UNIVERSIDAD DE LAS PALMAS DE GRAN CANARIA

Facultad de Ciencias de la Salud

Escuela de Doctorado de la ULPGC

Departamento de Ciencias Clínicas

TESIS DOCTORAL

PREVENCIÓN DE LA HIPOTERMIA PERIOPERATORIA EN CIRUGÍA UROLÓGICA

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Las Palmas de Gran Canaria, diciembre de 2021

AGRADECIMIENTOS

En primer lugar, quiero expresar mi agradecimiento al director de esta tesis, Aurelio Rodríguez Pérez, por sus consejos y por el apoyo que me brindó en este proceso; sus conocimientos, su motivación y su amor por la anestesiología son un verdadero ejemplo. A Lucía Valencia por ayudarme a encontrar la inspiración y la sonrisa cada día; sin duda, trabajar con ella lo ha hecho todo más sencillo y agradable. Asimismo, a Jesús Villar, por darle el enfoque y el empuje necesarios a esta investigación, y a Carlos Ferrando y Pedro Saavedra, por sus aportaciones en las diferentes publicaciones.

En segundo lugar, agradezco a la Universidad de Las Palmas de Gran Canaria y al Hospital Universitario de Gran Canaria Doctor Negrín los recursos que me han brindado para llevar a cabo este proyecto. Particularmente me gustaría agradecer a Aída Sánchez Morales, Mar Alonso, Raquel Gutiérrez, Estefanía Maldonado, Yurena Cardona y al resto del equipo de enfermería que me ha rodeado durante este tiempo, realizando la recogida de datos de una manera desinteresada y profesional, y al Servicio de Urología del Hospital Universitario de Gran Canaria Doctor Negrín su colaboración y la facilitación de datos. A mis compañeros anestesiólogos del Hospital Universitario de Gran Canaria Doctor Negrín, en especial Héctor Trujillo, Yurena Domínguez y Sergio Cabrera, su apoyo durante las 24 horas del día y a los residentes de mi servicio (especialmente a Marcos, Candela y Pedro) por ayudarme cada día a encontrar la motivación y la ilusión por mi trabajo.

Este proyecto se pudo realizar gracias a María del Carmen Bolaños Guerra y Fernando Becerra Ruiz. La constancia, el amor por crecer y la ilusión por aprender han sido y serán una constante en nuestra familia. Su apoyo incondicional y el ejemplo de mis hermanos, Antonio, Javier, África, Fernando, Juande y Pino, han sido fundamentales en la búsqueda del calor.

A mis sobrinos: Lucía, Daniel, Iván, Carolina, Fernando y Elisa, que seguirán nuestra estela

El objetivo de cualquier investigación en nuestro ámbito es encontrar soluciones a los problemas de los pacientes y proporcionarles la mejor atención, por lo que sin ellos esta no hubiera sido posible. A ellos va dirigido y dedicado este trabajo.

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PREVENCIÓN DE LA HIPOTERMIA PERIOPERATORIA EN CIRUGÍA UROLÓGICA

I. INTRODUCCIÓN

1. Hipotermia perioperatoria

Se define hipotermia perioperatoria al descenso de la temperatura central de los pacientes por debajo de 36ºC acontecido entre la inducción anestésica y el final de la cirugía.[1] Esta se considerará moderada cuando la temperatura se encuentre entre 36ºC y 35,5ºC y severa cuando sea inferior a 35,5ºC.

1.1. Prevalencia

La hipotermia inadvertida es el trastorno térmico más frecuente durante el perioperatorio, con una incidencia situada entre el 4% y el 90%, según las características del paciente, su manejo anestésico y el tipo de cirugía.[2 – 5] Ya en 1981 se reportó que el 60% de los pacientes tenían una temperatura < 36ºC al ingreso en la unidad de recuperación postanestésica.[6] El desarrollo tecnológico y el mayor conocimiento de las consecuencias derivadas del descenso perioperatorio de la temperatura deberían haber provocado un descenso en esta incidencia. Sin embargo, estudios más recientes señalan lo contrario.

Se ha analizado la prevalencia de hipotermia perioperatoria en diferentes grupos de pacientes. En un análisis retrospectivo que incluía a 2008 pacientes sometidos a duodenopancreatectomía entre 2007 y 2019, se apreció que el 55,7% sufrió hipotermia moderada y el 6%, hipotermia severa.[7] Otro estudio retrospectivo realizado entre 2010 y 2011 halló una incidencia de hipotermia del 74% en 255 pacientes sometidos a cirugía de resección de cáncer colorrectal.[8] Del mismo modo, en una investigación efectuada en 1714 pacientes sometidos a cirugía de *by-pass* coronario sin circulación extracorpórea durante un periodo de diez años (entre 2006 y 2016), se apreció que 722 pacientes (42,1%) sufrían hipotermia al final de la cirugía, situando al 7% de ellos en el rango de hipotermia severa.[9]

