450W with an approximate internal volume of $0.12m^3$ and bed surface area of $3168cm^2$. Device B has an access door opening of $1794cm^2$ and a handport opening of $283\ cm^2$; the ratio of air heater output to volume is $3750W/m^3$.

Typically, incubators come equipped with two types of control modes: air and baby mode. Baby mode functions control the actual body temperature of an infant by raising or lowering the air temperature in the incubator. Air mode can also be used to control the body temperature of the baby, but requires a clinician to manually adjust and monitor the condition of the baby during this process of temperature control. This data was derived by operating the incubators in air mode at a fixed temperature setting. The homoeothermic blanket system was independently controlled with feedback from a servo-sensor that was secured in the same location as the incubator air servo-sensor to allow for a common set point. The blanket mattress system provided 50W of heating and was placed on top of the baby bed. No vents or ports were blocked by the addition of the blanket. The incubators and blanket systems have internal temperature servocontrol systems, accurate to within 0.10°C.

Environmental Monitoring Equipment

Two monitoring systems were used for these studies, one for temperature monitoring with sensitivity of ±0.10°C and one to monitor humidity with sensitivity of ±0.10 %. Accuracy of the devices was assessed by a two-point calibration method. Based on clinically relevant priorities and preliminary studies demonstrating minimal regional variation in humidity, we prioritized the study to focus on measuring regional temperatures over regional humidity. The Traceable Hygrometer Dewpoint recorder system (Control Company, Houston, TX) was used in conjunction with the C3 Data Acquisition System software package (Control Company) to record the reference temperature and humidity at 10 cm above the middle of the mattress. Additionally, as shown in Figure 1, a matrix configuration of temperature probes was designed and used to assess regional temperature. The matrix configuration

consisted of a total of ten probes, with the center probe at the midpoint of the baby bed and the other probes equal distant to the center, level with and 10 cm above the mattress. The Digisense system (Barnant Company, Barrington, IL) was used in conjunction with the Scanlink 2.0 software package (Microtest, Inc., Phoenix, AZ) to record the temperature matrix.

Design and Paradigm

These studies evaluated the warm-up time to the desired set temperature of 37.5°C and 65% relative humidity and ability of each device to maintain the desired settings. Specifically, we measured the length of time to attain steady state conditions for temperature and percent relative humidity (% RH), change in temperature and % RH, and temperature at the predetermined matrix points in each device (Figure 1). Repeated measurements (n = 6/ condition) were performed in each of the following six conditions: each respective incubator either turned on (“Incubator” ON) or off (“Incubator” OFF) with either the heating blanket turned on (HB ON) or off (HB OFF).

All experimental conditions were performed with a warm-up period sufficient to reach an air set point of 37.5°C; temperature and humidity profiles were then measured during a series of perturbations (e.g. hand port opened, access door opened). For device A, the double wall panel was used throughout the study. The boost option of device B was used as suggested by the manufacturer and device B was always used in closed non-radiant warmer mode.

After the experiment, the data were imported into Excel (Microsoft Software Inc, Redmond, WA) for subsequent calculations. The air/humidity probe was used to calculate the: 1) temperature time constant assuming the system dynamics behaved as a first order system for a step-change in condition; 2) temperature change (Δ); 3) humidity change (Δ), and 4) % over/undershoot of set point. Additionally, to provide insight regarding regional temperature variation, the set point (37.5°C as the reference) along with the matrix of each of the 10 temperature probes was used to calculate the root mean square (RMS) percent as shown in the the equation below:

$$\mathrm{RMS}\ (\%)=\left[1/\mathrm{N}\sum_{\mathrm{i}=1}^{\mathrm{N}=10}\mathrm{sqrt}\left[(\mathrm{T_s}--\mathrm{T_i})^2\right]\right]^{*}100$$

T_s represents the air set point temperature, T_i represents individual matrix temperature values, N equals 10, and 1/N equals 0.10.

Statistical Analysis

Data were analyzed using 2-way analysis of variance, a standard statistical test for measuring the effects of two factors simultaneously, for incubator and blanket (Prism 5.0 - Graphpad Software, Inc., San Diego, CA), to determine differences between experimental conditions. Significance was accepted at $p < 0.05$, meaning that there is a probability of five percent or less that the difference between the means of the respective groups occurred by chance. Data is presented as the mean ± the standard error of the mean (SEM) for each respective group.

