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Intraoperative Temperature Monitoring with Zero Heat Flux Technology (3M SpotOn Sensor) in Comparison with Tympanic and Oesophageal Temperature and Hypothermia Risk Factors: An Observational Study

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Abstract

Objective: Inadvertent hypothermia (body temperature below 35°C) is a common and avoidable challenge during surgery under anaesthesia. It is related to coagulation (clotting) disorders, an increase in blood loss, and a higher rate of wound infection. One of the methods for non-invasive monitoring of the core body temperature is the 3M SpotOn zero heat flux method. In this approach, sensors placed at the frontal region of the patient measure the skin temperature by creating an isothermic channel. The study aimed to determine the risk factors for hypothermia and compare the 3M SpotOn zero heat flux method with the tympanic membrane (eardrum) and oesophageal (food pipe) temperature measurement methods.

Design: Observational.

Data sources: The patients' data were collected, including age, gender, weight, BMI, other illnesses, smoking history, type of anaesthesia, duration of surgery, operating room temperature, pulse rate, blood pressure, blood loss, and transfusions. Body temperature was measured by the tympanic membrane method before and after surgery, oesophageal method during surgery, and SpotOn measurements throughout all three periods were recorded.

Eligibility criteria: Inclusion criteria was: adult patients, both genders, who had undergone major abdominal cancer surgery at the trialists' institution, in whom the SpotOn zero heat flux, tympanic membrane, and oesophageal temperature measurement methods had all been used. Participant exclusion criteria was the absence of recorded data.

Results: In this study, inadvertent intraoperative hypothermia incidence was 38.1% in the recovery room. Although gender, presence of comorbidities, history of smoking, administration of epidural anaesthesia, and requirement of blood transfusion [red blood cells (RBCs) and fresh frozen plasma (FFP)] did not affect hypothermia significantly during admission to the recovery room, prewarming the patient throughout the operation prevented the occurrence of hypothermia significantly (p=0.004). Additionally, as the American Society of Anaesthesiologists (ASA) physical status score worsened, the rate of hypothermia increased significantly (Frequency: 1st degree, 29.4%; 2nd degree, 47.5%; 3rd degree, 66.7%; X^2_{Slope-} p=0.047).

Conclusion: The most significant risk factor was found to be not prewarming the patient as a strict procedure, and as the ASA physical status score worsened, the rate of hypothermia increased significantly. Besides, the SpotOn method provided temperature measurements as good as the oesophageal temperature measurements. Clinical Trial registration: ISRCTN 14027708.

Keywords: Anaesthesia, hypothermia, zero heat flux sensor

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Introduction

Intraoperative inadvertent hypothermia is the most frequent perioperative anaesthetic concern. In numerous studies published in the medical literature, unintentional hypothermia in the intraoperative period was reported as the most prominent cause of intraoperative complications and was shown to be related to numerous problems such as coagulation disorders, increase in blood loss, postoperative shivering, increased oxygen consumption leading to increased cardiac morbidity, and a higher rate of wound infection (1, 2). All of these and the other adverse effects of hypothermia lead to increased morbidity, increased duration of hospitalisation, and even mortality; thus, its efficient prevention will provide significant improvement in morbidity and mortality of the patients.

The severity of hypothermia has been reported to be related to various risk factors such as the type and amount of the general anaesthetic, as well as the type of surgery and the environmental temperature. In previous studies, the exposure to cold in the operating room (OR), heat loss from the surface of the skin, and impairment of thermoregulation and vasodilation because of anaesthesia were shown to be the most important causes of inadvertent intraoperative hypothermia in major abdominal surgery. However, the impairment of thermoregulation has been found to be a much more significant effect (1, 2). Although the patients are warmed intraoperatively, hypothermia cannot be sufficiently avoided in major abdominal surgeries and long-lasting operations still. Moreover, no algorithm based on the clinical risk predictors by which the anaesthesiologists can predict such a condition and use appropriate warming methods has been described yet. Determining the probable preoperative and intraoperative hypothermia risks would lead to the implementation of methods for avoiding hypothermia more meticulously during the intraoperative period, and thus, would augment the reduction in the rate of probable adverse outcomes.

