Influence of body core temperature on blood loss and transfusion requirements during off-pump coronary artery bypass grafting: A comparison of 3 warming systems

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Background: The aim of this prospective randomized trial was to evaluate the efficacy of 3 intraoperative warming systems (Warm-Touch, Thermamed SmartCare OP system, and Allon 2001) on maintenance of normothermia and to investigate their effects on perioperative bleeding and transfusion requirements in patients undergoing off-pump coronary artery bypass grafting.

Methods: With institutional approval/patient informed consent, 90 patients presenting for elective multiple off-pump coronary artery bypass grafting were randomly assigned to 1 of the 3 warming systems. Active warming was started after the induction of anesthesia. Perioperative transfusion was based on international guidelines. Body core temperature was recorded every 30 minutes during operation. Perioperative blood loss, autotransfusion, and allogenic transfusions were recorded. Analysis of variance was performed with post hoc Scheffé tests and χ^2 tests.

Results: Normothermia could be sufficiently maintained during operation by the Allon 2001 only. Final body core temperature was 34.7°C ± 0.9°C (Warm-Touch), 35.6°C ± 0.8°C (Thermamed SmartCare OP), and 36.5°C ± 0.4°C (Allon 2001; $P < .001$, Warm-Touch vs Thermamed SmartCare OP, Warm-Touch vs Allon 2001, and Thermamed SmartCare OP vs Allon 2001). Perioperative blood loss was 2683 ± 1049 mL (Warm-Touch), 2300 ± 788 mL (Thermamed SmartCare OP), and 1497 ± 497 mL (Allon 2001; $P = .195$, Warm-Touch vs Thermamed SmartCare OP; $P < .001$, Warm-Touch vs Allon 2001; $P = .001$, Thermamed SmartCare OP vs Allon 2001). Transfusion requirements were 1097 ± 874 mL (Warm-Touch), 986 ± 744 mL (Thermamed SmartCare OP), and 431 ± 387 mL (Allon 2001; $P = .838$, Warm-Touch vs Thermamed SmartCare OP; $P = .003$, Warm-Touch vs Allon 2001; $P = .013$, Thermamed SmartCare OP vs Allon 2001). Free of allogenic transfusion were 15 (51.7%; Warm-Touch), 18 (60%; Thermamed SmartCare OP), and 24 (82.8%; Allon 2001) patients ($P = .037$).

Conclusions: The goal of normothermia during off-pump coronary artery bypass grafting was best achieved by the Allon system. With this concept, overall blood loss and transfusion requirements were reduced, hence indicating improved quality of perioperative care.

Perioperative disturbances of hemostasis resulting in increased perioperative bleeding and transfusion requirements are common complications in patients undergoing cardiac operations.[1] Use of cardiopulmonary bypass is a major risk factor.[2] With the resurgence of the off-pump technique for coronary artery bypass grafting (OPCABG), reduced perioperative bleeding and reduced use of blood products could be demonstrated.[3] However, according to our clinical experience, still a considerable number of patients had to be given transfusions. One important reason for this finding may be the development of severe perioperative hypothermia during

OPCABG, because hypothermia may impair coagulation pathways.[4-6] Different systems to control intraoperative hypothermia are available. Patients can be warmed with a convective air warming system[7] (Warm-Touch system; Mallinckrodt Inc, St Louis, Mo) by using a total body garment before OPCABG and a sterile lower body blanket until the end of the operation after the preparation of venous grafts. With resistive heating electric carbon-fiber blankets[8] (Thermamed SmartCare OP system; Medeqco, Bad Oeynhausen, Germany), the upper extremities can be completely covered and the neck, body trunk, and lower extremities can be partially covered for warming during OPCABG. Finally, a disposable circulating-water warming garment[9] (Allon 2001 system; MTRE Advanced Technologies Ltd, Or-Akiva Industrial Park, Israel) can be wrapped around the patient's body, covering the back and upper parts of the extremities. The aim of this prospective randomized trial was to evaluate the efficacy of the 3 intraoperative warming systems on maintenance of normothermia, their effects on perioperative bleeding, their associated transfusion requirements, and costs during OPCABG.

