

BODY WRAP AND SYSTEM FOR INDUCING HYPOTHERMIA

TECHNICAL FIELD

[0001] The present subject matter relates, in general, to a body wrap and, in particular, to a body wrap and system for inducing hypothermia.

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BACKGROUND

[0002] Therapeutic hypothermia is a treatment technique for reducing a patient's body temperature and maintaining the lower temperature. Generally, therapeutic hypothermia is used to reduce damage caused to the patient's brain due to reduced blood flow caused due to various reasons, such as heart attack, stroke, neonatal asphyxiation, and the like. Typically, reducing the patient's body temperature, as part of first aid, is achieved by using ice packs, cold water blankets, and the like. Upon reaching a hospital, controlled hypothermia can be induced by using medical devices, such as cooling beds, or by using invasive techniques, such as injecting lactated Ringer's solution into the patient.

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BRIEF DESCRIPTION OF DRAWINGS

[0003] The detailed description is described with reference to the accompanying figures. In the figures, the left-most digit(s) of a reference number identifies the figure in which the reference number first appears. The same numbers are used throughout the drawings to reference like features and components.

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[0004] Fig. 1a illustrates a cross-section of a body wrap, in accordance with an implementation of the present subject matter.

[0005] Fig. 1b illustrates the cross-section of the body wrap comprising a Phase Change Material (PCM), in accordance with an implementation of the present subject matter.

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[0006] Fig. 2 illustrates the body wrap as viewed from a heat exchange layer side, in accordance with an implementation of the present subject matter.

[0007] Fig. 3 illustrates a system for inducing hypothermia, in accordance with an implementation of the present subject matter.

[0008] Fig. 4 illustrates components of a Thermo-Control Unit (TCU), in accordance with an implementation of the present subject matter.

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DETAILED DESCRIPTION

[0009] The present subject matter relates to a body wrap for inducing hypothermia in a patient.

[0010] The brain requires approximately 3.3 ml of oxygen per 100 g of brain
10 tissue per minute. Some medical conditions can cause reduced supply of oxygen to the brain. Reduction of oxygen to the brain may be caused due to heart attack, stroke, brain injury, birth asphyxiation, and the like.

[0011] Typically, in neonates, birth asphyxiation and related complication is a major cause of death. One complication of birth asphyxiation is called Hypoxic
15 Ischemic Encephalopathy (HIE). It is a condition where the baby's brain is starved of oxygen due to reduced blood flow causing permanent brain damage. On onset of HIE, babies may end up with brain disorders, such as cerebral palsy, mental retardation, and learning difficulties. HIE can also lead to multiple organ failure and ultimately to death. Although HIE is associated in most cases with oxygen
20 deprivation in the neonates due to birth asphyxia, it can occur in all age groups, and is often a complication of cardiac arrest.

[0012] Progression of HIE can be divided into a first phase and a second phase. During the first phase of deprivation of oxygen to the brain, the body responds by increasing blood supply upto twice the normal supply. If the increased blood supply
25 is not sufficient, then second phase of oxygen deprivation begins and symptoms of cerebral hypoxia, such as cognitive disturbances and decreased motor function, start to appear. It is during this second phase that neuronal damage occurs. Typically, a window period of 6-72 hours exists after the onset of the second phase during which

effective cooling of the patient's body can reduce neuronal damage and arrest the progress of HIE.

[00013] Therapeutic hypothermia is a treatment technique which involves cooling a patient's body and maintaining the patient at the lower temperature. Cooling the patient's body helps in reducing metabolic activity of the brain and release of neurotransmitters and, thereby reduces neuronal damage. Typically, body temperature is reduced to 33-34°C and the temperature is maintained for 72 hrs. Generally, to arrest progression of HIE, core body temperature must be reduced. Core body temperature is most effectively reduced by cooling the whole body rather than cooling individual parts of the body.

