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Prevention of peri-interventional hypothermia during endoscopic retrograde cholangiopancreatography using a forced-air heating system

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ABSTRACT

Background and study aims Perioperative hypothermia is associated with significant complications and can be prevented with forced-air heating systems (FAHS). Whether hypothermia occurs during prolonged endoscopic sedation is unclear and prevention measures are not addressed in endoscopic sedation guidelines. We hypothesized that hypothermia also occurs in a significant proportion of patients undergoing endoscopic interventions associated with longer sedation times such as endoscopic retrograde cholangiopancreaticography (ERCP), and that FAHS may prevent it.

Patients and methods In this observational study, each patient received two consecutive ERCPs, the first ERCP following current standard of care without FAHS (SOC group) and a consecutive ERCP with FAHS (FAHS group). The primary endpoint was maximum body temperature difference during sedation.

Results Twenty-four patients were included. Median (interquartile range) maximum body temperature difference was −0.9°C (−1.2; −0.4) in the SOC and −0.1°C (−0.2; 0) in the FAHS group ($P < 0.001$). Median body temperature was lower in the SOC compared with the FAHS group after 20, 30, 40, and 50 minutes of sedation. A reduction in body temperature of > 1°C ($P < 0.001$) and a reduction below 36°C ($P = 0.01$) occurred more often in the SOC than in the FAHS group. FAHS was independently associated with reduced risk of hypothermia ($P = 0.006$). More patients experienced freezing in the SOC group ($P = 0.004$). Hemodynmaic and respiratory stability were comparable in both groups.

Conclusions Hypothermia occurred in the majority of patients undergoing prolonged endoscopic sedation without active temperature control. FAHS was associated with higher temperature stability during sedation and better patient comfort.

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Introduction

Even moderate perioperative hypothermia can result in potentially serious complications [1]. These include increased mortality, cardiac complications such as arrhythmias and myocardial ischemia, coagulation disorders as well as increased transfusion requirements and oxygen consumption [2, 3, 4, 5]. Postoperative shivering, changes in potassium serum concentrations and peripheral vasoconstriction are also relevant side effects of perioperative hypothermia [6].

During complex endoscopic procedures such as endoscopic retrograde cholangiopancreatography (ERCP), deep medical sedation of the patient is routinely performed and theoretically, these patients also may be at high risk for developing hypothermia [7]. However, if hypothermia actually occurs in a significant portion of patients during prolonged endoscopic interventions is unclear to the present time.

Perioperative hypothermia can be prevented by using temperature control devices such as forced-air heating systems (FAHS) in accordance with current anesthesiology guidelines [8, 9, 10]. However, the prevention of hypothermia during endoscopic procedures by active warming devices has not been addressed in current endoscopic sedation guidelines due to lack of evidence of benefit in these patients [11, 12].

We hypothesized that in the context of endoscopic interventions associated with longer sedation time, such as ERCP, periinterventional hypothermia occurs in a significant proportion of patients and may be prevented by using FAHS.

This explorative prospective observational study, therefore, investigated the occurrence of hypothermia during ERCP interventions as well as its potential prevention by FAHS ("Forced Air Heating to Prevent Hypothermia During Endoscopic Retrograde Cholangiography" = FAIRHEC study).

Patients and methods

Study population

This was a prospective observational study at a tertiary endoscopy unit. All patients undergoing ERCP were screened for meeting pre-defined inclusion criteria from March 2022 to May 2023.

The local institutional review board (Nr. 9942_BO_S_2021) approved the study protocol, and written informed consent was obtained from all participants prior to study inclusion. The study was performed in accordance with the ethical standards laid down in the 1964 Declaration of Helsinki and its later amendments. The study was prospectively registered at clinicaltrials.gov (Identifier: NCT05138172).

Inclusion and exclusion criteria

For this study, only patients were recruited who foreseeably would receive multiple comparable ERCP interventions (e. g. patients with complex benign biliary obstructive disease), so that later comparison of sedation with and without use of FAHS would be possible in the same patient. This study design has the advantage of compensating for the otherwise large individual differences (pre-existing conditions, anesthesiologic risk, age, temperature sensibility) with regard to the risk of hypothermia occurrence.