Patients and Methods

This study was performed with institutional approval and patient informed consent. Ninety patients were admitted to the study according to the following criteria: (1) elective multiple OPCABG, (2) preserved left ventricular function (ejection fraction >40%), (3) absence of platelet glycoprotein inhibitor therapy, (4) exclusion of preexisting coagulation disorders, (5) preoperative hematocrit 30% or higher, and (6) preoperative normothermia.

On the day before operation, after the routine preoperative visit, the patients were assigned to 1 of the 3 intraoperative warming systems by a computer-generated randomization list. According to this list, the allocated warming system was prepared for the following day by the personnel responsible for patient positioning. Upon arrival in the operating room, all patients were covered with warmed sheets. After the induction of anesthesia, the different warming devices were mounted, and active warming was started. The Warm-Touch and Thermamed systems were both set to 42°C; the Allon system was set to a 36.7°C body core temperature. Operating room temperature was maintained at 22.2°C ± 0.9°C. Body core temperature was recorded via rectal probe every 30 minutes during the operation and during the rewarming period in the intensive care unit. An intraoperative fluid warmer (Astotherm Plus; Cincinnati Sub-Zero Products Inc, Cincinnati, Ohio) set to 40°C was used for transfusions in all patients. Intraoperative standard heparin therapy was reversed with protamine at the end of the operation according to institutional standards. The perioperative transfusion policy was based on international guidelines.[10] The trigger for perioperative allogenic red blood cell transfusion was a hematocrit of 25% or less. In all patients, autotransfusion was performed (Continuous Auto Transfusion System; Fresenius AG, Bad Homburg, Germany) during the operation. Perioperative blood loss (assessed by cell-saving device suction and chest tube drainage), the amount of autotransfusion, and the number of blood product transfusions were recorded before transfer to the intensive care unit and 24 hours after the operation. Hematocrit values and coagulation profiles were recorded before, immediately after, and 24 hours after the operation. The durations of the operation, the rewarming period (to reach 36.7°C), and mechanical ventilation were noted in the postoperative period.

The primary outcome measures were body core temperature at the end of the operation and maximal variations of intraoperative body core temperature. The maximal intraoperative body core temperature decrease was calculated as the difference between the baseline and minimal core temperatures, and maximal increase was calculated as the difference between the last intraoperative and minimal core temperatures. Secondary outcome measures were perioperative blood loss and transfusion requirements.

Cost analysis was performed for the 3 regimens on the basis of list prices for the devices, disposable materials, and blood products (direct costs are in US dollars). Costs of maintenance (ie, repairs) or special conditions (ie, leasing contracts) were not included in the calculation. Repayment for the different devices was calculated for a 5-year period by extrapolating the results of this study to a case load of 300 off-pump cases per year and considering red blood cell transfusion requirements only.

Statistical analysis was performed with StatView 5.01 software (SAS Institute Inc, Cary, NC). Analysis of variance with post hoc Scheffé tests was performed for comparison of continuous data, and χ^2 tests were performed for comparison of nominal data. Unless otherwise stated, data are presented as mean ± SD.

Results

Thirty patients were allocated to each intraoperative temperature-management group. All patients had American Society of Anesthesiologists status III. Demographic and preoperative clinical data of the 90 patients are listed in Table 1. Preoperative acetylsalicylic acid medication until the day before operation was present in 86 patients (96%). Two to 6 aortocoronary anastomoses (median, 4) were performed in the study sample. The duration of operation did not differ between groups (Table 2). Two patients (2.2%) were excluded from the study protocol after randomization as a result of conversion to cardiopulmonary bypass during the operation.

The intraoperative course of body core temperature showed a significant difference among the 3 groups (Table 3). At the end of the intervention, patients were normothermic in the Allon group only. By contrast, mild and severe hypothermia were observed in the Thermamed and Warm-Touch groups, respectively. This resulted in a shortened rewarming time and reduced postoperative ventilation time for the Allon group compared with the other groups. The duration of the intensive care unit stay was not significantly different between groups (Table 2).