[00014] Generally, the patient's body temperature is reduced by using ice packs, cooling blankets, and the like. It is difficult to obtain feedback and maintain the temperature when cooling is done using ice packs, cooling blankets, and the like. For babies who have suffered from birth asphyxiation, they are cooled in whole-body cooling devices. These devices are usually bulky and require a high amount of power to work the refrigeration units in these devices. Moreover, these devices are usually not portable. Also, these devices are not usable in rural environments with minimal power supply and where birthing is usually done by midwives and not medical professionals who are skilled to operate these devices.

[00015] To overcome the above mentioned problems, the present subject matter provides a body wrap and a system for inducing hypothermia in a patient. The body wrap comprises a heat exchange layer, an insulating layer, and an intermediate layer comprising a plurality of channels between the heat exchange layer and the insulating layer. The heat exchange layer is for contact with a patient's body. The plurality of channels comprises a main channel along at least a periphery of the body wrap and a plurality of sub-channels. The main channel is connected to the plurality of sub-channels. The body wrap further comprises an inlet and an outlet at a bottom end of the body wrap. The inlet is for flow of coolant fluid into the main channel and the

outlet is for flow of the coolant fluid from the plurality of sub-channels. The body wrap also comprises a hood portion at a top end of the body wrap for wrapping around the patient's head.

5 [00016] The system for inducing hypothermia comprises the body wrap coupled to a thermo-control unit comprising a cooler which utilizes peltier effect to cool the coolant fluid. The body wrap and the thermo-control unit also includes a plurality of temperature sensors for servo-controlled temperature management to maintain temperature of the patient. The thermo-control unit also comprises a cerebral function monitor which monitors the electrical activities in the patient's brain.

10 [00017] The body wrap and the thermo-control unit of the present subject matter are simple and economic in construction. In addition to final care, for example at medical centers, as the body wrap and thermo-control unit are portable, they can be used as part of first aid and also for care during transportation to a medical care center. The body wrap and thermo-control unit are also easy to use and do not require
15 highly skilled technicians. The peltier cooling mechanism of the cooler in the thermo-control unit also ensures that power consumption is low and therefore can be used in resource deficient areas, such as rural areas. The body wrap also ensures that the patient is completely enclosed in the body wrap to provide a closed system for heat transfer. Also, the configuration of the body wrap and flow path of the coolant fluid
20 ensures that cooling is first provided to the brain to minimize neuronal damage to the brain.

[00018] The above and other features, aspects, and advantages of the subject matter will be better explained with regard to the following description, appended claims, and accompanying figures. It should be noted that the description and figures
25 merely illustrate the principles of the present subject matter along with examples described herein and, should not be construed as a limitation to the present subject matter. It is thus understood that various arrangements may be devised that, although not explicitly described or shown herein, embody the principles of the present

disclosure. Moreover, all statements herein reciting principles, aspects, and examples thereof, are intended to encompass equivalents thereof. Further, for the sake of simplicity, and without limitation, the same numbers are used throughout the drawings to reference like features and components.

5 [00019] Fig. 1a illustrates a cross-sectional view of a body wrap 100, in accordance with an implementation of the present subject matter. The cross-section is taken along X-X as indicated in Fig. 2. The body wrap 100 comprises a heat exchange layer 102, an insulating layer 104, and an intermediate layer 103 comprising a plurality of channels 106 (106a, 106b) between the heat exchange layer
10 102 and the insulating layer 104. The heat exchange layer 102 is for contact with a patient's body. The heat exchange layer 102 may be fabricated from biocompatible material which does not cause skin irritation upon contact with the skin. In one implementation, the heat exchange layer 102 is fabricated from polyurethanes, silicones, and the like.

15 [00020] The heat exchange layer 102 helps to exchange heat between the patient's body and a coolant fluid circulating in the plurality of channels 106. Further, the insulating layer 104 prevents heat transfer from atmosphere to the coolant fluid in circulation within the body wrap 100. In one implementation, the insulating layer 104 is fabricated from cellulose sheets, polystyrene sheets, and the like. In one
20 implementation, the heat exchange layer 102 and the insulating layer 104 are fabricated such that they are transparent or translucent, thereby providing ease in monitoring skin condition of the patient.

