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## Preventing Inadvertent Hypothermia in Patients Undergoing Major Spinal Surgery

*A Nonrandomized Controlled Study of Two Different Methods of Preoperative and Intraoperative Warming*

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1 ABSTRACT

2 **Purpose:** To evaluate if a Full Access Underbody blanket (FAU) used pre- and intraoperatively in patients  
3 undergoing major spinal surgery prevents hypothermia compared to current practice and to explore patients'  
4 experiences of comfort.

5 **Design:** A non-randomized controlled trial.

6 **Method:** Sixty patients were included, 30 in each group. Temperature was assessed at arrival, after connecting to  
7 the bladder catheter, at the start and end of surgery. In the FAU group, comfort was evaluated at arrival and after  
8 ten minutes of prewarming.

9 **Findings:** The risk of hypothermia at the start of surgery was significantly lower (Relative Risk (95% CI) of  
10 0.28; (0.13 to 0.59). Before prewarming, 77% felt comfortable, 20% cold and 3% hot. After prewarming 60%  
11 felt comfortable, 37% hot and 3% very hot.

12 **Conclusions:** Patients using FAU had a 72% lower risk of hypothermia at the start of the operation. Attention to  
13 thermal comfort during surgery is important.

14

15 **Keywords:**

16 Inadvertent hypothermia, prewarming, Forced Air warming (FAW), Thermal Comfort

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26 INTRODUCTION

27 Hypothermia is defined as a core temperature of  $< 36^{\circ}\text{C}$ .<sup>1</sup> Inadvertent hypothermia of only  $1^{\circ}\text{C}$  increases the  
28 intraoperative blood loss and the need for blood transfusions due to a reduced formation of a platelet plug and a  
29 reduced clot formation, leading to a combination of platelet and enzyme impairment increasing blood loss by  
30 about 20%.<sup>2,3</sup> Vasoconstriction occurs when the patient is mildly hypothermic and results in reduced oxygen  
31 perfusion, reduced systemic immune activation and reduced tissue healing and thus triples the infection rate.<sup>2,3,4</sup>  
32 Mild hypothermia is defined as a core body temperature between  $34^{\circ}\text{C}$  and  $36^{\circ}\text{C}$ .<sup>5,6</sup> Previous research has  
33 indicated that intraoperative hypothermia influences the risk of myocardial ischemia and triples the risk of  
34 morbid cardiac output.<sup>2</sup> Anesthetics inhibit thermoregulatory control and affect the vasoconstriction potentially  
35 causing inadvertent hypothermia and shivering.<sup>7</sup> Although hypothermia is used deliberately in some surgical  
36 procedures to preserve cells, hypothermia is associated with several adverse effects for patients ranging from  
37 thermal discomfort to increased morbidity and mortality.<sup>1</sup>

38  
39 Major spinal surgery tends to be lengthy with an increased risk of hypothermia. Patients operated for spinal  
40 deformities have an increased risk of hypothermia due to length of operation, degree of exposed skin surface and  
41 positioning.<sup>8</sup> This emphasizes that length of operation, exposed skin surface, positioning, incision length and  
42 theatre temperature are considered predictors of hypothermia.<sup>9,10,11</sup> Post-operatively, patients can experience  
43 physical discomfort due to hypothermia during surgery.<sup>2,3</sup> Years after their operation, patients identify the  
44 feeling of being cold as their worst hospital experience.<sup>2,3</sup> Being warm is a substantial factor that influences the  
45 patient's experience of care during surgery. A survey among nurse anesthetists on patients' major concerns  
46 showed that 71% of the nurses found that being cold was a comfort problem.<sup>12</sup> Physical comfort needs include  
47 physiologic mechanisms that are disrupted such as thermoregulation. Preemptive warming is one technical  
48 comfort measure that has shown effectiveness in reducing inadvertent hypothermia<sup>13</sup>, and at the same time  
49 increased the patient's thermal comfort<sup>14</sup>.