También se han llevado a cabo trabajos prospectivos con la intención de analizar el descenso de temperatura en diferentes tipos de cirugía bajo anestesia general. Un estudio observacional que incluía a 2015 pacientes mostró que la incidencia de hipotermia fue del 78,6%,[10] mientras que otra investigación realizada entre 2016 y 2018 que incluyó a 529 pacientes sometidos a cirugía abdominal programada bajo anestesia general de más de una hora de duración mostró una incidencia del 63,3%.[11] En Francia se realizó entre 2014 y 2016 un estudio multicéntrico en el que se incluyó a 928 pacientes en el que se concluyó que el 53,5% se encontraba hipotérmico al final de la cirugía. La mitad de estos pacientes (26%) sufría de hipotermia severa.[12]

En aquellos estudios cuyo objetivo era disminuir el descenso perioperatorio de la temperatura mediante la incorporación de métodos de prevención de hipotermia, se siguen encontrando incidencias elevadas. En esta línea se encuentra un análisis retrospectivo de pacientes sometidos a cirugía ortopédica en el que se comparaban dos medidas diferentes de calentamiento activo. La incidencia de hipotermia encontrada fue del 56,4% en los 307 pacientes en los que se había empleado calentamiento por medio de resistencias y del 50,4% en los 119 pacientes calentados mediante aire caliente forzado.[13] Sin embargo, es preciso señalar que, a pesar de las altas incidencias encontradas, la utilización de medidas preventivas de calentamiento durante el periodo perioperatorio ha demostrado reducir la aparición de hipotermia entre el 19% y el 24%.[14 – 16]

Una de las principales razones de la elevada incidencia de hipotermia perioperatoria podría ser la falta de monitorización de la temperatura. Un estudio asiático, en el que se valoraron 1154 encuestas sobre el manejo perioperatorio de la temperatura, señaló que el 32,5% de los respondedores contestó que no monitorizaba esta constante en pacientes bajo anestesia general, mientras que solo el 26,6% la monitorizaba en pacientes bajo anestesia espinal. El 34,3% refirió tener una disponibilidad limitada de dispositivos de monitorización de temperatura.[17] En nuestro ámbito también se realizó una encuesta a 116 anestesiólogos de tres hospitales de tercer nivel, en la que solo el 20% afirmó monitorizar sistemáticamente la temperatura durante el intraoperatorio, a pesar de que el 75% consideraba importante su medición.[18] Es preciso señalar que este último estudio data de 2016, es decir, previo a la publicación de las guías de práctica clínica de prevención de hipotermia perioperatoria de la Sociedad Española de Anestesiología y Reanimación.[19]

1.2. Fisiopatología

La regulación térmica es el mecanismo fisiológico por el que se mantiene el balance entre la producción y la eliminación de calor en nuestro organismo. En el paciente no anestesiado, el hipotálamo actúa como un termostato que regula la temperatura central hormonalmente en respuesta a los cambios de temperatura. Para llevar a cabo esta función, utiliza la información de la temperatura central proveniente de termorreceptores localizados en la médula espinal, los órganos abdominales y en el propio hipotálamo. Asimismo, los termorreceptores periféricos de la piel también realizan aferencias hacia el hipotálamo, llevando información sobre la temperatura a nivel periférico. Al recibir toda la información térmica proveniente de los receptores periféricos y centrales, el hipotálamo es finalmente el encargado de controlar la temperatura y mantenerla en un estrecho rango que permita la homeostasis adecuada del organismo.[20]

El descenso de la temperatura corporal que ocurre durante el periodo perioperatorio se debe principalmente a la redistribución de calor desde los compartimentos centrales hacia los compartimentos periféricos. La administración de fármacos anestésicos altera el control de la termorregulación llevado a cabo por el sistema nervioso autónomo, disminuyendo entre 2 y 4ºC el umbral para la activación de vasoconstricción.[21 – 23] Tras la inducción de la anestesia general, la vasoconstricción termorreguladora tónica se elimina, por tanto, como consecuencia de la inhibición central.