[00021] As mentioned above, the body wrap 100 includes a plurality of channels 106 in an intermediate layer 103 between the heat exchange layer 102 and the
25 insulating layer 104 for flow of coolant fluid. In one implementation, the coolant fluid is selected from the group consisting of water, de-ionized water, propylene glycol, and the like. The coolant fluid can comprise additives selected from the group consisting of potassium acetate, potassium formate, and the like. The coolant fluid

flows through the plurality of channels 106a, 106b. In one implementation, the intermediate layer 103 comprising the plurality of channels 106a, 106b is merged or integrated with the heat exchange layer 102. In the said implementation, the plurality of channels 106a, 106b are etched in the heat exchange layer 102 as open channels.

5 Placement of the insulating layer 104 on the heat exchange layer 102 forms the plurality of channels 106 for flow of coolant fluid. In another implementation, the plurality of channels 106a, 106b is merged or integrated with the insulating layer 104. In said implementation, the plurality of channels 106a, 106b are etched in the insulating layer 104 as open channels. Placement of the heat exchange layer 102 on

10 the insulating layer 104 forms the plurality of channels 106. In another implementation, the intermediate layer 103 is formed by interposing channel barriers 108 between the heat exchange layer 102 and the insulating layer 104 to form the plurality of channels 106a, 106b. The channel barriers 108a, 108b can be fabricated from insulating material or conducting material. In an implementation, the heat

15 exchange layer 102, the insulating layer 104, and the intermediate layer 103 comprising the plurality of channels 106 are held together by means of a plastic weld, a stitch, and the like.

[00022] The plurality of channels 106 comprises a main channel 106a and a plurality of sub-channels 106b. The main channel 106a is flow connected to the plurality of sub-channels 106b. The configuration of the plurality of channels 106 and the flow of coolant fluid through the plurality of sub-channels 106b will be explained in detail later. In operation, the body wrap 100 comprising the heat exchange layer 102, the insulating layer 104, and the intermediate layer 103 comprising the plurality of channels 106 helps in inducing hypothermia. To induce hypothermia, the body

20 wrap 100 is wrapped around the patient's body with the heat exchange layer 102 being in contact with the patient's body. The heat exchange layer 102 withdraws heat from the patient's body, thereby cooling the patient. The heat exchange layer 102 then transfers heat absorbed from the patient to the coolant fluid circulating through

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the plurality of channels 106. Therefore, the heat exchange layer 102 exchanges heat between the patient's body and the coolant fluid. The insulating layer 104 interfaces between the intermediate layer 103 with the atmosphere and prevents heat transfer between the coolant fluid and the atmosphere. The insulating layer 104, therefore, improves efficiency of heat exchange between the patient and the coolant fluid.

[00023] In one implementation, as illustrated in Fig. 1b, to increase the effectiveness of cooling, a Phase Change Material (PCM) layer 110 is placed between the heat exchange layer 102 and the plurality of channels 106. PCMs can absorb heat from the patient's body without changing their temperature substantially, thereby cooling the patient's body and increasing the effectiveness of the cooling by the coolant fluid. PCM can be selected from the group consisting of organic materials like polymers, waxes, and combinations thereof.