50

51 Prewarming is defined as warming of peripheral tissues or skin surface before anesthetic induction. <sup>1,15</sup> Forced  
52 air warming (FAW) prevents intraoperative hypothermia effectively and thermal comfort provided by FAW is  
53 superior to other warming methods. <sup>9,11</sup> Prewarming is effective in preventing redistribution hypothermia,  
54 especially one hour after induction of anesthesia. <sup>2,3,12</sup> It is not known whether the use of a Full Access  
55 Underbody (FAU) blanket can prevent hypothermia during major spinal surgery pre- and intraoperatively. For  
56 that reason, the aims of this study were to evaluate if a FAU blanket used pre- and intraoperatively can reduce  
57 the number of patients having inadvertent hypothermia when undergoing major spinal surgery, as compared to  
58 current practice, and to evaluate the thermal comfort of patients using the FAU blanket. The hypothesis is that  
59 the FAU blanket will decrease the risk of hypothermia <36°C and increase the patient's experience of thermal  
60 comfort.

61

## 62 METHODS

### 63 *Study design*

64 The study is a non-randomized controlled trial conforming to the TREND statement <sup>16</sup> for reporting non-  
65 randomized studies.

66

### 67 *Patients and recruitment*

68 The study included 60 patients undergoing major spinal surgery; in this study defined as spine deformity  
69 surgery. Inclusion criteria were Danish speaking in order to ensure patients understood questions related to their  
70 thermal comfort, and age  $\geq 14$  years in order to match the included patients in the former quality improvement  
71 project. A tympanic temperature < 38<sup>0</sup> C or >36<sup>0</sup> C. Patients were excluded if they weighed more than 115 kg  
72 (FAU has a 115 kg limit), had a preoperative temperature > 38 ° C or  $\leq 36$  ° C (Normothermia is defined as a  
73 core temperature range of 36<sup>0</sup> - 38<sup>0</sup> C), <sup>1</sup> or had cognitive impairment to such an extent that they were not capable  
74 of cooperating. Patients were included consecutively at the Clinic for Anesthesiology, Child Diseases,  
75 Circulation and Women, Aalborg University Hospital and divided into two groups of 30 patients depending on

76 time of inclusion. Patients for the control group were included as part of a quality improvement project in the  
77 period from September 2012 - February 2013. Patients for the intervention group were included from November  
78 2015 - October 2016. The time span between the two data collection periods was caused by lack of options of  
79 how we could prevent inadvertent hypothermia effectively in this group of patients. The acquisition of the FAU  
80 blanket challenged the current warming practice and gave ideas as to how the number of patients with  
81 inadvertent hypothermia might be reduced.

82

### 83 *Study treatments*

84 In the control group, patients were covered with a lint free quilt and a reflective blanket before entering the  
85 operating theatre. When the patient was placed on the operating table, the quilt and reflective blanket were  
86 placed on top of the patients' legs and arms so as not to interfere with the preoperative preparations consisting of  
87 positioning of the patient, x-rays, marking of the patients' back position and ending with the sterile draping. A  
88 Full Body Blanket with surgical access (FBBSA) (Bairhugger blanket model 570 - warming unit) and cotton  
89 blankets on the upper limbs were applied and FBBSA activated shortly before the start of the operation.

90

91 In the intervention group, the FAU blanket (Bairhugger blanket Model 635 – warming unit 775) was placed  
92 upon the patient under a lint free quilt before entering the operating theatre. In the operating theatre, the patient  
93 was asked to assess his or her thermal comfort. The FAU blanket was then connected to the warming unit and  
94 started at 43<sup>0</sup> C. Prior to induction of anesthesia, patients once again were asked to assess their thermal comfort.  
95 The FAU blanket was switched off and placed on the operating table before placing the patient on top of it in  
96 prone position. The FAU blanket was turned on and kept running throughout the remaining preoperative  
97 preparations only to be switched off momentarily while the sterile drapings were placed. In both the intervention  
98 and the control group, the temperature of the warming unit was adjusted either in accordance with the patient's  
99 statements of thermal comfort or alterations in the bladder temperature. In both groups, the temperature of the  
100 operating theatre was set at 20<sup>0</sup> C. This temperature is controlled and monitored by a central heating system and

101 is digitally visible in the operating theatre.