El otro factor importante que influye en la magnitud del descenso de la temperatura durante el perioperatorio es el gradiente térmico entre los compartimentos centrales y periféricos. El flujo de calor que va del núcleo a la periferia es proporcional a la diferencia de temperaturas entre ambos compartimentos.[23] Por tanto, la redistribución térmica será menor cuanto menor sea este gradiente. A pesar de que los compartimentos periféricos, compuestos por los brazos y las piernas, representan aproximadamente solo el 48% de la masa corporal total, la redistribución del calor desde los compartimentos centrales a los periféricos contribuye hasta un 81% a la caída de la temperatura, lo que supone una redistribución de unas 46 kcal durante la primera hora tras la inducción de la anestesia general.[24] La vasodilatación cutánea producida en el preoperatorio y la reducción del gradiente térmico entre tejidos centrales y periféricos que se produce durante el intraoperatorio limitan la magnitud de la redistribución térmica, reduciendo el descenso de temperatura en procedimientos de corta duración bajo anestesia general.[25]

En pacientes sometidos a anestesia regional, el descenso de la temperatura es tan pronunciado y frecuente como en pacientes sometidos a anestesia general.[26] Además de la redistribución del calor desde los compartimentos centrales hacia los periféricos, el bloqueo simpático secundario a la anestesia espinal o epidural altera de manera significativa la termorregulación corporal debido a la inhibición vasomotora y como consecuencia de la inhibición completa de la aparición de escalofríos en los miembros bloqueados.[27] Además, dado que la monitorización de la temperatura corporal es menos frecuente en pacientes sometidos a procedimientos bajo anestesia regional,[28] la hipotermia pasa desapercibida y por tanto es infradiagnosticada en muchos de estos pacientes.

1.3. Factores de riesgo de sufrir hipotermia perioperatoria

Múltiples estudios se han focalizado en detectar los principales factores de riesgo para sufrir un mayor descenso de la temperatura corporal durante el perioperatorio. A continuación, se señalan algunos de los principales factores de riesgo conocidos en la población adulta, diferenciando aquellos que son inherentes al paciente de aquellos que son dependientes de la cirugía y del manejo anestésico. Cabe resaltar que, por su propia naturaleza, la mayoría de los factores que dependen del paciente no son modificables. Por tanto, como anestesiólogos, tenemos la responsabilidad de actuar en la manera de lo posible en aquellos factores que son modificables con la intención de disminuir la prevalencia de hipotermia.

1.3.1. Factores de riesgo dependientes del paciente

- Edad mayor o igual a 70 años.[1,2,11,12,29,30] En la bibliografía parece sufícientemente constatado que las edades extremas constituyen uno de los principales factores de riesgo para sufrir hipotermia. Sin embargo, algunos estudios consideran que no hay suficiente evidencia para considerar este factor como factor de riesgo independiente.[20]
- Valoración de la escala de riesgo de la ASA (American Society of Anesthesiologists) mayor de I o presencia de comorbilidades.[1,2,11,29 – 32]
- Índice de masa corporal bajo[1,2,29,31] o pérdida importante de peso preoperatoria.[32] Por otro lado, aunque el sobrepeso se considera comúnmente un factor protector de sufrir hipotermia, un análisis prospectivo a 2015 pacientes concluyó que los pacientes hipotérmicos tenían un índice de masa corporal significativamente mayor que aquellos que no sufrían hipotermia.[10]
- Temperatura corporal preoperatoria baja.[1,20,33,34]

- Pacientes con quemaduras, traumas o ansiedad.[30]
- Sexo. Se ha postulado que ser mujer puede ser factor de riesgo,[30] aunque otros estudios señalan que ser varón predispone a sufrir mayor hipotermia en cirugía mayor abdominal.[11,32]

1.3.2. Factores de riesgo dependientes del procedimiento anestésico y de la cirugía

- Combinación de anestesia general y regional.[1,29] La anestesia espinal acelera la pérdida del calor.[20]
- Duración de la cirugía o de la anestesia.[2,11,12,30 – 35] La duración prolongada del procedimiento quirúrgico incrementa el tiempo de exposición al ambiente frío del quirófano, en el que el paciente presenta alteración de la termorregulación y durante el cual se puede producir la pérdida de calor al ambiente, así como la potencial pérdida de sangre y fluidos.[20]
- Cirugía mayor o intermedia.[1,29,35] Estas cirugías de mayor complejidad van a requerir normalmente un mayor tiempo quirúrgico y mayor exposición cutánea al ambiente.[20]
- Temperatura ambiente del quirófano baja.[1,30,33]
- Utilización de preparados cutáneos húmedos y exposición cutánea.[30]
- Utilización de fluidos de irrigación corporal fríos o a temperatura ambiente[30,36] o infusión de grandes cantidades (> 1000 ml) de fluidos intravenosos no calentados.[11,35]
- Importante intercambio de fluidos intraoperatorios[30] o transfusión perioperatoria.[11]
- Premedicación con benzodiacepinas.[12]

Como se puede apreciar, son múltiples los potenciales factores de riesgo que se han definido a lo largo de los años. Sin embargo, es interesante señalar que algunas publicaciones se contradicen entre sí a la hora de establecer un factor como de riesgo. Por tanto, debido a la imposibilidad de eliminar las variables de confusión, no existe actualmente evidencia suficiente para correlacionar cualquier variable de manera independiente como factor individual causal del incremento del riesgo a sufrir hipotermia durante el perioperatorio.[20] La individualización y la detección de aquellos pacientes que podrían estar predispuestos permitiría establecer medidas dirigidas a disminuir el descenso de temperatura en cada caso concreto.