Inclusion criteria, therefore, were: 1) an indication to receive repeated (≥ 2 expected interventions) ERCPs due to chronic benign obstructive biliary disease, including primary sclerosing cholangitis (PSC), ischemic-type biliary lesion (ITBL) after liver transplantation (LTX), anastomotic stenosis after LTX, and secondary sclerosing cholangitis (SSC); and 2) necessary intravenous medical sedation expected to be required for > 30 minutes. Exclusion criteria were pregnancy, inability to give informed consent, and age <18 years.

Intervention: Standard of care and forced-air heating system

Each patient received two consecutive ERCP procedures. The first ERCP was performed with sedation following current SOC recommendations in Germany without using FAHS (SOC group) [11]. SOC consisted of wrapping patients in their own bedspread without further active warming measures. A consecutive second ERCP was then performed using additive FAHS (FAHS group). In the FAHS group, a Twinwarm (Generation III, Moeck & Moeck GmbH, Hamburg, Germany) was used for FAHS. Prewarming was performed for an average of 10 minutes before the start of the examination and the administration of sedation agents. The warming device was set to a ventilation level of 5 and a temperature of 43°C. It was specified that if the body temperature was > 37.5°C, the temperature of the device should be lowered accordingly, but the ventilation level should be maintained to prevent burns. These specifications were taken from the April 2021 local SOP "Thermal Management" guidelines of April 2021 of the Department of Anesthesiology and Intensive Care Medicine at MHH and the German S3 guideline on prevention of inadvertent perioperative hypothermia [10]. All procedures were performed in the same examination room. Room temperature and humidity were kept constant by a ventilation/air conditioning system at around 22°C and 41%, respectively. Room temperature was measured at three time points during sedation, with later calculation of a mean value using a room thermometer (Bresser GmbH, Rhede, Germany).

During interventions, in addition to intermittent assessment of standard vital signs (heart rate, non-invasive blood pressure, oxygen saturation, electrocardiogram), the nasopharyngeal core body-temperature was continuously measured using a 10F nasopharyngeal temperature sensor (Teleflex Medical, Athlone, Ireland) and recorded every 10 minutes. The nasopharyngeal temperature sensor has a measuring accuracy of ± 0,2°C over a temperature range of 25°C to 45°C. During ERCP, no procedures requiring electrocautery devices (e. g. sphincterotomy or argon plasma coagulation) were performed.

Sedation was administered intravenously (IV) with an initial bolus of approximately 0.1 mg/kg of individual patient body weight of propofol and subsequent repeated preservation doses of 10 to 20 mg of propofol depending on sedation needs. Additional midazolam was only used if sedation with propofol alone did not yield satisfactory depth of sedation or if occurrence of hypotension temporarily prohibited the further use of

propofol. No continuous administration of propofol or midazolam was used.

Directly before the start and after the end of sedation, a venous blood gas analysis was performed using a point of care (POC) system (Radiometer, Bronshoj, Denmark).

Endpoints

The primary endpoint was the patient's maximum body temperature difference, based on the body temperature at the start of sedation and the lowest body temperature during intervention.

The two key secondary endpoints were the percentage of patients with a decrease below 36°C for ≥ 2 minutes (the threshold of mild hypothermia) at any time during intervention and the percentage of patients with a decrease in temperature from baseline of > 1°C at any time during intervention.

Further secondary endpoints were hemodynamic and respiratory stability during intervention and subjective patient satisfaction after intervention.

For hemodynamic stability, the following parameters were assessed: lowest mean arterial pressure (MAP) during sedation; percentage of patients with a reduction of MAP to below 65 mm Hg; percentage of patients with a reduction of MAP of at least 25% from baseline; percentage of patients with a heart rate (HR) > 100 beats per minute (bpm); percentage of patients with an increase in HR of at least 25% from baseline; cumulative amount of IV fluid administered during sedation; and percentage of patients requiring vasopressors.