102

### 103 ***Data collection procedure***

104 The patients' tympanic temperature was measured. Anesthesia was induced and maintained with Propofol,  
105 Ultiva and Fentanyl and in some cases supplemented by a volatile anesthetic. The patient was intubated and  
106 ventilated mechanically. The patients in the control group continued with non-active warming since the FBBSA  
107 interfered with the preoperative procedures due to its placement on top of the patient. The patients in the  
108 intervention group had the FAU blanket placed beneath them; thus resuming active warming during the  
109 continuous preoperative procedures. According to current practice, all patients acquired a bladder catheter after  
110 the induction of anesthesia, thus avoiding the pain and discomfort associated with the insertion. Bladder  
111 temperature was measured and documented when the bladder catheter was connected to the monitor, at the start  
112 and end of the operation. In order to be able to alternate the temperature of the blankets, the bladder temperature  
113 was observed on the monitor and reacted upon, yet not documented with 15 minutes intervals throughout the  
114 operation and on arrival to the recovery room. Furthermore, the patient's thermal comfort was assessed when  
115 using the FAU blanket as active prewarming.

116

### 117 ***Measurements***

118 Preoperatively, demographic and morphometric characteristics were documented including age, gender, weight,  
119 ASA and tympanic temperature. Ear canal temperature (Braun Welch Allyn Thermoscan Pro 4000  $\pm$  0,2 ° C for  
120 the thermometer at 35.5 -42.0 ° C) <sup>17</sup> was measured upon arrival due to its unobtrusive nature and ease of  
121 management, <sup>18</sup> although it is considered inferior compared to other temperature sites. <sup>3,19,20</sup> The accuracy of this  
122 measurement was, however, of less importance since it was used to in- or exclude patients in the study. A Foley  
123 bladder catheter measured the bladder temperature with a temperature sensor (Smiths Medical level 1FC 400/  
124 12-14). The bladder temperature is considered suitable for clinical use providing an adequate urine flow. <sup>3</sup>  
125 Hypothermia was defined as temperature  $<36^{\circ}\text{C}$ . Patients thermal comfort was assessed with a modified 5-point

126 Likert visual scale consisting of 5 points: 1: very cold, 2: cold, 3: comfortable, 4: hot, 5: very hot. The Likert  
127 scale is a psychometric scale of five point that allow individuals to express how much they agree or disagree to a  
128 particular statement.<sup>21</sup> For the purpose of this study, the Likert scale was modified and included digits and  
129 smileys so it was easier for patients to see and make the grade.

130

### 131 ***Data analysis***

132 Potential between-group differences in demographics and treatment-related variables were compared using the  
133 two-sample t-test, Pearson's Chi squared test or Fischer's exact test depending on data type and cell numbers.  
134 Relative risk (95% CI) and Pearson's Chi squared test or Fischer's exact test were used to compare hypothermia  
135 (temperature <36°C) between groups. Thermal comfort was numerically calculated and presented in a diagram.  
136 The significance level was set at P<0.05 and all analyses were performed in IBM SPSS Statistics Version 24  
137 (IBM Corporation, Armonk, NY).

138

### 139 ***Ethics and registration***

140 The study was registered at ClinicalTrials.gov (NCT03193905) and was carried out in accordance with The  
141 Helsinki Declaration.<sup>22</sup> The patients (and their legal guardians if under 18), were informed about the study prior  
142 to surgery and informed about their rights to withdraw from the study at any time. Confidentiality and anonymity  
143 was ensured. In accordance with Danish legislation, formal ethics approval of the study was not required since  
144 the study was an analysis of current practice and thus had no implications for the treatment of the patient.  
145 Authorization by the regional Danish Data Protection Agency Identity number 2015-135 was obtained.