1.4. Complicaciones secundarias a la hipotermia perioperatoria

La hipotermia, debido a que altera la función enzimática, prolonga la acción de diversos fármacos, entre los que se encuentran los bloqueantes neuromusculares. Además, incrementa la concentración plasmática de propofol debido a la reducción del flujo sanguíneo hepático. Esta alteración farmacológica puede prolongar el tiempo de recuperación postanestésica en pacientes hipotérmicos.[37]

El descenso de la temperatura corporal incrementa el riesgo de sufrir escalofríos postoperatorios, una de las causas más importantes de malestar del paciente. La presencia de escalofríos puede ser incluso peor que la del propio dolor postoperatorio, ya que los pacientes hipotérmicos tienden a concentrarse en el frío y en los escalofríos, en lugar de en el dolor.[37] Esta aparición de escalofríos provoca insatisfacción del paciente,[38] además de incremento del consumo de oxígeno y de la intensidad del dolor postoperatorio.[25,37]

La hipotermia también ha demostrado aumentar el riesgo de sangrado perioperatorio,[39] debido a la alteración de la función plaquetaria, de los factores implicados en la cascada de la coagulación y la fibrinólisis.[25,40,41] Aunque el número de plaquetas se mantenga normal en estos pacientes, su función se encuentra alterada a nivel local, con la consecuente disminución de la liberación de las enzimas que favorecen la agregación.[25] La coagulopatía hipotérmica no es diagnosticable en las pruebas de coagulación convencionales, ya que estas se realizan en condiciones *in vitro* a 37ºC, lejos de la temperatura real del paciente. Se ha descrito que la reducción de la temperatura puede incrementar la pérdida sanguínea un 20%.[37] Sin embargo, algunos autores ponen en duda que estas alteraciones hematológicas tengan alguna repercusión clínica,[42,43] tal vez como consecuencia de que ha mejorado la técnica quirúrgica y que los procedimientos son cada vez menos invasivos. Fuera de toda duda queda el hecho de que el mantenimiento de la normotermia reduce el sangrado perioperatorio.[44,45]

La hipertensión inducida por el frío se asocia con un incremento en las concentraciones plasmáticas de noradrenalina, que aumenta la irritabilidad cardíaca y facilita el desarrollo de arritmias ventriculares e isquemia miocárdica.[25] Sin embargo, el mecanismo exacto por el cual la hipotermia desencadena eventos miocárdicos no está claro. Incluso en aquellos casos en los que la hipotermia postoperatoria es leve y de corta duración, su aparición se ha asociado con un aumento de la mortalidad en pacientes sometidos a cirugía de *by-pass* de arteria coronaria sin circulación extracorpórea.[9]

El descenso de la temperatura también incrementa el riesgo de sufrir infección de herida quirúrgica.[46] La vasoconstricción local disminuye la tensión de oxígeno a nivel subcutáneo.[25] La función inmune se encuentra alterada en estos pacientes de manera indirecta, debido a la vasoconstricción subcutánea, la hipoxia tisular[25] y la disminución de la motilidad de los macrófagos.[37] Además, la hipotermia altera de manera directa la función inmune, afectando la producción de anticuerpos mediada por linfocitos T y la muerte bacteriana oxidativa a cargo de neutrófilos. Por otro lado, la hipotermia puede producir alteraciones en la cicatrización de la anastomosis pancreático-yeyunal, incrementando el riesgo de fístula pancreática tras duodenopancreatectomía.[7]

2. Prevención de la hipotermia perioperatoria

Entre los mecanismos para la prevención de la hipotermia perioperatoria es preciso diferenciar aquellos que provocan un calentamiento activo mediante la transferencia de calor al paciente (mantas de aire caliente forzado, mantas eléctricas, calentadores por radiación, colchón de agua, mantas calentadas, calentador de fluidos, humidificadores térmicos o intercambiador de calor y humedad) de aquellos que producen un aislamiento térmico del paciente para evitar la pérdida de calor hacia el ambiente (mantas o ropa reflectante).[47]