With normothermic perioperative blood loss, transfusion of scavenged red blood cells and overall red blood cell transfusions were reduced. The lowest total transfusion requirements of allogenic red blood cells were observed for the Allon group (Table 4). Free of allogenic transfusion were 24 patients (82.8%) in the Allon group, 18 patients

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TABLE 1. Patient characteristics

Variable	W	T	A
Age (y)	66.3 ± 10.9	64.4 ± 10.7	65.6 ± 11.8
Male sex, n (%)	25 (83)	24 (80)	23 (77)
BMI (kg/m^2)	27.8 ± 3.9	27.9 ± 3.1	27.5 ± 2.8
EF (%)	57.7 ± 12.5	59.5 ± 14.4	57.8 ± 13.1
EuroSCORE	5.6 ± 3.8	4.9 ± 2.8	5.6 ± 3.2
Diabetes mellitus type II, n (%)	10 (33)	8 (27)	8 (27)
PAOD, n (%)	3 (10)	2 (7)	1 (3)
Renal disease, n (%)	8 (27)	10 (33)	8 (27)

W, Warm-Touch, *T,* Thermamed; *A,* Allon; *BMI,* body mass index; *EF,* left ventricular ejection fraction; *PAOD,* peripheral arterial occlusive disease. Data are presented as mean ± SD unless otherwise noted.

TABLE 2. Procedure times

Variable	W (n = 29)	T (n = 30)	A (n = 29)	$P_{W\ vs\ T}$	$P_{W\ vs\ A}$	$P_{T\ vs\ A}$
Operation time (min)	232 ± 65	248 ± 46	249 ± 68	.423	.354	.991
Rewarming time (min)	288 ± 96	214 ± 104	82 ± 101	.034	<.001	<.001
Postoperative ventilation time (min)	701 ± 226	600 ± 226	470 ± 211	.943	.007	.018
Intensive care unit stay (d)	1.4 ± 0.7	1.5 ± 0.6	1.4 ± 0.6	.978	.996	.993

W, Warm-Touch; *T,* Thermamed; *A,* Allon. Data are presented as mean ± SD.

TABLE 3. Perioperative body core temperatures

Variable	W (n = 29)	T (n = 30)	A (n = 29)	$P_{W\ vs\ T}$	$P_{W\ vs\ A}$	$P_{T\ vs\ A}$
Body core temperatures (°C)						
Baseline	36.3 ± 0.3	36.1 ± 0.3	36.2 ± 0.3	.228	.699	.685
60 min after baseline	35.2 ± 0.5	35.4 ± 0.5	36.0 ± 0.6	.646	<.001	.001
90 min after baseline	35.0 ± 0.7	35.3 ± 0.6	36.1 ± 0.5	.189	<.001	<.001
120 min after baseline	34.8 ± 0.6	35.2 ± 0.8	36.2 ± 0.5	.011	<.001	<.001
End of operation	34.7 ± 0.9	35.6 ± 0.8	36.5 ± 0.4	<.001	<.001	<.001
Intraoperative temperature changes (°C)						
Maximal temperature decrease	−1.8 ± 0.7	−1.1 ± 0.5	−0.6 ± 0.4	<.001	<.001	.001
Maximal temperature increase	+0.2 ± 0.2	+0.4 ± 0.3	+1.0 ± 0.5	.068	<.001	<.001

W, Warm-Touch; *T,* Thermamed; *A,* Allon; *baseline,* induction of anesthesia; *end of operation,* before transfer to the intensive care unit. Data are presented as mean ± SD.

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(60.0%) in the Thermamed group, and 15 patients (51.7%) in the Warm-Touch group ($P = .037$). Perioperative administration of fresh frozen plasma was 410 ± 570 mL (range, 0-1800 mL) in the Warm-Touch group, 310 ± 449 mL (range, 0-1200 mL) in the Thermamed group, and 103 ± 181 mL (range, 0-600 mL) in the Allon group ($P = .682$, Warm-Touch vs Thermamed SmartCare OP; $P = .033$, Warm-Touch vs Allon 2001; $P = .206$, Thermamed SmartCare OP vs Allon 2001). Small amounts of platelets were transfused during the study period (Warm-Touch: 70 ± 170 mL; range, 0-600 mL; Thermamed SmartCare OP: 80 ± 156 mL; range, 0-600 mL; Allon 2001: 10 ± 56 mL; range, 0-300 mL; $P = .961$, Warm-Touch vs Thermamed SmartCare OP; $P = .258$, Warm-Touch vs Allon 2001; $P = .159$, Thermamed SmartCare OP vs Allon 2001). Hematocrit values and coagulation profiles before and after surgery and on the first postoperative day were comparable for the 3 groups (Table 5).