For respiratory stability, the following were assessed: percentage of patients with a reduction in peripheral oxygen saturation (O_2-sat) to < 90%; percentage of patients requiring oxygen nasal flow > 2 L/min; maximum needed oxygen flow; percentage of patients requiring Wendel tube insertion and mask ventilation in case of a critical drop in O_2-sat.

Subjective patient satisfaction was examined 6 hours after intervention by employing three quantitative scoring systems. The "Quality of Recovery Score, German modification of Eberhart et al." [13] (score ranging from 0 to 18 points, with higher scores indicating higher patient satisfaction) and a "modified Deutsche Gesellschaft für Anästhesiologie und Intensivmedizin Score (mDGAI)" (score ranging from 0 to 8 points with higher scores indicating higher patient satisfaction) [14] were used to assess general satisfaction with sedation. In addition, a quantitative assessment of subjective degree of freezing during or following sedation (ranging from 0 to 10 points with higher scores indicating more intense feeling of freezing) was performed.

Case number calculation

The required number of cases for the study was calculated prior to study initiation using the following hypothetical assumptions: patients are normothermic (37°C body temperature) at baseline; the temperature decreases by an average of 1.1°C during the initial examination without the use of FAHS and during the second examination - with the use of FAHS - the body temperature drops by an average of only 0.5°C. This results in an effect size of 0.6; with an alpha of 0.05 and a study power of 80%, a case number of 24 patients results. To compensate for possible drop-outs, an additional 12% were added to the number of cases (total of 27 patients). For final analysis, 24 patients (linked comparison) were included (two excluded due to sedation < 30 minutes and one for invalid temperature measurements).

Statistical analysis

Data are presented as median (25% to 75% interquartile range [IQR]). Two-tailed $P < 0.05$ was considered to indicate statistical significance. Comparisons of population characteristics between the SOC and the FAHS group were performed using paired t-tests, Wilcoxon signed-rank tests and χ^2 tests, as appropriate. In order to compare temperature courses within groups during predefined time points (baseline and every 10 min until end of sedation) ANOVA tests were used. Univariate and multivariate logistic regressions were conducted. In the multivariate analysis, all characteristics that were tested in univariate analysis before were entered in a forward conditional model. Statistical analysis was performed using GraphPad Prism 7 (La Jolla, California, United States) and SPSS Statistics (IBM); graphs were generated by GraphPad Prism.

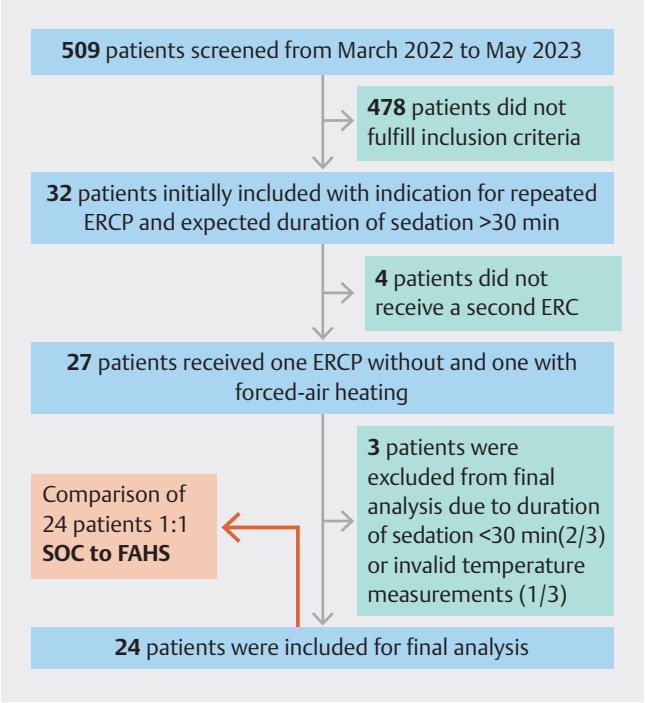
Results

Patient cohort

Based on the strict inclusion criteria allowing later linked comparison in the same patient, of 509 initially screened patients undergoing ERCP, 24 patients were included for final analysis (▶ **Fig. 1**). All 24 patients received the first ERCP without FAHS (SOC group) and the following ERCP with FAHS (FAHS group) and were then compared in a linked strategy. Demographic, clinical and procedural characteristics are demonstrated in ▶ **Table 1**. The most common indications for ERCP were PSC and ITBL after LTX. Lab values of cholestasis, MELD scores, procedure duration, performed endoscopic procedures, and cumulative sedation doses were comparable between the two groups.