Results

The reference temperature and humidity data was derived by the respective sensors within the probe suspended from the center of the incubator, 10cm above the mattress. Between experiments, there were no external environmental variables. There was no difference in

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starting temperature between groups (20.99 ± 0.18°C). The Incubator OFF HB ON groups did not reach 37.5°C after 8 hours of warming; therefore, no further studies were performed with these groups.

From room temperature to a set temperature of 37.5°C the time constant of device A (17.65 ± 0.59 min) was less (−33.87% ; $p < 0.05$) than that of device B (26.69 ± 0.58 min) (Figure 2 A). The heating blanket decreased (−15 % ; $p < 0.05$) the time constant of device A and had no impact on device B time of warmup to 37.5°C. There was no difference in the time constant between devices (device A = 2.26 ± 0.08 min ; device B = 2.11 ± 0.15 min) when the handports or side access door were opened (Figure 2B and Figure 2C).

During warm up (Figure 3A), there was no difference in Δ temperature (16.03 ± 0.18°C) between devices; this value represents the summarized data for all devices. When the side access door was opened (Figure 3B), the Δ temperature in device A (2.90 ± 0.34°C) was smaller (−30.1% ; $p < 0.05$) than in device B (4.15 ± 0.31°C) There was no difference in Δ temperature between device A ON HB ON and device A ON HB OFF conditions. Compared to all other groups, device B ON HB ON had the smallest Δ temperature (2.16 ± 0.12°C) when the side door was opened (Figure 3B). When the handports were opened (Figure 3C), device B group had a smaller Δ temperature (−26.5% : $p < 0.05$) than device A. The addition of the heating blanket attenuated the Δ temperature in both devices (Figure 3C); this effect was greater ($p < 0.05$) in device A.

Figure 4 displays the temperature variation, expressed as RMS %. During the warm up (Figure 4A), device A (58.95 ± 5.44% RMS) had a greater ($p < 0.05$) variation than device B (21.97 ± 2.02% RMS). The addition of the heating blanket decreased (−45.99% ; $p < 0.05$) this variation in device A, but not in device B. The RMS % of device A with the heating blanket was not different than device B with or without the heating blanket. With the side access door open (Figure 4B), the RMS % in device A (167.20 ± 4.78% RMS) was smaller (−16.5 % ; $p < 0.05$) as compared to device B (200.27 ± 20.50% RMS); the heating blanket decreased the temperature variation in both devices to the same degree (device A: −35%; device B: −33%, respectively)., there was no difference between groups in temperature variation when the handports were opened.

Figure 5 displays the Δ % RH when the side door was opened (Figure 5A), and when the handports were opened (Figure 5B). When the side access door was opened, device A had a lower Δ %RH (−49.8%, $p < 0.05$) than device B; likewise, when the handports were opened, device A had a lower Δ % RH (−49.3 %, $p < 0.05$) than device B. In either incubator and when either opening conditions were tested, there was no difference in the Δ % RH as a function of the HB (ie. device A or device B ON plus HB ON and OFF groups (Figure 5A and 5B).

Figure 6 displays the results for the % over/undershoot of the set temperature during the warmup period. These responses were different ($p < 0.05$) between devices. Device A undershot the set temperature, of 37.5°C, by up to 0.5% (0.19°C) and device B overshot the set temperature by up to 4.3% (1.6°C). There was no difference in either group due to the addition of the heating blanket (device A % undershoot = 0.27 ± 0.04 % and device B % overshoot = 1.76 ± 0.48 %).

Discussion

In this study, we evaluated the thermal characteristics of an experimental hybrid concept of a heating pad and incubator warming system, using two different incubator warming devices. Between incubators, device A warms faster and maintains steady state humidity better then device B. It does not overshoot the temperature set point, like device B, and it has a smaller

temperature variation on open door perturbations. Initially this was believed to be because of the larger heater wattage in device A (500W) vs. device B (450 W) alone, despite the smaller ratio of heater wattage to volume between the units. As an additional mechanism, these results lead to the suggestion that device A may have a more effective air velocity and circumferential pattern supporting more efficient air mixing and faster warming. The hypothesized lower air velocity across the mattress and larger incubator volume might also explain the increased temperature variation in device A during the warmup period.