En 2015 se publicó en Alemania una "Guía de práctica clínica para la prevención de la hipotermia inadvertida perioperatoria" (*German S3 guideline*). En ella se establece que el calentamiento activo previo a la inducción anestésica es muy eficaz para prevenir la hipotermia perioperatoria (recomendación fuerte). Además, se recomienda que este precalentamiento dure de 10 a 30 minutos en pacientes que van a ser sometidos a anestesia general (recomendación fuerte). Sin embargo, el grado de recomendación en cuanto al precalentamiento en aquellos pacientes que van a ser sometidos a anestesia epidural o espinal disminuye a débil.[1] Dos años más tarde, se publicaron unas recomendaciones para implementar el uso de esta guía y facilitar su puesta en práctica, en la que se recomienda realizar un precalentamiento durante 20–30 minutos si es posible, aunque también se reconoce que tan solo 10 minutos de precalentamiento puede ser efectivo en pacientes que van a ser sometidos a anestesia general (recomendación fuerte). Además, se remarca que el precalentamiento puede ser suficiente en intervenciones quirúrgicas de menos de una hora de duración, con lo que se evita utilizar medidas de calentamiento activo durante el intraoperatorio. Asimismo, también recomienda calentar activamente a los pacientes previo a la aplicación de la anestesia espinal, aunque esta recomendación sigue siendo débil.[48]

Esta guía alemana estaba ampliamente fundamentada en las guías americana y canadiense publicadas en 2009.[49,50] En la guía americana se recomienda valorar el riesgo de cada paciente de padecer hipotermia perioperatoria, medir la temperatura preoperatoria, implementar medidas de calor pasivo en todos los pacientes y considerar el precalentamiento para reducir el riesgo de hipotermia durante los periodos intra y postoperatorio. Aunque estas recomendaciones sobre el uso del precalentamiento se basaban en datos aportados por pocos estudios y en poblaciones limitadas, se refuerza la idea de que el beneficio de utilizar el precalentamiento es igual al riesgo. Según esta guía un mínimo de 30 minutos de precalentamiento podría reducir el riesgo de hipotermia subsecuente.[49] Por su parte, la guía canadiense recomienda el calentamiento activo con aire caliente forzado durante el intraoperatorio en todas las cirugías abdominales de más de 30 minutos de duración y reconoce que el precalentamiento con aire caliente forzado ralentiza el descenso de la temperatura intraoperatoria y previene la hipotermia perioperatoria cuando se combina con un calentamiento activo intraoperatorio. No se especifica la duración óptima del precalentamiento.[50]

El *National Institute for Health and Clinical Excellence* (NICE) había publicado ya en 2008 la "Guía de práctica clínica para el manejo de hipotermia perioperatoria inadvertida en adultos", en la que se concluye que existe aceptable evidencia que demuestra una menor incidencia de hipotermia al ingreso en la URPA con el uso de calentamiento con aire forzado durante el periodo preoperatorio en comparación con las mantas de aislamiento térmico. Asimismo, se recomienda aplicar aire caliente forzado durante el intraoperatorio en los pacientes sometidos a anestesia general para obtener temperaturas centrales significativamente más altas durante el intraoperatorio a los 30, 60, 120 minutos (evidencia aceptable), a los 180 minutos (evidencia débil) y al ingreso en las unidades de cuidados intensivos (evidencia fuerte). Sin embargo, en pacientes bajo anestesia regional, se concluye que la evidencia en cuanto a la aplicación del calentamiento con aire forzado en la parte superior del cuerpo durante el intraoperatoria para obtener una temperatura significativamente más alta al final de la cirugía es débil.[47] Estas mismas guías se actualizaron posteriormente en 2016, para especificar que en los pacientes de mayor riesgo de sufrir una pérdida de temperatura debe iniciarse el calentamiento activo desde el preoperatorio, ya sea en la sala de hospitalización o en urgencias si su temperatura es inferior a 36° C. Se consideran pacientes de riesgo a quienes cumplan al menos dos de las siguientes condiciones: ASA > I, riesgo de complicaciones cardiovasculares, temperatura preoperatoria < 36° C, pacientes que vayan a someterse a anestesia combinada general y regional, o cirugía mayor – intermedia. En el caso de que la temperatura del paciente sea 36° C o superior, el calentamiento activo debe iniciarse al menos 30 minutos antes de la inducción de la anestesia, a menos que esto retrase la cirugía de emergencia. En todos los pacientes, el calentamiento activo debe mantenerse durante toda la fase intraoperatoria.

En 2018, la SEDAR publicó la “Guía de práctica clínica de hipotermia perioperatoria no intencionada”, en la que se recomienda el uso de algún método activo de prevención de la hipotermia durante el perioperatorio en las personas adultas que van a ser sometidas a cirugía que requieran anestesia general o regional (recomendación fuerte). Además, se sugiere el uso de sistemas de calentamiento activo durante el preoperatorio, al menos 30 minutos previo a la inducción anestésica, en pacientes que van a ser sometidos a cirugía bajo anestesia local o general (recomendación débil). Este calentamiento debe priorizarse en aquellos pacientes de riesgo: ASA II – V, anestesia general, mayor riesgo vascular, edad superior a 50 años o temperatura preoperatoria < 36ºC.[19]

