New ideas - Coronary

Evaluation of a new temperature management system during off-pump coronary artery bypass∗

Thomas A. Vassiliades Jr*, James L. Nielsen, James L. Lonquist

Pensacola Heart Institute, Pensacola, FL, USA

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Abstract

Objective: We evaluated the performance of a new temperature management system (Arctic Sun™, Medivance, Inc.) in maintaining normothermia during off-pump coronary artery bypass (OPCAB). Patients and methods: Ninety-eight unselected patients were prospectively randomized to either a conventional temperature management method (consisting of a sterile forced-air warming blanket, warm intravenous fluids, and maintenance of a warm OR) or the new Arctic Sun system (two pads, Arctic Sun Energy Transfer Pads™ placed on the patient’s back with temperature-controlled water flowing through the pads). Results: The mean age, body surface area, and total operating time were similar in both groups. Despite significantly lower room temperatures \( p < 0.001 \) in the Arctic Sun group, the system maintained higher bladder and nasopharyngeal temperatures \( p < 0.001 \) and \( p < 0.001 \), respectively. A core temperature of at least 36\(^\circ\)C was achieved in 97% of the Arctic Sun patients compared with 42% in the conventional group. Additionally, intra-operative blood loss for the Arctic Sun patients was significantly less \( p = 0.01 \). Conclusions: The Arctic Sun system significantly outperformed conventional techniques in achieving and maintaining normothermia during off-pump coronary artery bypass.

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1. Introduction

Hypothermia in the cardiac surgical patient during the early post-operative recovery period has been demonstrated to prolong the time of extubation, contribute to coagulopathy, increase cardiac demand [1–3] and has been associated with adverse outcomes [4,5]. In the case of the patient undergoing off-pump coronary artery bypass (OPCAB) grafting, the open chest exposed to room air temperature may cause a further decrease in core body temperature. This study compares the results of achieving normothermia in using standard techniques currently employed in our OPCAB protocol versus a new temperature management system (Arctic Sun™, Medivance, Louisville, CO).

2. Patients and methods

Eligible patients included all patients undergoing elective OPCAB grafting. Patients were prospectively randomized to either conventional warming methods (conventional group) or the Arctic Sun™ temperature management system (Arctic Sun group). Patients in the conventional group were managed by warming the operating room temperature, infusing warm intravenous fluids, and applying a sterile lower body forced-air warming blanket. Subjects in the Arctic Sun group had their temperatures controlled by the Arctic Sun Temperature Management System™ (Medivance, Louisville, CO). The Arctic Sun temperature management system is comprised of Arctic Sun Energy Transfer Pads™ and a control module. The energy transfer pads are placed on the patient’s back while he/she is awake (Fig. 1). The energy transfer pads consist of a tri-layer construction. The outermost layer is insulated with molded fluid channels. The middle layer is a polymeric film that is laminated to the outer layer to seal the thin fluid channels. The inner layer is a biocompatible hydrogel that adheres to the patient’s skin on application and provides
intimate pad to skin contact for efficient heat transfer. Temperature-controlled water flows from the control module through the pads under negative pressure at a flow rate of approximately 1 l per min per pad resulting in heat exchange from the water to the patient. The transfer pads are single use for each patient and are approximately US$350 per case. Temperature set points are programmed in the control module allowing for precise cooling or warming of the patient. Energy transfer pads, designed to be placed on the legs, are also available but were not used in this study. No additional methods of warming, including a whole-body heating blanket, were used. At our institution, the use of reflective warming by whole-body warming blankets was replaced 3 years ago by the convective warming method of forced-air warmers. The room temperature was not increased but rather set at the beginning of the procedure as dictated by the comfort of the surgical team. Fluid warmers, water blankets, or forced-air warmers were not used. The Arctic Sun treatment was discontinued at the completion of surgery and the energy transfer pads were removed before the patient left the operating room. Bladder and nasopharyngeal temperatures were downloaded into a computer in both arms of the study.

The primary endpoint of this study was to determine whether the Arctic Sun system enabled patients undergoing OPCAB to achieve normothermia, defined as temperature greater than 36.0 °C, without the use of other measures, more quickly and reliably than patients receiving standard care. Standard patient outcome data were also recorded as secondary endpoints.

2.1. Statistical analysis

Continuous variables were analyzed using a Student’s t test or a Mann–Whitney rank sum test as appropriate. Categorical variables were analyzed using a chi-squared test or Fisher exact test as appropriate. Repeated measures were analyzed using repeated measures analysis of variance (ANOVA). If the ANOVA was significant (p < 0.05), then t tests were done at the individual time points using the Bonferroni correction for multiple testing.

3. Results

Four patients (two conventional and two Arctic Sun) were converted to cardiopulmonary bypass intra-operatively and withdrawn from the study. No significant differences in patient profiles were found between groups (Table 1). The distribution of incision types (sternotomy or thoracotomy) used to perform the OPCAB was similar in both groups. The mean room temperature for the conventional group was 24.3 °C ± 1.6 (75.8 °F ± 2.8) compared with 22.5 °C ± 1.6 (72.5 °F ± 2.8) for the Arctic Sun (p < 0.001). Patient nasopharyngeal/esophageal (NP/E) and bladder temperatures throughout the course of the procedure are plotted in Fig. 2(A, B). The NP/E temperature at the beginning of the procedure (time of intubation) was significantly higher in the Arctic Sun group (p = 0.003). This is due to the ability to place functioning pads on the patient before moving into the operating room. The total area under the curve and the time less than 36 °C for both NP/E and bladder temperatures were significantly less in the Arctic Sun group (all p < 0.001). The NP/E and bladder temperatures at the end of the procedure were significantly higher in the Arctic Sun group (p < 0.001 for both). Mean intra-operative shed blood (auto-transfusion volume plus lost blood) was 609.1 cm^3 ± 523.1 for the conventional patients and 802.8 cm^3 ± 548.9 for the Arctic Sun patients (p = 0.015). The pre-operative profiles of anti-thrombotic drugs and coagulation function were similar in both groups. There was no difference in intra-operative mean fluid requirements between groups. Mediastinal drainage recorded for 24 h was similar in both groups (p = 0.853).