Many monitoring methods are available for the measurement of the core body temperature (CBT) such as sublingual nasopharyngeal, oesophageal, tympanic membrane, and pulmonary arterial catheter, which is currently described as the gold standard among these methods (3). The temperature measurement by inserting a heat probe into the oesophagus was first described by Cooper in 1957; the temperature measured by inserting a device into the oesophagus at the level of the heart was defined as the non-invasive measurement method (4). Another method is the tympanic membrane temperature measurement. The tympanic membrane temperature was first used by Benzinger (5) and improved by Cabanac and Caputa (6, 7). The blood supply of the tympanic membrane is provided by two sources, the anterior tympanic artery (glaserian artery) and caroticotympanic artery (8). This anatomical configuration has led to the hypothesis that the tympanic membrane follows the carotid arterial temperature (9). This non-invasive method can also result in disturbances in the awake state in patients and cause difficulties in the measurements during head and neck operations. The temperature measurement method using the SpotOn sensors is a novel method for monitoring CBT; it is based on the zero heat flux principle, which was first described in the early 1970s (10). In this process, the SpotOn sensors placed on the forehead (frontal region) of the patient measure the body temperature of the skin by creating an isothermic channel. The measurement is accomplished by the reflection of the core temperature on the sensor adherent to the skin at the point of "zero heat flux" (11). However, it is still uncertain as to how the non-invasive measurement of CBT of the patient should be performed. The search for a non-invasive, cheap, and effective method is still on. We have not found any previous study comparing the temperature measurements by the tympanic membrane, oesophageal, and 3M SpotOn zero heat flux methods. In this study, we aimed to determine the risk factors for hypothermia together with the most appropriate temperature monitoring method that would cause the least amount of damage to the patient. Our first purpose was to determine the risk factors for hypothermia by analysing the interactions of probable risk factors with CBT. Our second purpose was to compare the oesophageal temperature measurement method, tympanic membrane measurement method, and 3M SpotOn zero heat flux sensor method.

Methods

After obtaining the approval of the Dokuz Eylul University Local Institutional Ethics Committee (ref:2015/16-15 2168-GOA), the hospital records and anaesthesia cards of the patients who had undergone major abdominal cancer surgeries at our institution, and in whom the SpotOn zero heat flux method, tympanic membrane measurement method, and oesophageal temperature measurement method had all been used, were investigated retrospectively. The inclusion criteria of the study were defined as being previously operated and data of all measurements recorded; the exclusion criterion was defined as the absence of recorded data. In the intervention group, patients were warmed according to the standard protocol. According to this protocol, in this group, when the patient is in the preoperative waiting room in OR, all parts of the anterior body are covered by thee blankets; patients were warmed with forced air warming (FAW) system (3M Bair Hugger™ Temperature Management Blanket, Arizant Healthcare Inc., Eden Prairie, Minesota, USA) actively adjusted to 43°C for 30 min. Then, the patients were transferred to OR. After the anaesthesia induction and skin preparation, the patients were covered with an operation specific blanket, which we placed on the patient and started forced warm air.

If the patient's body temperature was higher than 38°C, active warming was discontinued either in the preoperative room or. Active warming was also continued in the post-anaesthesia care unit (PACU) or intensive care unit (ICU), if necessary, as when admitted in the preoperative period, only if the temperature of the patient was <38°C.

In the control group, no standardised warming protocol was used. Patients were warmed with the traditional methods of our institution. So, these patients were not prewarmed preoperatively. There were no specific blankets for these patients to be used in OR. The upper extremities and upper bodies of these groups of patients' were covered with simple cotton covers by rolling these cotton covers around the replacement hose of the device at the end by making an air hole. A Warm Touch Nellcor System® (Medtronic Parkway, Minneapolis, Minesota, USA) was inserted between the layers during the PACU or ICU period, only if necessary (in case the body temperature was <36°C, but not routinely), and during the entire surgery, intraoperatively. We defined hypothermia as <36°C, as measured by SpotOn zero heat flux at any time (preoperative, intraoperative, or postoperative).