2.1. Precalentamiento mediante aire caliente forzado

Los dispositivos de aire caliente forzado distribuyen aire calentado a la temperatura seleccionada desde una unidad central, a través de una cobertura desechable específicamente diseñada para transferir calor a la superficie corporal del paciente, evitando la pérdida de calor que se produce como consecuencia de la radiación y la convección.[1] En el paciente despierto, existe un gradiente de temperatura natural entre los compartimentos centrales y periféricos de unos 5 – 8ºC. Al administrar calor a la superficie corporal antes de la inducción anestésica, se transfiere calor a la superficie cutánea y se reduce este gradiente, de modo que disminuye el descenso inicial de temperatura como consecuencia de la redistribución térmica tras la inducción.[1] Por tanto, el mayor efecto del precalentamiento con dispositivos de aire caliente no se debe al propio incremento de la temperatura corporal, sino a que reduce la redistribución del calor entre los compartimentos periféricos y centrales al igualar las temperaturas de estos compartimentos.[51]

Las mantas de aire caliente forzado son el método de calentamiento corporal más utilizado, seguro y coste-efectivo y solo su uso combinado para el precalentamiento y el calentamiento intraoperatorio ha logrado demostrar prevenir el descenso de temperatura corporal por debajo de 36ºC al ingreso en la unidad de recuperación postanestésica.[12]

2.2. Duración óptima del precalentamiento

El tiempo ideal durante el que se debe aplicar el precalentamiento previo a la inducción anestésica ha sido un tema largamente investigado en los últimos años. Los primeros estudios se basaban en que el calentamiento con aire caliente forzado transfería calor al cuerpo; así, a mayor duración de precalentamiento, mejor prevención de la hipotermia perioperatoria. Por ello, los primeros estudios utilizaban tiempos de precalentamientos de larga duración: 120,[52] 90[51] o 60 minutos,[53] sustentando en toda hipótesis inicial que el precalentamiento durara al menos 60 minutos. Otras investigaciones posteriores observaron que el precalentamiento durante una hora no lograba prevenir completamente la hipotermia, aunque atenuaba el descenso de la temperatura.[54,55] Debido a la ineficiencia que supondría realizar un calentamiento activo de tan larga duración previo a la inducción anestésica, se realizaron posteriormente otros estudios para dilucidar cuál sería el tiempo óptimo de precalentamiento. Así, se observó que el calentamiento de aire forzado activo durante solo 30 minutos antes de la inducción anestésica reducía el descenso de temperatura perioperatoria en pacientes sometidos a anestesia general[56 – 59] y que incluso 10 minutos de precalentamiento podría reducir la caída de temperatura y la presencia de escalofríos postoperatorios.[60,61]

Los primeros artículos publicados sobre el precalentamiento lograron un menor efecto a pesar de que la duración de precalentamiento era más prolongada que la utilizada en los publicados posteriormente, que lograron demostrar que, con tiempos de precalentamiento más cortos, también se disminuía la hipotermia por redistribución. Esto puede deberse a que tiempos de precalentamiento largos pueden provocar una mayor vasodilatación periférica y, por tanto, una mayor pérdida de calor corporal. Por otro lado, es preciso tener en cuenta que los segundos trabajos fueron publicados posteriormente a la instauración de las guías de práctica clínica, en las que se recomendaba la utilización del calentamiento activo intraoperatorio en las cirugías de larga duración.

Se ha investigado mucho menos el efecto del precalentamiento en pacientes sometidos a cirugía de corta duración. Teniendo en cuenta que la pérdida de calor es más acusada durante la primera hora intraoperatoria, en las cirugías de menos de una hora de duración, su efecto podría ser incluso más importante que en las cirugías de larga duración.[62] Una vez la temperatura ha descendido, revertir la hipotermia durante el intraoperatorio se ve dificultado por el tiempo necesario para que el calor administrado llegue desde los compartimentos periféricos a los centrales y disminuya el gradiente térmico entre compartimentos. La corta duración del procedimiento no permitiría que el calentamiento aplicado únicamente durante el periodo intraoperatorio compense la hipotermia por redistribución. No es de extrañar, por tanto, que el precalentamiento lograra también disminuir el descenso de temperatura y sus efectos secundarios en las pocas investigaciones que se han realizado en cirugías de corta duración.[63 – 65]

II. JUSTIFICACIÓN

La resección transuretral es un procedimiento realizado usualmente en varones, de edad avanzada y con múltiples comorbilidades, por lo que están en riesgo elevado de sufrir hipotermia durante el perioperatorio. Por otro lado, el abordaje laparoscópico de otras intervenciones urológicas como la prostatectomía o la nefrectomía ha demostrado disminuir el sangrado perioperatorio, la infección de herida quirúrgica o la estancia hospitalaria. Por ello, el descenso de la temperatura puede desencadenar en pacientes con comorbilidades previas la aparición de complicaciones, tales como complicaciones cardiacas o hemorrágicas y contrarrestar los beneficios secundarios a la técnica laparoscópica. La prevención de la aparición de hipotermia perioperatoria debería ser obligatoria en pacientes sometidos a intervenciones urológicas.