The use of a heating mattress or pad has been described previously[5,6] and there is currently an FDA approved product, the Inditherm system,[7] currently on the market. This product is only a warming mattress and does not offer a controlled humidified and heated environment. This study shows that the use of a heating pad with either device A or device B could offer advantages in the form of smaller changes in temperature and regional temperature variation due to clinical manipulations, while still providing a humidified environment.

Another note, maybe somewhat obvious, was that opening the side access doors versus the handports caused a greater change in temperature, humidity, and temperature variation. Using the handports versus opening the side door offers access while better maintaining a controlled environment. Therefore, it is suggested here that the least invasive method, if possible, to access a neonate should be used.

Overall, we demonstrated that the addition of the experimental heating blanket augmented the function of both incubator devices A and B. We also showed that device A outperforms device B through a variety of different tests and parameters. Development of the incubator plus heating blanket hybrid and comparison between incubators will be addressed further with an *in vivo* animal model in a forthcoming study.

Acknowledgments

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References

1. Bell EF, Weinstein MR, Oh W. Heat Balance in Premature Infants: Comparative Effects of Convectively Heated Incubator and Radiant Warmer, With and Without Plastic Heat Shield. Journal of Pediatrics. 1980; 96:460–465. [PubMed: 7359242]
2. Baker JP. The Incubator Controversy: Pediatricians and the Origins of Premature Infant Technology in the United States, 1890 to 1910. Pediatrics. 1991; 87:654–662. [PubMed: 2020510]
3. Chessex P, Blouet S, Vacher J. Environmental Temperature Control in Very Low Birth Weight Infants (Less Than 100 grams) Cared for in Double–walled Incubators. Journal of Pediatrics. 1988; 113:373–380. [PubMed: 3397804]
4. Greenspan JS, Cullen AB, Touch SM, Wolfson MR, Shaffer TH. Thermal Stability and Transition Studies With a Hybrid Warming Device for Neonates. Journal of Perinatology. 2001; 21:1–7.
5. Boo NY, Selvarani S. Effectiveness of a Simple Heated Water-filled Mattress for the Prevention and Treatment of Neonatal Hypothermia in the Labour Room. Singapore Journal of Medicine. 2005; 46:387–391.
6. Gray PH, Flenady V. Cot-nursing Versus Incubator Care for Preterm Infants. Cochrane Database Systematic Review. 2003:CD003062.
7. Inditherm Medical. [Accessed June 10, 2009] Cosytherm and CosyCrib Neonatal Warming System. Available at: www.inditherm.co.uk
8. Bethod, P. dissertation. La Couveuse et le Gavage a la Maternite de Paris.

9. Singhaus CJ, Touch SM, Greenspan JS, Wolfson MR, Shaffer TH. A Prototype Infant Incubator for Heliox Therapy. Biomedical Instrumentation & Technology. 2006; 40:150–163. [PubMed: 16649483]

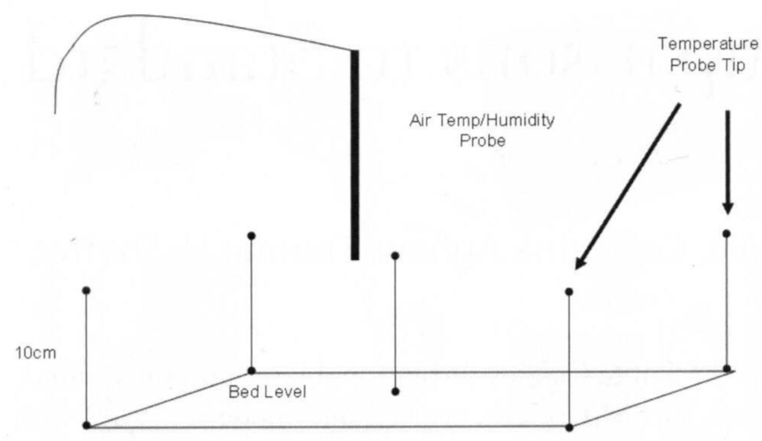

Figure 1.
Schematic of the reference air temperature probe and temperature probe matrix.