First, the preoperative core temperature of patients was measured indirectly with the SpotOn zero heat flux and tympanic membrane probe. Then, indirect core temperature measurement via the SpotOn zero heat flux was repeated before induction of general anaesthesia. All patients had a temperature probe inserted approximately to one-third of the distal part of the oesophagus under direct vision, after induction of anaesthesia. Body temperatures were measured by the tympanic membrane method only in the preoperative and postoperative periods; oesophageal temperatures were measured in the intraoperative period at intervals of 60 minutes; and SpotOn measurements were recorded through all three periods. The standard maintenance temperature of OR was 21°C.

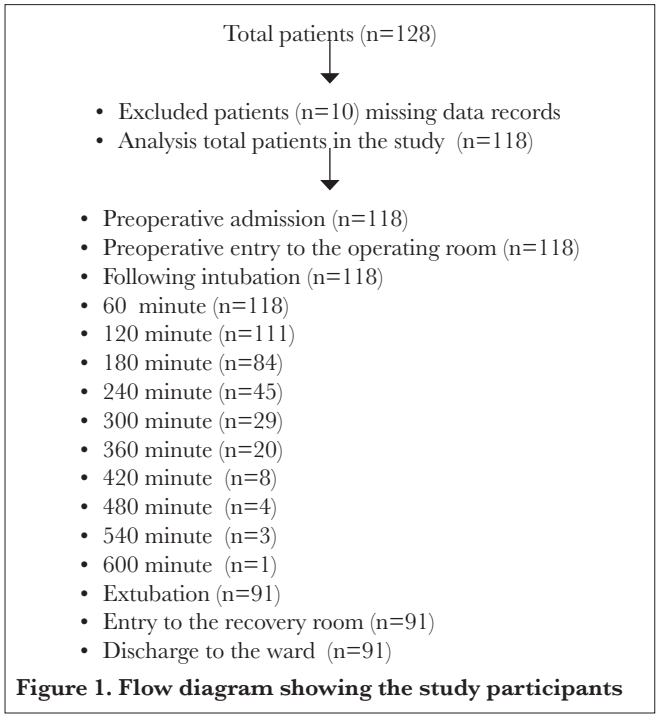

Figure 1. Flow diagram showing the study participants

The data concerning age, gender, weight, body mass index (BMI), comorbidities, smoking history, preoperative haemoglobin and albumin levels, amount of perioperatively administered colloids and crystalloids, American Society of Anaesthesiologists (ASA) physical status classification of patients' type of anaesthesia, central catheter usage, patient warming, duration of the operation, OR temperature, pulse rate, arterial blood pressure, amount of blood loss, transfused red blood cells (RBCs) (units) and fresh frozen plasma (FFP) (units), and postoperative haemoglobin (Hb) and albumin levels were recorded.

Statistical analysis

The continuous variables are presented as mean ± standard deviation, and the classified data are presented as number-percentage tables.

Concerning the determination of the risk factors for hypothermia, the independent variables of the study were patients' demographic data including age, gender, type of surgery, administered fluids, and duration of surgery. The dependent variable of the study was the CBT measured by the 3M SpotOn method. The effects of these variables on CBT were analysed. SPSS 15.0 software was used for statistical analysis. The singular analysis was made by using either the t-test or chi-square test. Following these singular tests, the logistic regression models were used for determining the factors affecting hypothermia. $P<0.05$ was considered statistically significant.

Concerning the comparison of measurement methods, the tympanic membrane temperature measurements obtained in the preoperative and the postoperative periods were compared to the body temperature measurements obtained by the 3M SpotOn heat flow sensor using McNemar and chi-square correlation tests. The 3M SpotOn, oesophageal, and tympanic temperatures for the intraoperative period were compared. The comparisons were made by correlation and consistency analyses. $P<0.05$ was considered as statistically significant.

Results

Among patients involved in the study (n=118) (Figure 1), the average age was 57.18±13.62 (range 24-87) years, and 50% (n=44) were females with an average BMI of 26.90±5.04. A total of 55.7% patients had a smoking habit, and 48.9%

had comorbidities. Approximately one-fifth of the patients were determined to receive blood transfusion; among these, one unit of blood was transfused in five, two units in eleven, and three units in one patient. Additionally, FFP was given to one patient. Approximately half (42%) of the patients were warmed in the preoperative period and during the operation. The characteristic features of the patient group together with the data related to the performed anaesthesia and operations are presented in Table 1.

The average values and standard deviations of the parameters related to the preoperative period, operation, and early postoperative period are presented in Table 2, together with the range in which they were distributed.