La elevada prevalencia de la hipotermia perioperatoria y las graves complicaciones asociadas a su aparición hacen necesario incorporar en la práctica clínica métodos para prevenir el descenso de la temperatura corporal durante el intraoperatorio. Además, las medidas empleadas para la prevención de la hipotermia (precalentamiento) deben ser compatibles con la actividad diaria en quirófanos de procedimientos de corta duración, en los que se deben optimizar los tiempos perioperatorios y minimizar el retraso de la inducción anestésica. Por ello, es preciso establecer cuál es el tiempo de precalentamiento óptimo y de menor duración en pacientes sometidos a intervenciones urológicas, tanto de larga como de corta duración para disminuir el descenso de temperatura durante el periodo perioperatorio y sus consecuencias.

III. OBJETIVOS

Objetivos primarios:

- Valorar el efecto de diferentes tiempos de precalentamiento con aire caliente forzado de corta duración (15, 30 o 45 minutos) en la temperatura perioperatoria de pacientes intervenidos de resección transuretral bajo anestesia espinal.

- Analizar el efecto de diferentes tiempos de precalentamiento con aire caliente forzado de corta duración (5 – 15 o 15 – 30 minutos) en la temperatura perioperatoria de pacientes sometidos a cirugía urológica laparoscópica.

- Estudiar el efecto de diferentes tiempos de precalentamiento con aire caliente forzado de corta duración (15, 30 o 45 minutos) en la prevención del descenso de temperatura perioperatoria de pacientes intervenidos de resección transuretral bajo anestesia general.

Objetivos secundarios:

- Dimensionar el efecto de diferentes tiempos de precalentamiento con aire caliente forzado de corta duración (15, 30 o 45 minutos) en la duración de estancia en la unidad de recuperación postanestésica y en la incidencia de escalofríos postoperatorios en pacientes intervenidos de resección transuretral bajo anestesia espinal.

- Establecer la relación entre diferentes variables perioperatorias y una menor temperatura al final de la cirugía en cirugía urológica laparoscópica.

- Evaluar el impacto de diferentes tiempos de precalentamiento con aire caliente forzado de corta duración (5 – 15 o 15 – 30 minutos) en la aparición de escalofríos postoperatorios; la duración de la estancia en la unidad de recuperación postanestésica; la aparición de complicaciones postoperatorias y la evolución postoperatoria del paciente en pacientes sometidos a cirugía urológica laparoscópica.

- Valorar la prevalencia de hipotermia a la llegada a unidad de recuperación postanestésica en diferentes grupos de precalentamiento con aire caliente forzado de corta duración (15, 30 o 45 minutos) en pacientes intervenidos de resección transuretral bajo anestesia general.

- Examinar el efecto de diferentes tiempos de precalentamiento con aire caliente forzado de corta duración (15, 30 o 45 minutos) en disminuir la incidencia de escalofríos postoperatorios, la intensidad del dolor postoperatorio, la estancia en la unidad de recuperación postanestésica y las complicaciones postoperatorias de pacientes intervenidos de resección transuretral bajo anestesia general.

IV. PUBLICACIONES

Resúmenes y conclusiones

SCIENTIFIC REPORTS
natureresearch

Prospective observational study of the effectiveness of prewarming on perioperative hypothermia in surgical patients submitted to spinal anesthesia

Ángel Becerra[1,2*], Lucía Valencia[1], Carlos Ferrando[3,4], Jesús Villar[3,5] & Aurelio Rodríguez-Pérez[1,2]

Título: Prospective observational study of the effectiveness of prewarming on perioperative hypothermia in surgical patients submitted to spinal anesthesia.

Autores: Ángel Becerra, Lucía Valencia, Carlos Ferrando, Jesús Villar, Aurelio Rodríguez-Pérez

Publicado el 11 de noviembre de 2019 en Scientific Reports, Q1 (Journal Citation Reports), Factor de impacto: 3.998 (2019):

Sci Rep. 2019; 9: 16477. doi: 10.1038/s41598-019-52960-6

Resumen en castellano:

Introducción: El precalentamiento ha demostrado prevenir la hipotermia inadvertida intraopera-toria, aunque la mayoría de los estudios que avalan esta idea se han realizado en pacientes sometidos a anestesia general. Existe aún poca evidencia sobre la importancia del precalentamiento en pacientes sometidos a anestesia regional, ya que la mayoría de los estudios realizados sobre hipotermia perioperatoria en esta población se ha focalizado en la importancia del calentamiento activo intraoperatorio.