Temperature-associated endpoints

Baseline body temperature at the start of sedation was comparable between the two groups (SOC: 36.0°C (35.6; 36.5); FAHS: 36.0°C (25.5; 36.2), $P = 0.713$, ▶ **Fig. 2a**, ▶ **Fig. 2b**). While patient temperature started to continuously decrease in the SOC group from shortly after the start of sedation ($P < 0.001$), it remained stable in the FAHS group ($p = 0.152$) (▶ **Fig. 2a**). At 20 minutes after the start of sedation, patient temperature was already significantly lower in the SOC group and remained significantly lower at all further routinely recorded time points at 30, 40, and 50 minutes (▶ **Fig. 2a**). The lowest recorded temperature was 35.2°C (34.6; 35.7) in the SOC and 35.8°C (35.5; 36.2) in the FAHS group ($P < 0.001$) (▶ **Fig. 2b**). Consequently, patient maximum body temperature difference (based on the body temperature at the start of sedation and the lowest body temperature during intervention) was −0.9°C (−1.2; −0.4) in the SOC and −0.1°C (−0.2; 0.0) in the FAHS group ($P < 0.001$) (▶ **Fig. 2c**). The relative drop in temperature was −2.5% (−3.3; −1.2) in the SOC and −0.3% (−0.6; 0.0) ($P < 0.001$) in the FAHS



▶ **Fig. 1** Flow chart of study participants. Shown are the screening and enrollment of patients into the observational study. Included were adult patients undergoing repeated endoscopic retrograde cholangiopancreatography (ERCP) with an expected sedation duration of more than 30 minutes. The study compared the standard of care (SOC group) with additive use of a forced-air heating system (FAHS group) in a linked comparison.

group (▶ **Fig. 2d**). A reduction in core body temperature > 1°C ($P < 0.001$) occurred significantly more often in the SOC than in the FAHS group (▶ **Table 2**). Mild hypothermia–defined as a drop of temperature < 36°C - occurred in 88% and 54% of patients in the SOC and the FAHS groups ($P = 0.011$), respectively (▶ **Table 2**). Subjective feeling of freezing during or following sedation was significantly more pronounced in the SOC group (4/10 [3/10–7/10]) than in the FAHS group (0/10 [0/10–1.5/10]) ($P = 0.004$) (▶ **Fig. 2e**). Importantly, mean room temperature was not different between the two groups (▶ **Fig. 2f**).

Further secondary endpoints

Hemodynamic and respiratory stability during sedation was mostly comparable between the two groups (▶ **Table 2**). There was a numerical but not significant trend toward lower cumulative IV fluid administration in the FAHS group. Subjective general patient satisfaction with sedation, measured by QoR and mDGAI score, was high in both groups. BGA analysis demonstrated a slight increase in venous pCO_2 pressures during sedation that were comparable between the two groups (**Supplementary Fig. 1a**). No significant abnormalities or differences were observed in pH, lactate, or potassium concentration in either group (**Supplementary Fig. 1b**, **Supplementary Fig. 1c**, **Supplementary Fig. 1d**).

Parameters associated with occurrence of hypothermia

As an exploratory analysis, the parameters age, sex, BMI, cumulative propofol dose, procudure duration, room temperature, MELD score, baseline temperature and FAHS were first entered in a univariate model, followed by a multivariate logistic regression model for the endpoint occurrence of hypothermia (temperature < 36°C) (▶ **Table 3**). In both the univariate and multivariate analyses, only higher baseline temperature and use of FAHS had a significant and protective effect on hypothermia risk (OR multivariate for FAHS: 0.009 (0–0.26), $P = 0.006$)).