[00024] Fig. 2 illustrates a top view of the body wrap 100 as seen from the insulating layer 104 side, in accordance with an implementation of the present subject matter. Fig. 2 depicts the main channel 106a along at least a periphery 202 of the body wrap 100. The body wrap 100 further comprises an inlet 204 and an outlet 206 at a bottom end 208 of the body wrap 100. The inlet 204 is for flow of the coolant fluid into the body wrap 100 through the main channel 106a and the outlet 206 is for flow of the coolant fluid from the body wrap 100 through the plurality of sub-channels 106. In one implementation, the main channel 106a is separated from the plurality of sub-channels 106b by a main channel barrier 108b. The main channel barrier 108b can be fabricated from an insulating material to prevent heat transfer from the coolant fluid in the plurality of sub-channels 106b to the coolant fluid in the main channel 106a. In addition to the inlet 204 and the outlet 206, the body wrap 100 also comprises a hood portion 210 at a top end 212 of the body wrap 100 for wrapping around the patient's head. The body wrap 100 can be wrapped around the patient's body so as to form a closed system for heat transfer. In one example, the body wrap 100 includes a plurality of fasteners 218a, 218b, 218c, 218d, 218e, 218f to

prevent the body wrap 100 from opening after being wrapped around the patient's body and head.

[00025] Fasteners 218a, 218b are present at the hood portion 210 of the body wrap 100 to secure the hood portion to the patient's head. The body wrap 100 may also include fasteners 218c, 218d, 218e, 218f throughout a length of the body wrap 100 to ensure secure fastening around the patient's body. The plurality of fasteners 218 can be a Velcro, cellotape, and the like. In operation, after the body wrap 100 is secured around the patient's body and head, the coolant fluid is introduced into the body wrap 100.

10 [00026] The coolant fluid flows into the body wrap 100 through the inlet 204 into the main channel 106a to the hood portion 210. The coolant fluid, therefore, starts to cool the patient's brain before cooling the patient's body. Also, since the coolant has not substantially exchanged heat with the body before it reaches the hood portion 210, its cooling effectiveness is also high. At the hood portion 210, the main channel 15 106a opens into the plurality of sub-channels 106b. In an implementation, the plurality of sub-channels 106b are formed by curved channel barriers 108a. In another implementation, the plurality of sub-channels 106b are formed by segmented channels barriers 108a. In an implementation, the segmented channel barriers 108a and curved channel barriers 108a are provided in a zig-zag manner such that each segment is parallel to the other segments of the channel barrier 108a and substantially parallel to the periphery 202 of the body wrap 100 to form the plurality of sub-channels 106b.

20 [00027] The body wrap 100 and the plurality of sub-channels 106b constrict at a neck portion 214 of the body wrap 100. The constriction at the neck portion 214 slows the flow of fluid down from the hood portion and allows for longer heat exchange time between the coolant fluid and the patient's head, thereby increasing cooling. Beyond the neck portion 214, the plurality of sub-channels 106b further branch out for distribution of the coolant fluid through the body wrap 100 for uniform

cooling of the patient's body. In an implementation, beyond the neck portion, the plurality of sub-channels 106b are formed by curved channel barriers 108a. The coolant fluid flows from the neck portion 214 through a mid-portion 220 of body wrap 100. In an implementation, the plurality of sub-channels 106b in the mid-portion 220 of the body wrap 100 are formed by segmented channel barriers 108a arranged in a zig-zag manner such that each segment is parallel to the other segments of the channel barrier 108a and substantially parallel to the periphery 202 of the body wrap. From the mid-portion 220 of the body wrap 100 the coolant fluid flows into the outlet 206.

10 [00028] At the bottom end 218, the body wrap 100 is constricted allowing for higher heat exchange time between the coolant fluid and the patient's body, thereby providing uniform cooling of the patient. The configuration and flow of the coolant fluid as described provides uniform and rapid cooling of the patient. Further, the body wrap 100 provides a single structure that can be used to cool the whole body, thereby, reducing complexity in supplying and removing coolant fluid from the body wrap 15 100. In one implementation, the coolant fluid flows from the outlet 206 of the body wrap 100 to a thermo-control unit (TCU) coupled to the body wrap 100.