<table>
<thead>
<tr>
<th>Variable</th>
<th>Arctic Sun (n = 41)</th>
<th>Conventional (n = 57)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td>64.3 ± 12.5</td>
<td>65.8 ± 9.8</td>
</tr>
<tr>
<td>Sex (% female)</td>
<td>14 (34.1)</td>
<td>16 (28.1)</td>
</tr>
<tr>
<td>Body surface area (M^2)</td>
<td>1.98 ± 0.23</td>
<td>2.00 ± 0.20</td>
</tr>
<tr>
<td>Hypertension</td>
<td>28 (68.3)</td>
<td>32 (56.1)</td>
</tr>
<tr>
<td>Peripheral vascular disease</td>
<td>10 (24.3)</td>
<td>15 (26.3)</td>
</tr>
<tr>
<td>Diabetes</td>
<td>12 (29.2)</td>
<td>19 (33.3)</td>
</tr>
<tr>
<td>Number of grafts</td>
<td>2.49 ± 1.05</td>
<td>2.51 ± 1.17</td>
</tr>
<tr>
<td>Surgical time (min)</td>
<td>181.8 ± 58.2</td>
<td>171.6 ± 48.3</td>
</tr>
<tr>
<td>Operating room time (min)</td>
<td>231.9 ± 57.4</td>
<td>217.0 ± 50.0</td>
</tr>
</tbody>
</table>

Numbers in parentheses indicate percentages. No significant differences were found between groups.
4. Comment

During cardiopulmonary bypass, a heat exchanger in the bypass circuit is used to actively cool at the onset of bypass, and then re-warmed prior to terminating bypass. However, in performing OPCAB procedures, there are no precise means of controlling the patient’s temperature. To minimize hypothermia, several methods to warm the patient are initiated simultaneously. The operating room temperature may be raised to temperatures over 70°F; warmed IV fluids may be infused; and external warming devices, such as forced-air warming blankets can be sterilized and then draped over the patient. Several issues exist with the current standards of care: (1) excessively warm room temperature creates an uncomfortable environment for the surgical team, (2) large volumes of warm fluids must be infused to obtain a significant effect, (3) forced-air warmers are bulky and may impact the surgical field; they tend to be inefficient and must be used for extended periods of time in the operating room, (4) none of these systems adequately control or manage temperature, which could lead to either overheating or, more often, inadequate warming.

The primary objective of this study was to evaluate the performance of a new temperature management system (Arctic Sun™, Medivance, Inc.) in achieving and maintaining normothermia (defined as 36.5–37 °C) during OPCAB. The patient profiles of the conventional patients and the Arctic Sun patients were similar as shown in Fig. 1. Characteristics that might influence heat exchange were also similar: body surface area, age, gender, and the presence of peripheral vascular disease. Despite a 1.8 °C lower mean room temperature in the Arctic Sun patients, the bladder and nasopharyngeal temperatures were consistently high throughout the entire operation. Normothermia was achieved at the end of the operation in nearly all of the Arctic Sun patients (97%) compared with only 40% of the conventional patients. The Arctic Sun system allows the energy transfer pads to be placed on the patient’s back before entering the relatively cold operating room. This would account for the higher starting core temperatures in the Arctic Sun patients compared to the conventional patients. A significant amount of heat is dissipated while the patient is exposed. Additionally, a greater level of efficiency is achieved by the transfer of heat using warmed water closely opposed to the patient’s skin, rather than with forced air. We found that conventional warming methods could only slow the inevitable descent of the patient’s core body temperature. Some OPCAB centers have employed a forced-air warmer to the patient’s head and neck area. We have not employed this technique because of the known neurological protective effects of hypothermia [6]. In evaluating the two methods of temperature management used during OPCAB, the previous standard of care falls short of achieving the characteristics of our ideal temperature management system. In contrast, the Arctic Sun system was able to maintain normothermia and even raise the patient’s core body temperature when necessary. Of added benefit is that the system is essentially invisible to the surgical team. The room temperature can be set at a comfortable level, the operative sites are not affected and the energy transfer pads are applied before the patient becomes significantly hypothermic. We used back pads so that the legs were not affected during saphenous vein harvesting. There was no significant difference in operative blood loss or post-operative mediastinal drainage between the two study groups. We did not specifically examine the cost effectiveness of this system. Previous studies have demonstrated economic benefit in maintaining normothermia [7]. Nonetheless, our findings demonstrate that our previous standard of care for maintaining normothermia during OPCAB performed poorly. The Arctic Sun temperature management system is user friendly, does not impact on the operating field and is more effective than conventional methods in achieving and maintaining normothermia during OPCAB surgery.

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References