No burnings or decubitus were observed in this series of patients. Two major sternal infections resulting in re-exploration were recorded (1 case each in the Warm-Touch and Thermamed groups). One of these patients had diabetes, and the other was obese (body mass index, 37 kg/m^{-2}).

Acquisition costs and prices for disposables were higher for the Allon system (device, US$12,100; 1-way wrap, US$110) compared with the Thermamed system (device and reusable blankets, US$5650) and the Warm-Touch system (device, US$2160; 1-way garment, US$15). Cumulative transfusion costs with the most expensive system (the Allon system) were US$3548, compared with US$13,952

TABLE 4. Perioperative red blood cell transfusion requirements and blood loss

Variable	W (n = 29)	T (n = 30)	A (n = 29)	$P_{W\ vs\ T}$	$P_{W\ vs\ A}$	$P_{T\ vs\ A}$
Perioperative RBC transfusion (mL)	1097 ± 874	986 ± 744	431 ± 387	.838	.003	.013
Intraoperative scavenged RBC transfusion	588 ± 348	456 ± 210	276 ± 190	.168	<.001	.042
Perioperative allogenic RBC transfusion*	510 ± 631 (0–2400)	530 ± 689 (0–2100)	155 ± 285 (0–900)	.991	.055	.048
Intraoperative allogenic RBC transfusion	200 ± 328 (0–1200)	280 ± 406 (0–1200)	104 ± 224 (0–900)	.677	.572	.159
Postoperative allogenic RBC transfusion	310 ± 382 (0–1200)	250 ± 418 (0–1200)	50 ± 138 (0–600)	.788	.014	.076
Perioperative blood loss (mL)	2683 ± 1049	2300 ± 788	1497 ± 497	.195	<.001	.001
Intraoperative blood loss	1392 ± 687	1345 ± 634	928 ± 428	.954	.014	.031
Postoperative blood loss	1291 ± 778	955 ± 511	566 ± 243	.070	<.001	.029

W, Warm-Touch; *T,* Thermamed; *A,* Allon; *RBC,* red blood cells. Data are presented as mean ± SD (range).
*Patients free of transfusion: W, 15 (51.7%); T, 18 (60%); and A, 24 (82.8) ($P = .037$).

TABLE 5. Perioperative laboratory parameters

Variable	W (n = 29)	T (n = 30)	A (n = 29)	$P_{W\ vs\ T}$	$P_{W\ vs\ A}$	$P_{T\ vs\ A}$
Hematocrit (%)						
Baseline	39.7 ± 5.6	40.4 ± 5.8	38.6 ± 5.0	.743	.689	.267
ICU	28.6 ± 4.7	28.2 ± 3.7	28.3 ± 3.9	.889	.502	.739
1st postop d	29.2 ± 3.0	29.7 ± 3.9	29.6 ± 3.5	.995	.898	.855
INR						
Baseline	1.0 ± 0.1	1.0 ± 0.1	1.0 ± 0.2	.937	.905	.996
ICU	1.2 ± 0.2	1.2 ± 0.1	1.2 ± 0.3	.581	.624	.682
1st postop d	1.1 ± 0.1	1.1 ± 0.1	1.1 ± 0.1	.168	.193	.997
aPTT (s)						
Baseline	36.9 ± 4.9	37.3 ± 5.7	37.2 ± 10.2	.502	.445	.988
ICU	39.3 ± 8.3	40.1 ± 9.7	38.8 ± 11.1	.843	.826	.436
1st postop d	39.1 ± 5.7	38.8 ± 7.9	35.9 ± 4.1	.987	.363	.416
Platelets (10^9/L)						
Baseline	267 ± 117	269 ± 89	280 ± 52	.994	.863	.910
ICU	156 ± 79	142 ± 51	156 ± 61	.709	.999	.693
1st postop d	182 ± 62	167 ± 54	172 ± 42	.558	.769	.939
Fibrinogen (g/dL)						
Baseline	346 ± 112	319 ± 141	366 ± 180	.863	.942	.681
ICU	218 ± 80	228 ± 93	245 ± 104	.806	.322	.697
1st postop d	271 ± 65	294 ± 102	289 ± 74	.558	.769	.938

W, Warm-Touch; *T,* Thermamed; *A,* Allon; *baseline,* induction of anesthesia; *ICU,* intensive care unit after the operation; *1st postop d,* 24 hours after the operation; *INR,* international normalized ratio; *aPTT,* activated partial thromboplastin times. Data are presented as mean ± SD.

for the Thermamed system and US$18,654 for the Warm-Touch system. Therefore, the lowest costs for the study period could be obtained for the Thermamed system (Warm-Touch, US$21,252; Thermamed SmartCare OP, US$19,586; Allon 2001, US$20,000). Extrapolating costs for a 5-year period and considering only the expenses for the systems and the allogenic red blood cell transfusions, a temperature management regimen with the Allon system may be the least expensive (Warm-Touch, US$334,500; Thermamed SmartCare OP, US$296,250; Allon 2001, US$293,300).