[00029] Fig. 3 illustrates a system 300 for inducing hypothermia, in accordance with an implementation of the present subject matter. The system 300 comprises a TCU 302 coupled to the body wrap 100. The TCU 302 includes an inlet port 304 flow coupled to the outlet 206 of the body wrap 100 and an outlet port 306 flow coupled to the inlet 204 of the body wrap 100 via coupling means 308. The coupling means 308 can be one of rubber tube, one-way snap-in connectors, and the like. The TCU 302 includes a plurality of sensors for sensing various parameters such as temperature, brain waves, and the like. The TCU 302 comprises an electroencephalogram (EEG) port 310 that couples EEG leads 312 to a cerebral function monitor present in the TCU 302. The EEG leads 312 are for placing on the patient's head to record and monitor brain waves of the patient.

[00030] The TCU 302 also includes a temperature sensing port 314 that couples a plurality of temperature sensors present on the body wrap 100 and on the patient to the microcontroller present in the TCU 302. The TCU 302 also includes a display 316 which displays the brain activity as provided by the cerebral function monitor, temperature measured by the plurality of temperature sensors, and other parameters. The TCU 302 also comprises a keyboard 318 to enable an operator to enter and set the values of parameters, such as cooling temperature to be maintained, cooling duration, and the like. In one implementation, the TCU 302 also interfaces with a rectal and an esophagus temperature probe to monitor Core Body Temperature (CBT) and to adjust the cooler 412 to heat or cool the coolant fluid to maintain the CBT. The rectal and the esophagus temperature probes or sensors may be integrated with the body wrap 100 or the TCU 302. Internal components of the TCU are as depicted in Fig. 4.

[00031] Fig. 4 depicts various internal components of the TCU 302, in accordance with an implementation of the present subject matter. The TCU 302 includes an inlet valve 402 internally at the inlet port 304 to receive the coolant fluid from the body wrap 100. The TCU 302 also includes a reservoir 404 to receive the coolant fluid from the inlet valve 402 during a treatment cycle and to store the coolant fluid during non-usage of the body wrap 100 and the TCU 302.

[00032] The reservoir 404 is coupled to a pressure sensor 406. The pressure sensor 406 is for measuring pressure of the coolant fluid in the reservoir 404 and communicating the measured pressure to the microcontroller 408. Based on the measured pressure and a required pressure set by the operator, the microcontroller 408 communicates with a pump 410 for pumping the coolant fluid from the reservoir 404 to a cooler 412. The pump 410 can be a brushless DC pump and the like. The pump 410 drives the coolant fluid flow within the body wrap 100 using positive pressure, thus, enabling a granular control over the flow of the coolant fluid.

[00033] The cooler 412 receives the coolant fluid from the reservoir 404. An inlet temperature sensor 414 and an outlet temperature sensor 416 are provided at an inlet and an outlet of the cooler 412. The inlet temperature sensor 414 and the outlet temperature sensor 416 measure temperature of the coolant at the inlet and outlet of the cooler 412 and communicate this to the microcontroller 408. In one implementation, the cooler 412 is a thermo-electric cooler which works on Peltier cooling mechanism. The cooler 412 can either cool or warm based on the direction of the current supplied to it. The direction of the current supplied is controlled by the microcontroller 408 as will be explained later. The peltier cooling allows for low power usage as compared to traditional refrigeration units. Further, the peltier cooling also allows for maintaining the temperature of the coolant fluid and thereby the Core Body Temperature within a small range of +/-0.5-degree Celsius. This further provides flexibility of usage in resource constrained areas and during transportation. Further, peltier cooling provides high cooling effectiveness, thereby, eliminating the need for introduction of turbulence creation mechanisms, making the system simpler and easier to manufacture and use. The cooler 412 is also coupled to a flow meter 418 at the outlet of the cooler 412.

[00034] The flow meter 418 measures a flow rate of the coolant fluid from the cooler 412 and communicates the measured flow rate to the microcontroller 408. Based on the measured flow rate and a flow rate set by the operator, the microcontroller controls an outlet valve 420 to increase or decrease the flow rate of the coolant fluid into the body wrap 100.