Table 1. Characteristic features and data related to the performed anaesthesia and operations

	Number	%
Gender (F/M)		50/50
*Comorbidity (+)	43	48.9
Smoking history (+)	49	55.7
ASA		
I	17	19.3
II	59	67.0
III	12	13.6
Type of anaesthesia		
General	23	26.1
General + epidural	34	38.6
General + intrathecal opioid	31	35.2
RBC transfusion	17	19.3
Prewarming of the patient	37	42.0

*Hypertension and diabetes mellites are defined as comorbidities. F: female; M: male; RBC: red blood cell (unit)

Table 2. Other findings related to the preoperative period, operation, and the early postoperative period

	Number	%
Preoperative Hb (mg dL^{-1})	11.80±1.48	8.90-14.70
Preoperative Albumin (mg dL^{-1})	3.67±0.50	2.08-4.80
Crystalloid (mL)	3130.80±1359.95	0-7000
Colloid (mL)	452.84±14.21	0-2000
Duration of the operation (min)	228.16±118.53	60-665
Operating room temperature (°C)	21.59±2.07	16-26
Pulse rate (per min)	78.15±14.21	45-115
Mean arterial blood pressure (mmHg)	87.76±12.39	60-123
Blood loss (mL)	265.85±364.94	0-2000
Postoperative Hb (mg dL^{-1})	11.06±1.58	7.90-15.20
Postoperative Albumin (mg dL^{-1})	2.86±0.53	1.50-4.12

Hb: haemoglobin

Although gender, presence of comorbidities, history of smoking, administration of epidural anaesthesia, and requirement for blood transfusion (RBC and FFP) did not affect hypothermia significantly during admission to the recovery room, prewarming the patient throughout the operation prevented the occurrence of hypothermia significantly (p=0.004). Additionally, as the ASA physical status score worsened, the rate of hypothermia increased significantly (Frequency: 1st degree, 29.4%; 2nd degree, 47.5%; 3rd degree, 66.7%; X^2_{Slope} p=0.047).

The factors affecting hypothermia in the recovery room following operation were analysed; it was determined that age, BMI, duration of operation or anaesthesia, type of anaesthesia, blood loss, arterial blood pressure, amount of perioperatively administered colloids, and preoperative and postoperative Hb and albumin levels did not have any effect on hypothermia during admission to the recovery room.

The body temperatures of the patients and the frequency of hypothermia in the preoperative, intraoperative, and postoperative periods together point to the effect of warming, which are presented in Table 3. Approximately 60% of the patients were determined to have encountered hypothermia concerning the operations with durations less than 300 minutes. Although no significant difference was found between the patients who were prewarmed and those not prewarmed in the preoperative period, the significantly low rate of hypothermia in patients who were prewarmed throughout the operation was remarkable. Concordantly, the patients who had been warmed with a standard protocol during the operation were found to be significantly less hypothermic in the postoperative period. This difference disappeared when the patients were transferred to their rooms following the recovery process.

When the SpotOn and the other body temperature measurements were compared, it was found that the average body temperature measured by the SpotOn method during preoperative admission, preoperative entry, and the following intubation were significantly higher as compared to the average values of the other measurement methods (p<0.001). In the other periods, no difference was found between the measurement methods. Although a significant correlation of moderate degree was observed between the measurement methods in the preoperative period, this relationship progressively strengthened in the course of time and a strong, significant correlation was determined between the two measurements throughout the operation (between 60 minutes and 600 minutes). The correlation was found to have a moderate-levelled significance during the transfer from the recovery room to the ward. The results of the comparison of the measurement methods are shown in Table 4.