Discussion

Comparing 3 different warming systems, this trial demonstrated that normothermia during OPCABG can best be achieved by a circulating-water garment (the Allon thermoregulation system). The 2 other systems failed, although studies have shown the efficacy of both the resistive heating electric blanket (the Thermamed system) and forced air warming (the Warm-Touch system) in the prevention of perioperative hypothermia.[7,8,11] Prolonged procedures (induction of anesthesia, positioning, shaving, and the surgical procedure), whole-body disinfection, and large areas of the

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body surface being exposed to the ambient temperature complicate the prevention of hypothermia during OPCABG compared with noncardiac operative interventions. The circulating-water garment best covered the upper extremities and the back of the body. With the electric blankets, roughly the same parts of the body could be wrapped, whereas the forced air warming blankets could be mounted to the lower part of the body only before and after harvesting of the venous grafts.

The main benefit of successful maintenance of intraoperative body core temperature was a reduced perioperative overall blood loss and a reduced total red blood cell transfusion requirement. A significant reduction of allogenic red blood cell transfusion volumes was observed only for the comparison of the Allon and the Thermamed groups. Sample size in this study may be the reason that we found a tendency for reduced allogenic red blood cell transfusion only in the Allon group compared with the Warm-Touch group. However, most importantly, the number of patients receiving allogenic blood products could be significantly decreased, hence reducing the risk of infection, transfusion reactions, and immunosuppression related to the administration of allogenic transfusions.[10,12]

Maintenance of intraoperative normothermia during cardiac operations with cardiopulmonary bypass with the support of the Allon system has been shown to be favorable in terms of reduced myocardial injury,[13] enhanced cardiac function, and increased hemodynamic stability.[14] These studies did not address the effects on hemostasis and transfusion. Some investigations comparing hypothermic and normothermic cardiopulmonary bypass results regarding transfusion requirements have shown conflicting results.[15-17] Performing OPCABG per se has been shown to significantly reduce transfusion of allogenic blood products.[3] The present data now indicate a further positive effect on bleeding and transfusion requirements if normal body core temperature can be maintained during OPCABG. This effect of perioperative normothermia has previously been reported for orthopedic[18] and visceral[19] surgical patients. Surgical bleeding and, thus, coagulation during hypothermia may be influenced by reduced clotting factor activity,[5] impaired platelet function,[4] and activated fibrinolysis.[6] Comparable prothrombin and activated partial thromboplastin times for different body core temperatures, as in this study, are not conflicting findings, because routine laboratory testing is performed at 37°C. Only temperature-adjusted performance of these temperature-sensitive tests may allow a correct assessment and reveal prolonged values.[20]

Today, improvement of patient outcomes at minimal cost is a primary goal for most clinicians. This goal can sometimes be achieved only by a relatively high initial capital expenditure. Conservative cost calculation for the different warming systems and transfusion management based on the study data gives reason to assume that improved patient management is possible at balanced expenses with the most expensive system. However, only direct costs were taken into account in our calculation. Indirect costs were not assessed: the cost effects of a reduced wound infection rate[21] and a significantly shortened postoperative rewarming and ventilation period, as demonstrated in this study, are difficult to determine. For instance, the duration of the postoperative ventilation period is biased by a variety of factors, and postoperative normothermia is only one prerequisite for successful endotracheal extubation. Finally, despite the favorable results of improved intraoperative temperature management, the risk of complications from the different warming systems should be considered.[22,23]

In conclusion, this prospective study evaluating the efficacy of 3 intraoperative warming systems during OPCABG demonstrates that the goal of normothermia was best achieved by the Allon system. With this system, perioperative blood loss and transfusion requirements were reduced, hence indicating improved quality of perioperative care.

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