146

### 147 ***Findings***

148 Table 1 presents the demographic and morphometric characteristics and treatment-related variables of the  
149 patients included. Length of stay in the operation theatre (P=0.003) and length of operation (P=0.002) were  
150 significantly shorter in the intervention group compared to the control group. There were no other statistically

151 significant differences found between the two groups in demographic or treatment-related variables. When  
152 connecting to the bladder catheter, no significant between-group difference was found (RR (95% CI) of 0.20  
153 (0.03 to 1.61); Table 2) in the risk of hypothermia with mean (SD) temperatures of 36.3 (0.5) °C in the control  
154 group and 36.5 (0.4) °C in the intervention group. At the start of the operation, the risk of hypothermia (<36° C)  
155 was significantly lower in the intervention group compared to the control group (RR (95% CI) of 0.28 (0.13 to  
156 0.59); Table 2) with mean (SD) temperatures of 35.8 (0.5) °C in the control group and 36.3 (0.3) °C in the  
157 intervention group. At the end of the operation, no significant between-group difference was found (RR (95% CI)  
158 of 0.33 (0.04 to 3.03); Table 2) in the risk of hypothermia with mean (SD) temperatures of 36.8 (0.7) °C in the  
159 control group and 37.1 (0.4) °C in the intervention group. When asked, 77% (23) of the patients in the  
160 intervention group indicated that they felt thermally comfortable, 20% (6) cold and 3% (1) hot before  
161 prewarming, while 60% (18) felt thermally comfortable, 37% (11) hot and 3% (1) very hot after prewarming.

162

### 163 *Discussion*

164 We found that inadvertent hypothermia at the start of the operation was lowered by 72% when using the FAU  
165 blanket pre- and intraoperatively compared to the use of passive prewarming and active warming with the  
166 FBBSA commencing at the start of the operation. This corresponds partly with Pu et al. who found that  
167 significantly less patients with intraoperative hypothermia were observed in a group of patients who were  
168 actively warmed with an underbody warming system intraoperatively compared to a passively warmed group of  
169 patients.<sup>23</sup> Also, they found no significant alteration in the temperature at the beginning of surgery until 30  
170 minutes later, despite differences in warming methods.<sup>23</sup> We found no significant difference in the number of  
171 patients with inadvertent hypothermia between the control group and the intervention group when the patients'  
172 bladder catheters were connected to the monitor. However, both our groups experienced a small decrease in  
173 bladder temperature at the start of the operation. This corresponds with Akhtar et al. who found only a small  
174 redistribution hypothermia in patients who were not prewarmed, thus supporting our findings.<sup>24</sup> Sessler argues  
175 that the initial reduction in core temperature is difficult to treat since it is caused by redistribution of heat from



176 the core to the peripheral tissue due to anesthetic induced vasodilatation and impaired autonomic temperature  
177 regulation.<sup>2</sup> Moola and Lockwood argue that prewarming is effective in preventing redistribution hypothermia,  
178 especially one hour after induction of anesthesia.<sup>25</sup> Sessler found that prewarming for as little as 30 minutes  
179 probably prevents considerable redistribution,<sup>2</sup> whereas Horn et al. comparing three periods of prewarming at  
180 10, 20 and 30 minutes respectively, suggest that prewarming for only 10 or 20 minutes in most cases prevents  
181 hypothermia.<sup>26</sup> Connelly et al. suggest that 10 minutes prewarming is sufficient in reducing intraoperative  
182 hypothermia.<sup>27</sup> In our study, patients in the intervention group were actively prewarmed between 2 – 20 minutes  
183 and significantly maintained their bladder temperature  $\geq 36^{\circ}$  from start and throughout surgery in contrast to the  
184 control group. According to Leslie & Sessler, one hour of active forced air warming with  $43^{\circ}$  C prior to  
185 anesthesia is sufficient to counter act a redistribution core temperature drop, but may result in sweating and  
186 discomfort for the patient.<sup>28</sup> We found that 40 % of the patients felt hot and very hot after between 2 – 20  
187 minutes of prewarming with  $43^{\circ}$ C. The National Institute for Health and Care Excellence (NICE) recommends  
188 that active warming be maintained throughout the intraoperative phase.<sup>29</sup> In our study, active warming of the  
189 patients in the intervention group were resumed immediately after positioning and draping; thus minimizing the  
190 heat loss before the start of the operation in contrast to the patients in the control group where active warming  
191 was initiated just prior to the start of the operation. That might suggest active warming to be continued during  
192 further preparation of the patient before the start of the operation.