Table 3. Body temperatures and frequency of hypothermia in the preoperative, intraoperative, and postoperative measurement points, together with the effects of warming

	Average ± Standard Deviation	The frequency of hypothermia (%)*	Warming		
			Prewarming group (%)	No prewarming group (%)	p‡
Preoperative admission (n=118)	36.95±0.47	2.5	3.7	1.6	0.881
Preoperative entry to the operating room (n=118)	36.96±0.46	3.4	0.0	6.3	0.174
Following intubation (n=118)	36.51±0.56	11.0	1.9	18.8	0.009
60 minutes (n=118)	35.95±0.63	41.5	25.9	54.7	0.003
120 minutes (n=111)	35.92±0.76	52.3	32.0	68.9	<0.001
180 minutes (n=84)	35.90±0.87	51.2	22.9	71.4	<0.001
240 minutes (n=45)	35.86±0.97	48.9	11.8	71.4	<0.001
300 minutes (n=29)	36.24±0.99	37.9	9.1	55.6	0.019‡
360 minutes (n=20)	36.56±1.02	25.0	10.0	40.0	0.303‡
420 minutes (n=8)	36.38±0.75	12.5	25.0	0.0	NA†
480 minutes (n=4)	36.80±0.75	25.0	50.0	0.0	NA†
540 minutes (n=3)	36.33±0.94	0.0	0.0	0.0	NA†
600 minutes (n=1)	36.20	0.0	0.0	0.0	NA†
Entry to the recovery room (n=88)	36.33±0.75	38.1	20.5	55.6	0.003
Discharge to the ward (n=88)	36.08±0.78	38.3	20.4	53.1	0.001

*Hypothermia: The body temperature, measured by the SpotOn method, being less than 36°C

‡Fisher's Exact test: the bold figure indicates the significant difference.

†Since the number of patients whose operations continued after this minute was very low, the p value was not calculated.

Table 4. The results of comparison of the measurement methods in the course of time

	SpotOn	Other	p‡	r‡‡
Preoperative admission (n=118)	36.95±0.47	36.50±0.54*	<0.001	0.326
Preoperative entry to the operating room (n=118)	36.96±0.46	36.58±0.51*	<0.001	0.345
Intubation (n=118)	36.51±0.57	36.22±0.65†	<0.001	0.454
60 minutes (n=118)	35.95±0.63	35.89±0.62†	0.275	0.477
120 minutes (n=111)	35.92±0.76	35.81±0.68†	0.018	0.754
180 minutes (n=84)	35.90±0.87	35.77±0.81†	0.015	0.841
240 minutes (n=45)	35.86±0.97	35.83±0.99†	0.637	0.885
300 minutes (n=29)	36.24±0.99	35.97±0.97†	0.115	0.696
360 minutes (n=20)	36.56±1.02	36.35±0.94†	0.181	0.807
420 minutes (n=8)	36.37±0.75	36.35±0.63†	0.833	0.599
480 minutes (n=4)	36.80±0.94	36.85±0.70†	0.854	1.000
540 minutes (n=3)	36.33±0.94	36.63±0.40†	0.276	0.500
600 minutes (n=1)			NA	NA
Extubation (n=91)	36.34±0.75	36.15±0.78*	0.003	0.770
Entry to the recovery room (n=91)	36.12±0.76	36.06±0.80*	0.345	0.740
Discharge from the recovery room to the ward (n=91)	36.59±0.62	36.47±0.66*	0.078	0.495

*Tympanic measurement, †Oesophageal measurement, ‡T Test in independent groups. The bold figure shows the significant difference, ‡‡Correlation coefficient, the bold figure shows the significant difference. NA: Since the number of patients whose operations continued after this minute was very low, the p value was not calculated.

Discussion

The essential results of our study may be summed up as follows: the most significant risk factor for the intraoperative and postoperative hypothermia in major abdominal surgeries was not using prewarming in the patients using a standard warming protocol throughout the operation. Worsening of the ASA physical status score also increased the hypothermia rate significantly. Throughout the operation, the SpotOn measurement was strongly correlated with the oesophageal measurement, and there was no significant difference between the two methods; however, the SpotOn measurement method revealed significantly higher values than the other methods from the preoperative period to the time of intubation.

In their prospective study, Winslow et al. (12) found that the risk for unintentional hypothermia increased in the presence of risk factors such as old age, a BMI of >30, and low OR temperatures. However, we were not able to show any increase in risk with such factors. This difference between the studies may have originated from several factors. The average ASA was 1.9 (range 1-3) in our patient group whereas it was 2.7 (range 1-4) in their study group; thus, the ASA was higher in their study. Secondly, the preoperative site of measurement was different (they used the bladder temperature measurements for core temperature determination) concerning these two studies. Thirdly, the standard for maintenance of the OR temperature was different in the two studies; theirs was 22°C-24°C, ours was 21°C. They had used intraoperative warming in all patients as our study but in our study, we used a strict warming protocol. Since we used the prewarming protocol in 42% of our patients, we could make a comparison between the prewarming and not prewarming of the patients. Remarkably, the most significant risk factor found in our study was not warming the patient with a strict protocol throughout the operation.