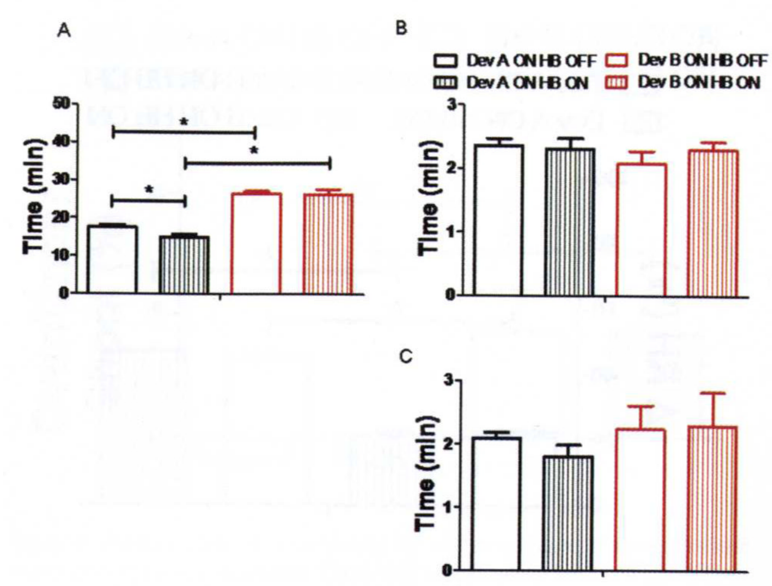

Figure 2.

(A) From room temperature to a set temperature of 37.5°C warmer device A showed a shorter ($p < 0.05$) time constant relative to warmer device B. The heating pad also decreased ($p < 0.05$) the time constant in the warmer device A during warmup. (B) There is no difference ($p < 0.05$) between groups when the side access door was opened. (C) There is no difference ($p < 0.05$) between groups when the handports were opened. (Mean ± SEM)

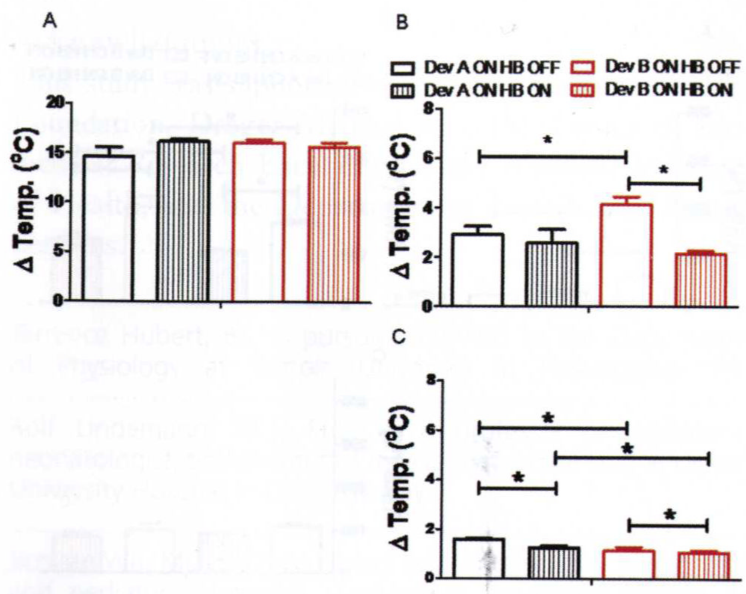

Figure 3.

(A) There is no difference ($p < 0.05$) in the Δ temperature between groups during warmup. (B) When the side access door was opened, warmer device A had a smaller Δ temperature than warmer device B; warmer device B with the heating blanket had the smallest Δ temperature, ($p < 0.05$). (C) When the handports were opened, warmer device B had a smaller ($p < 0.05$) Δ temperature than warmer device A. The addition of the heating blanket decreased the Δ temperature in warmer device A and B ($p < 0.05$). (Mean ± SEM)