Discussion

This pilot prospective observational study, employing 1:1 matching in repeated ERCP procedures for chronic biliary obstruction, investigated occurrence of hypothermia and the use of FAHS to prevent it during prolonged endoscopic sedation. Hypothermia occurred in a significant proportion of patients and FAHS was associated with significantly higher temperature stability during sedation as well as better patient comfort.

Perioperative inadvertent hypothermia occurs quite commonly and is defined as a patient core body temperature < 36.0°C [15]. In contrast, no data exist regarding whether hypothermia also occurs in a significant proportion of patients undergoing prolonged sedation for complex endoscopic procedures. In the present study, hypothermia occurred in 88% of patients (if no prophylaxis by FAHS was initiated) and temperature dropped in these patients by approximately 1°C. Median sedation time was still < 50 minutes, prompting speculation as to whether such an effect might have been even more pronounced in complex endoscopic procedures requiring longer sedation times; for example, endoscopic submucosa dissections, peroral endoscopic myotomies, or endoscopic ultrasonography by the rendezvous technique. Of note, no interventions requiring electrocautery devices (e. g. sphincterotomy, argon plasma coagulation) potentially causing hot gas development and, therefore, potentially falsifying temperature measurements were used during the study.

Today, most gastrointestinal endoscopies are performed under moderate sedation. Numerous studies from Europe and North America have shown that nurse-administered propofol sedation (NAPS) is feasible and safe, provided it is performed in appropriately selected patients and endoscopies [16, 17, 18, 19]. In Germany, uncomplicated endoscopic examinations have been carried out by properly trained non-anesthesia staff in outpatient and inpatient settings for years and this is supported by the sedation guideline from the German Society for Gastroenterology and Digestive and Metabolic Diseases (DGVS) [12]. However, in contrast to the regular monitoring of vital signs under moderate sedation, the measurement of body temperature is not implemented as a standard during endoscopic procedures [11, 12, 20]. In contrast, in anesthesiology, body temperature remains one of the most closely monitored parameters in the perioperative setting. Due to the further development of endoscopic techniques and new methods in re-