Andrzejowski et al. (13) reported that warming the patient preoperatively resulted in less reduction of CBT in the intraoperative period, together with less inadvertent perioperative hypothermia. However, our results did not reveal any differences between the preoperatively warmed and not prewarmed patients; this might have been caused by the differences in the warming method and duration of warming (14). According to our study results, the increased ASA physical status score had a significant correlation with the higher rate of hypothermia. In accordance with our study, Belayneh et al. (15) showed that patients with higher ASA physical status scores had higher hypothermia risk. Kongsayreepong et al. (16) also found similar results regarding the ASA physical status score. However, in their study, besides higher ASA physical status score, the use of combined epidural and general anaesthesia and duration of surgery were reported as the other risk factors, which were found as irrelevant in our study. The difference between the results of the studies might have originated from variations in the time and place of measurement of CBT; theirs was at the time of admission to ICU, whereas our measurements were not obtained at that point. Our measurements were obtained only in the recovery room and were discharged to the ward.

We have not seen another study comparing the measurement method using 3M SpotOn sensors with the tympanic membrane and oesophageal measurement methods, as in ours. However, one of the several studies with 3M SpotOn sensors showed that the method was adequate when compared to the sublingual measurements (17). Another study compared the sublingual measurement to the tympanic membrane measurement and reported that the two measurement methods were highly correlated (18). Axillary et al. (19) in their comparison of the measurement methods, indicated that no significant difference was present between the oesophageal and tympanic membrane measurement methods.

The overall determination following the analysis of these studies would be that the SpotOn, tympanic, and oesophageal measurements revealed similar results concerning the medical literature. However, in our study, the SpotOn measurements were significantly higher than the tympanic measurement taken preoperatively and the oesophageal measurement following intubation. The difference was the greatest, particularly between the SpotOn and tympanic membrane measurements, during the entry to OR (0.85°C). This result might have originated from the preoperative warming of the patients; because of the effect of the applied external heating, the skin would still be warmer than the body core and would reflect such a difference. Although significant, the other differences were smaller than 0.5°C, not prohibiting the interchangeable clinical use.

The limitations of this study were that the sample size was too small to detect the small changes in temperature, and we could not compare the tympanic, oesophageal, and SpotOn temperatures for all the intervals because we did not measure the intraoperative tympanic temperature. Our surgical procedures were all major abdominal cancer surgeries, and we should consider different types of surgeries for further investigations.

Conclusion

The most significant risk factor was found to be not prewarming the patient with a strict protocol; as the ASA physical status score worsened, the rate of hypothermia increased significantly. Besides, the SpotOn method provided a temperature measurement that was as good as the oesophageal

temperature measurement. Since it performs the measurements non-invasively, we consider that the SpotOn method can be beneficial in situations such as head and neck surgery and oesophageal surgery in which the oesophageal temperature monitoring cannot be used.

Ethics Committee Approval: Ethics committee approval was received for this study from the ethics committee of Dokuz Eylül University Local Ethic Committee (ref:2015/16-15 2168-GOA).

Informed Consent: Written patients informed consent was obtained who participated in this study.

Peer-review: Externally peer-reviewed.

Author Contributions: Concept – H.A.E., S.Ö., C.T., A.K.D.; Design – S.Ö., H.A.E., C.T.; Supervision – S.Ö., C.T.; Resources – H.A.E., S.Ö., A.K.D.; Materials – S.Ö., A.K.D., C.T.; Data Collection and/or Processing – H.A.E., S.Ö., C.T., A.K.D.; Analysis and/or Interpretation – R.M.D., A.K.D., C.T., S.Ö.; Literature Search – H.A.E., S.Ö.; Writing Manuscript – H.A.E., S.Ö., R.M.D.; Critical Review – S.ö., C.T., H.A.E., A.K.D., R.M.D.; Other – R.M.D.

Conflict of Interest: The authors have no conflicts of interest to declare.

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