[00035] The TCU 302 also comprises a cerebral function monitor 422 which interfaces with the EEG leads 312 and records brain waves and the like as measured by the EEG leads 312. The EEG leads 312 are coupled to the cerebral function monitor 422 through the EEG sensing port 310. Based on the measured brain waves, the cerebral function monitor 422 displays an amplitude integrated EEG which is an aggregation of the brain activity over longer durations. In one implementation, data

obtained from the cerebral function monitor 422 can be analyzed by a medical professional during the treatment to prescribe and change the treatment protocol. In another implementation, the cerebral function monitor 422 analyzes the pattern of the waveforms, classifies them to diagnose severity of the HIE. The cerebral function monitor 422 can also provide a prognosis with and without the whole-body cooling treatment. In another implementation, the microcontroller 408 controls the cooler 412, the pump 410, the outlet valve 420 based on feedback provided by the cerebral function monitor 422 included in the TCU 302.

[00036] The TCU 302, therefore, comprises the electrical component. As the TCU 302 includes all the electrical components, the patient's body is electrically isolated, preventing damages caused due to electrical shocks and the like. Electrical isolation also ensures that there is no electrical or electromagnetic interference between different body signals, such as ECG, EEG, and any other device monitoring the patient. Interaction of the microcontroller 408 with the plurality of temperature sensors, pressure sensor 406, flow meter 418, and the outlet valve 420 is explained as follows.

[00037] In operation, the TCU 302 functions as follows. The microcontroller 408 of the TCU 302 is configured to maintain the patient's Core body temperature (CBT) at the set temperature. The set temperature is set by the operator. The operator can include medical professionals or other people. The set temperature is the temperature to which the patient's body is to be cooled. The microcontroller 308 is also configured to receive and set the set temperature, a set flow rate, and a set pressure. The microcontroller 308 is also configured to continuously receive the measured temperature from the plurality of temperature sensors corresponding to temperature of the coolant fluid in a reservoir and the patient's body temperature.

[00038] The microcontroller 408 is also configured to continuously receive the measured flow rates of the coolant fluid and measured pressure of the coolant fluid. The microcontroller 408 is further configured to compare the measured temperature,

the measured flow rate, and the measured pressure with the set temperature, the set flow rate, and the set pressure to obtain compared values. Based on the compared values, the microcontroller 408 is configured to control the cooler 412, the outlet valve 420, and the pump 410. In an implementation, the microcontroller 408
5 compares the CBT measured rectally or through esophagus to the set temperature. Based on the comparison, the microcontroller 408 controls the operation of the cooler 412. In one implementation, when the CBT is higher than the operator set temperature, the cooler cools the coolant. In another implementation, when the CBT temperature goes below the operator set temperature, the cooler can either reduces the
10 cooling or warms the coolant to restore the CBT to the set temperature. In an implementation, the microcontroller 408 provides servo-control, thereby, minutely controlling temperature of the coolant fluid based on CBT measured rectally or through esophagus.

[00039] In one implementation, the body wrap 100 of the present subject matter
15 maintains the CBT of the patient at 33.5°C for 72 hours. CBT can be brought down from the normal body temperature (~37) to 33.5 degrees in the first 30 mins. The body wrap 100 along with TCU 302 maintains the CBT at 33.5 °C with variations not exceeding +/- 0.2 degrees during the treatment period. In the subsequent 8 hours, the body wrap 100 can bring the CBT to normo-therm, i.e. 37°C, unless otherwise
20 advised by the medical practitioner. CBT is measured rectally or via the esophagus continuously. Skin temperature is also measured by the plurality of temperature sensors present on the body wrap and communicated to the microcontroller 408 continuously. Therefore, the body wrap 100 and the TCU can be used to effectively cool the patient's body and prevent the progression of HIE.

25 [00040] Although the subject matter has been described in considerable detail with reference to certain examples and implementations thereof, other implementations are possible. As such, the appended claims should not be limited to the description of the preferred examples and implementations contained therein.