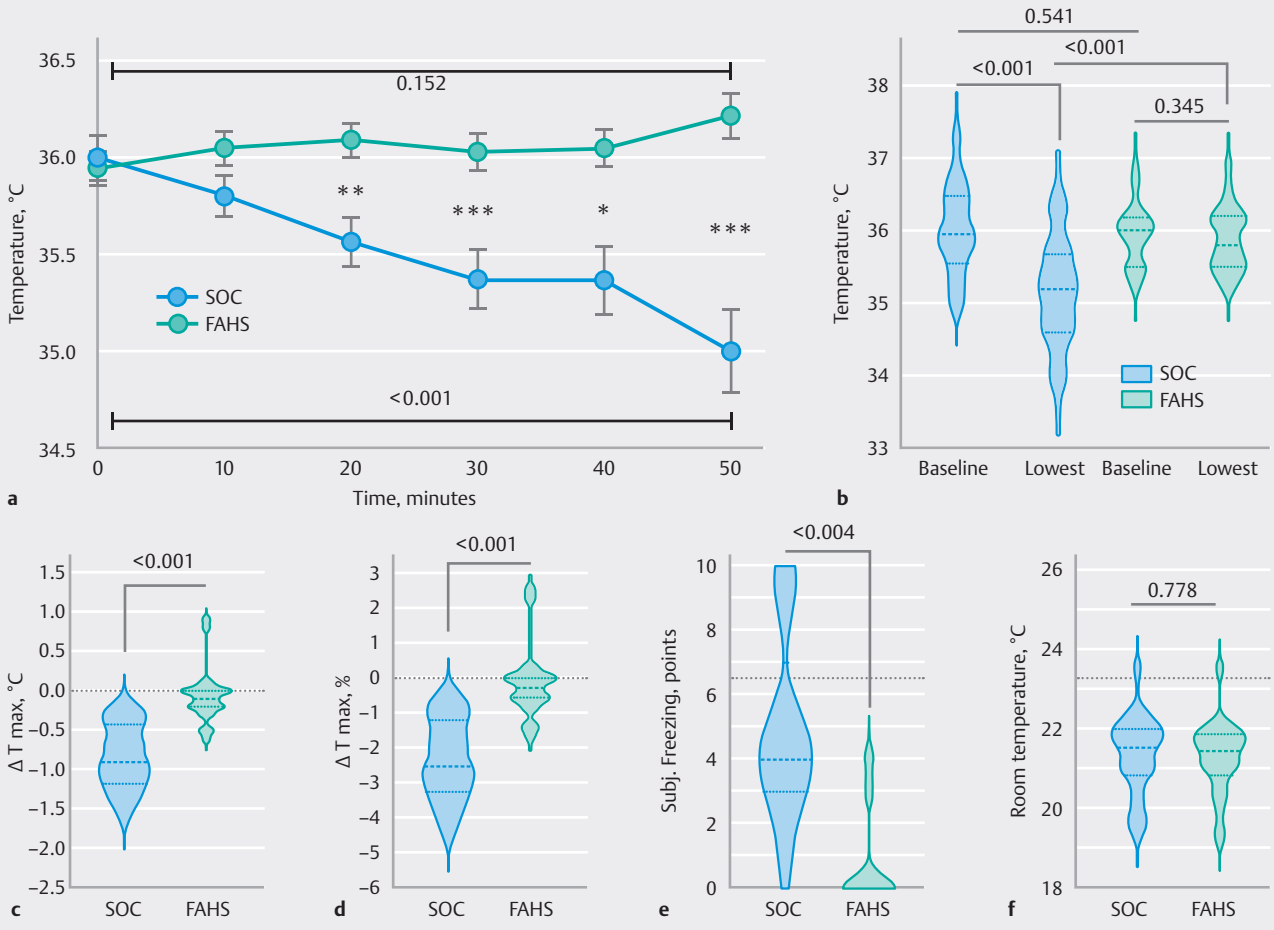
▶ **Table 1** Demographic, clinical, and procedure characteristics

Category	All (n = 24)	SOC (n = 24)	FAHS (n = 24)	*P*
Age, years	55 (39–63)			
Sex, no (%)				
Female	7 (29)			
Male	17 (71)			
BMI, kg/m^2	23.4 (20.5–62.5)			
Indication for ERCP, no (%)				
PSC	13 (54)			
ITBL	10 (42)			
Anastomotic stenosis	4 (17)			
Liver cirrhosis, no (%)	4 (17)			
LTX, no (%)	12 (50)			
AP, U/L		272 (167–470)	242 (178–365)	0.67
GGT, U/L		208 (46–382)	213 (47–471)	0.772
Bilirubin total, µmol/L		17 (9–39)	15 (9–26)	0.789
MELD		8 (6–13)	8 (6–13)	0.834
Endoscopic procedures performed, no (%)				
Sphincterotomy		0 (0)	0 (0)	–
Biliary dilation		17 (71)	18 (75)	0.745
Biliary stenting		10 (42)	10 (42)	1
Procedure duration, min		42 (35–50)	48 (34–65)	0.541
Room temperature, °C		22 (21–22)	22 (21–22)	0.778
Cumulative propofol dose, mg		475 (408–673)	530 (390–673)	0.659
Cumulative midazolam dose, mg		3 (2–5)	3 (2–5)	0.56

AP, alkaline phosphatase; BMI, body mass index; FAHS, with forced-air heating system; GGT, gamma glutamyl transferase; ITBL, ischemic-type biliary lesions; LTX, liver transplantation; MELD, model of end-stage liver disease; SOC, standard of care (without forced-air heating).