193

194 Length of operation and length of stay in the operating room were significantly lower in the intervention group  
195 than in the control group. Length of operation and length of stay in the operating room could have contributed to  
196 the significantly lower heat loss in the intervention group. Journaux suggests in a review that patients undergoing  
197 longer procedures are in increased risk of hypothermia.<sup>30</sup> Lynch et al. argue that to prevent hypothermia in  
198 procedures lasting more than one hour it might be advisable to increase the operating room temperature.<sup>11</sup>  
199 However, a recent study showed that the operating room ambient temperature has a negligible effect on core  
200 temperature when patients are warmed with forced air.<sup>31</sup> The effect is larger when the patient is passively

201 insulated, but with a small magnitude. <sup>31</sup> Wagner et al problematized the lack of research on the benefits of  
202 prewarming as a comfort intervention or anxiolytic mean to decrease patient anxiety. <sup>32</sup> Fossum et al. indicated  
203 that application of forced warm air preoperatively provides positive feelings of comfort. <sup>33</sup> However,  
204 thermoregulation also presents a nursing care challenge. <sup>10</sup> We found that 20 % of the patients felt cold arriving  
205 to the operating theatre. This correlates with Wagner's study where patients often mentioned that they felt cold  
206 in the preoperative phase of the surgery. <sup>32</sup> Most of the patients in our study, however, felt comfortable. After  
207 prewarming, the patients no longer felt cold (37% felt hot; 3% felt very hot adding risk of discomfort). This  
208 underlines the need for nurses to intervene successfully and effectively pre- and intraoperatively to increase  
209 thermal comfort, be aware of, and control the thermal environment. It is possible to adjust the active warming  
210 device from 43 °C to either 38 °C. or 32 °C. Further research on patient experiences of thermal comfort is  
211 needed.

212

### 213 ***Limitations***

214 The validity of this study would have been strengthened if the study was a randomized controlled trial as this  
215 would have eliminated selection bias and ensured that any known and unknown confounders would have been  
216 balanced between groups <sup>34</sup>. Alongside further standardization of the practical methods applied during surgery  
217 between treatment groups, this would have ensured that any potential inconsistencies in time of prewarming and  
218 preparation after induction of anesthesia, clothing worn when the patients arrived at the operation theatre and  
219 differences in time uncovered during for example catheterization and positioning would have been equally  
220 distributed between groups. However, as this were individual and not systematic differences between groups, we  
221 have no reason to believe that they would significantly affect the results. Finally, as we did not conduct a sample  
222 size calculation a priori, we cannot rule out that significant between-group differences in hypothermia would  
223 have also been found when connecting the bladder catheter or at the end of the operation, had we included more  
224 patients.

225

226 ***Conclusion***

227 Patients using FAU blanket were at a 72% lower risk of hypothermia at the start of the operation, suggesting that  
228 this might be an appropriate pre- and intraoperative warming method in major spinal surgery. When using the  
229 FAU blanket, the time and amount of skin surface receiving forced air warming was extended because the  
230 blanket allowed all the preoperative procedures to go on due to its placement underneath the patient; thus  
231 minimizing the loss of heat to the environment leaving heat production to exceed heat loss. The comfort scores  
232 indicate that nurses should pay careful attention to the patient's thermal comfort and adjust accordingly.

233

234 ***Declaration of interest & funding***

235 The authors declare that there is no conflict of interest.

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238

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