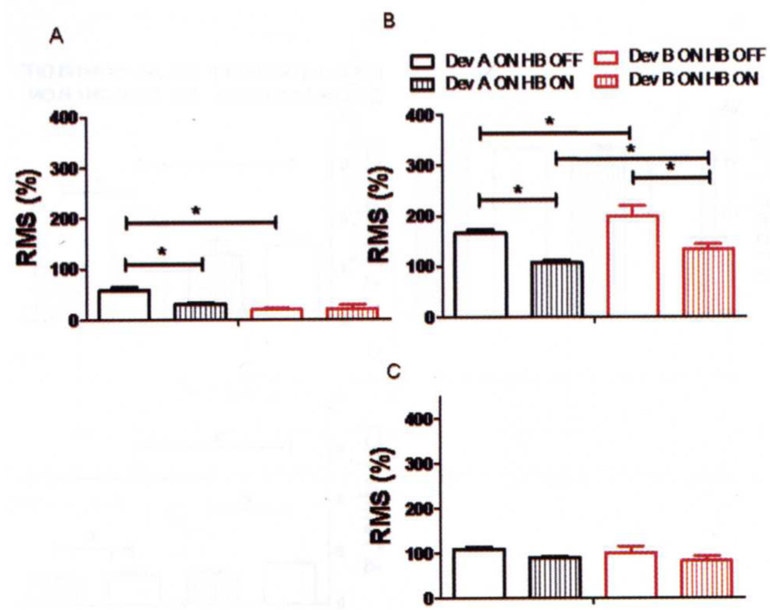

Figure 4.
(A) During warmup, warmer device A had the largest ($p < 0.05$) temperature variation, which was attenuated ($p < 0.05$) by the addition of the heating blanket. (B) With the side access door open, warmer device A had a lower ($p < 0.05$) temperature variation than warmer device B. The heating blanket decreased ($p < 0.05$) the variation for both units. (C) With the hand ports open, both units with and without the heating blanket had little temperature variation. (Mean ± SEM)

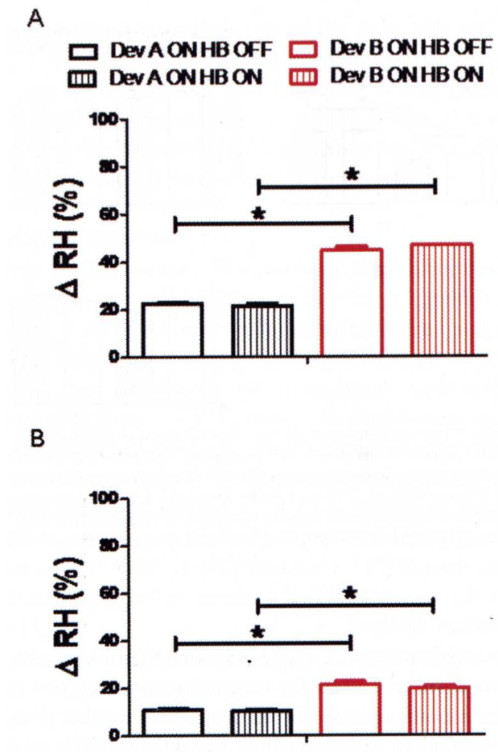

Figure 5.

(A) Warmer device A demonstrates a smaller ($p < 0.05$) Δ % relative humidity (Δ % RH) when the side access door is opened. (B) Warmer device A demonstrates a smaller ($p < 0.05$) Δ % RH when the handports are opened.

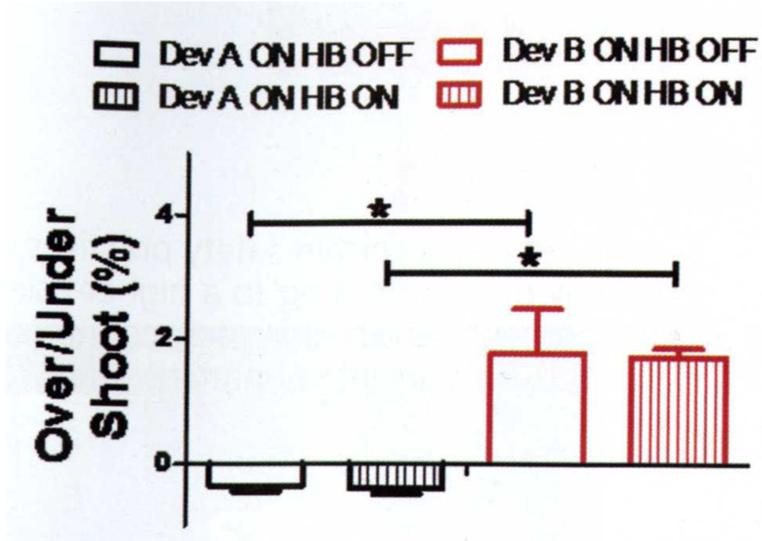

Figure 6.

Warmer device A undershoots the set temperature. Warmer device B overshoots the set temperature. There was no difference between respective Incubator ON HB OFF and Incubator ON HB ON groups ($p < 0.05$). (Mean ± SEM)