cent years, endoscopic interventions are becoming longer and more complex and, therefore, longer, so that greater attention must also be paid to temperature monitoring and hypothermia prophylaxis. Optimized perioperative thermal management is comparatively simple but contributes significantly to patient safety and comfort and is firmly established in anesthesia and surgery guidelines for pre-intervention, peri-intervention, and post-intervention [20, 21]. The American Society of Anesthesiologists (ASA) guidelines recommend that "every patient receiving anesthesia shall have temperature monitored when clinically significant changes in body temperature are intended, anticipated or suspected" [22]. According to the ASA, temperature measurement is a basic SOC and should be continually monitored during an anesthesia [22]. The World Health Organization (WHO) released a systematic review demonstrating the benefits of maintaining normothermia preoperatively through postoperatively [23]. Of interest, the baseline temperature at the start of sedation of approximately 36°C (despite active prewarming) was lower than initially expected in both groups. At the same time, in the present study, lower baseline temperature was associated with an increased risk of hypothermia during later sedation. This together demonstrates that we may still underestimate individual patient waiting time and its inherent risk of promoting later onset of hypothermia during subsequent sedation.

Options for hypothermia prophylaxis include pre-warming and peri-interventional active or passive warming. Active prewarming using a FAHS has been shown to be effective in preventing unintended hypothermia during the perioperative period [24] and active prewarming should be performed over a period of 10 to 30 minutes [25]. Active peri-interventional warming can be achieved by using a FAHS, as opposed to passive warming, which is done by using blankets. Studies have shown that active warming by FAHS is superior to passive warming in preventing inadvertent hypothermia during surgery and postoperatively [26]. It was unclear, however, if FAHS can



▶ **Fig. 2** Temperature-associated endpoints. Shown are primary and secondary temperature-associated clinical outcomes of patients receiving standard-of-care treatment (SOC) and of patients who received additive treatment with a forced-air heating system (FAHS). **a** Temperature course in both groups at the start of sedation and at 10-, 20-, 30-, 40-, and 50-minute sedation time. The mean ± standard error of the mean (SEM). Between-group differences at the same time point are compared using paired *t*-tests. Within-group longitudinal differences are compared using ANOVA tests. $^{*}P < 0.05$, $^{**}P < 0.01$, $^{***}P < 0.001$. **b** Violin plots showing baseline and lowest temperature. **c** Patient maximum absolute body temperature difference (based on the body temperature at the start of sedation and the lowest body temperature during the intervention). **d** Patient maximum relative body temperature difference. **e** Subjective impression of freezing during or following sedation (ranging from 0 to 10 points, with higher scores indicating a more pronounced impression of freezing). **f** Mean room temperatures in both the SOC and the FAHS group.

also be safely and effectively used in the context of prolonged sedation for endoscopic procedures.

In the present study, temperature dropped in the SOC group by almost 1°C, while it remained constant in the same patients then receiving a second ERCP with active temperature control by FAHS. Hypothermia occurred significantly more often in patients not receiving FAHS and FAHS use was significantly associated with protection from hypothermia in both univariate and multivariate regression analyses.

Although most anesthesiology sedation guidelines consider it standard that a sedation time > 30 minutes requires active temperature control and preservation measures [8, 9, 10], these recommendations are missing in endoscopic guidelines due to a lack of data supporting their routine use [11]. To our knowledge, this is the first prospective evaluation of active temperature control during prolonged sedation for endoscopic procedures showing a benefit of such a strategy in preservation of patient temperature.

This study has some limitations, mainly its relatively small sample size and non-randomized nature. In addition, inherent in the linked comparison design of this investigation, only a subset of the initially screened patients with benign biliary strictures then expected to receive repeated comparable complex ERCP procedures, were included, imposing the risk of a selection bias on the results of this study. On the other hand, this study design, allowing for repeated measures calculations and therefore yielding comparable baseline and procedural characteristics, has the advantage of compensating for the otherwise potentially large individual patient differences (pre-existing conditions, anesthesiologic risk, age, temperature sensibility) with regard to the risk of hypothermia occurrence. An additional limitation is the measuring inaccuracy of ± 0,2°C of the tem-

▶ **Table 2** Secondary endpoints

Category	SOC (n = 24)	FAHS (n = 24)	*P*
Temperature stability			
Temperature reduction > 1°C, no (%)	10 (42)	0 (0)	< 0.001
Temperature < 36°C, no (%)	21 (88)	13 (54)	0.01
Temperature reduction max, % from baseline	−2.5 (−3.3/−1.2)	−0.3 (−0.6/0)	< 0.001
Hemodynamic stability			
MAP lowest, mmHg	81 (68–92)	79 (69–92)	1
MAP < 65 mm Hg, no (%)	1 (4)	2 (8)	0.551
MAP reduction >25% from baseline, no (%)	5 (21)	4 (17)	0.712
HR > 100 bpm	5 (21)	6 (25)	0.731
HR increase >25% from baseline, no (%)	4 (17)	8 (33)	0.182
Cumulative IV fluids, mL	1000 (175–1000)	500 (0–700)	0.058
Requiring vasopressor, no (%)	1 (4)	0 (0)	0.312
Respiratory stability			
Reduction of O_2-Sat < 90%, no (%)	2 (8)	4 (17)	0.383
Requiring oxygen flow > 2 L/min, no (%)	3 (13)	6 (25)	0.267
Max. required oxygen flow, L/min	2 (2–2)	2 (2–3.5)	0.945
Requiring Wendel tube insertion, no (%)	1 (4)	1 (4)	1
Requiring mask ventilation, no (%)	0 (0)	0 (0)	–
Subjective patient satisfaction			
Subjective freezing (0–10 points)	4 (3–7)	0 (0–1.5)	0.004
QoR score	16 (14–18)	17 (16–18)	0.47
mDGAI score	3 (2–4)	3 (1–4)	0.547

FAHS, with forced-air heating system; HR, heart rate; IV, intravenous; MAP, mean arterial pressure; mDGAI score, modified Deutsche Gesellschaft für Anästhesiologie und Intensivmedizin score; O_2-sat, (peripheral) oxygen saturation; QoR score, quality of recovery score; SOC, standard of care (without forced-air heating).

▶ **Table 3** Parameters associated with occurrence of hypothermia (temperature < 36°C).

Parameter		Univariate			Multivariate	
	OR	95% CI	*P*	OR	95% CI	*P*
Age, years	1.04	0.99–1.09	0.079			
Sex, female	0.75	0.2–2.8	0.669			
BMI, kg/m^2	0.95	0.83–1.1	0.505			
Cumulative propofol dose, mg	1	0.98–1	0.85			
Procedure duration, min	0.99	0.96–1.03	0.707			
Room temperature, °C	0.99	0.51–1.94	0.984			
MELD score, points	0.97	0.84–1.13	0.724			
Baseline temperature, °C	0.05	0.01–0.34	0.002	0.002	0–0.15	0.005
FAHS	0.17	0.04–0.72	0.016	0.009	0–0.26	0.006

BMI, body mass index; CI, confidence interval; FAHS, forced-air heating system; MELD, model of end-stage liver disease; OR, odds ratio.

perature probe with respect to the absolute temperature difference of 0.9°C and the temperature recording interval of 10 minutes.

This study was primarily designed as a pilot study demonstrating superior temperature control by using FAHS and thus, it was not powered to demonstrate differences in clinical outcome parameters such as hemodynamic or respiratory stability. Therefore, secondary endpoints should be assessed only with significant caution. Sedation time might be even longer in other complex endoscopic procedures, such as endoscopic submucosa dissections, and the present data reporting exclusively on ERCP procedures are not readily transferrable to these patient populations. In summary, this study should be interpreted as a pilot investigation that needs further exploration in larger future studies.

Conclusions

This is the first prospective study that suggests that hypothermia is indeed occurring in a significant proportion of patients undergoing prolonged endoscopic examinations, and further, that FAHS is effective in preventing hypothermia in these patients. Future larger interventional studies are need to evaluate whether active temperature control is also associated with improved clinical outcomes and patient comfort during prolonged endoscopic sedation.

Conflict of Interest

The authors declare that they have no conflict of interest.

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