Objetivos:

- Valorar el efecto de diferentes tiempos de precalentamiento con aire caliente forzado (15, 30 o 45 minutos) en la temperatura perioperatoria de pacientes intervenidos de resección transuretral bajo anestesia espinal.

- Evaluar el efecto de estos tiempos de precalentamiento en la estancia en la unidad de recuperación postanestésica y en la incidencia de escalofríos postoperatorios.

Registro en Clinicaltrials.gov: NCT 03527329

Métodos: Estudio observacional prospectivo en varones consecutivos programados de forma electiva para resección transuretral de vejiga o próstata bajo anestesia espinal entre marzo de 2014 y abril de 2015. Tras la medición de la temperatura timpánica, los pacientes eran precalentados por la enfermería que los recibía en el antequirófano durante un tiempo no establecido de antemano de la siguiente manera: si la estancia en el antequirófano se estimaba inferior a

cinco minutos, el paciente no era precalentado (non-pw), mientras que el resto de pacientes fueron clasificados en tres grupos según la duración del precalentamiento: menos de 15 minutos (pw15), entre 15 y 30 minutos (pw30) y entre 30 y 45 minutos (pw45). El anestesiólogo responsable del manejo clínico de los pacientes desconocía la duración del precalentamiento. Durante el intraoperatorio, todos los pacientes recibieron calentamiento activo mediante aire caliente forzado y la temperatura timpánica se registró cada 15 minutos. En el postoperatorio, se valoró la presencia de escalofríos a la llegada a la unidad de recuperación postanestésica y la duración de la estancia en la unidad.

Resultados: Los 140 pacientes incluidos fueron clasificaron en diferentes grupos: 56 en non-pw, 34 en pw15, 29 en pw30 y 21 en pw45. Las características de los pacientes fueron similares entre los grupos. La temperatura tras el precalentamiento en los grupos pw15 y pw30 fue 0,23ºC y 0,44ºC superior al grupo non-pw ($p = 0,02$ y $p < 0,001$ respectivamente). Al final de la cirugía la temperatura de los pacientes incluidos en el non-pw fue 35,04ºC, mientras que en los grupos pw15 y pw30 fue 0,49ºC y 0,59ºC más alta ($p < 0,001$). A pesar de que las temperaturas tras el precalentamiento y al final de la cirugía también fueron superiores en el grupo pw45 en comparación con el grupo non-pw, estas diferencias no fueron estadísticamente significativas.

El 96,4% de los pacientes no precalentados estaban hipotérmicos al final de la cirugía, siendo este porcentaje estadísticamente superior a los encontrados en los grupos pw15 (73,5%, $p = 0,002$) y pw30 (75,9%, $p = 0,006$). El 90,5% de los pacientes del pw45 sufría hipotermia al final de la cirugía. El 42,5% de los pacientes del grupo non-pw padeció escalofríos postoperatorios, en comparación con ningún paciente de los grupos pw15 y pw30 ($p < 0,001$) y el 9,5% de los pacientes de pw45 ($p = 0,006$). Además, la duración de la estancia en la unidad de recuperación postanestésica fue mayor en los pacientes non-pw que en los pacientes pw15 ($p = 0,015$) y pw30 ($p = 0,011$).

Conclusiones: El precalentamiento con aire caliente forzado de corta duración (inferior a 30 minutos) logró reducir el descenso de la temperatura perioperatoria, la aparición de hipotermia al final de la cirugía, la estancia en la unidad de recuperación postanestésica y la incidencia de escalofríos postoperatorios en pacientes sometidos a resección transuretral bajo anestesia espinal.

Journal of
Clinical Medicine

Article

Short-Periods of Pre-Warming in Laparoscopic Surgery. A Non-Randomized Clinical Trial Evaluating Current Clinical Practice

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Título: Short-Periods of Pre-Warming in Laparoscopic Surgery. A Non-Randomized Clinical Trial Evaluating Current Clinical Practice.

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Publicado el 3 de marzo de 2021 en Journal of Clinical Medicine, Q1 (Journal Citation Reports), Factor de impacto: 4.242 (2020):

J Clin Med. 2021; 10: 1047. doi: 10.3390/jcm10051047.

Resumen en castellano:

Introducción: El abordaje laparoscópico ha demostrado disminuir múltiples complicaciones postoperatorias. Sin embargo, el descenso perioperatorio de la temperatura puede contrarrestar los beneficios de esta técnica quirúrgica. A pesar del auge de la cirugía laparoscópica, aún se desconoce qué efecto tiene el precalentamiento en la temperatura corporal de pacientes sometidos a este tipo de cirugía, cuál es su duración óptima y qué efecto puede tener en reducir la aparición de complicaciones postoperatorias.

Objetivos:

- Valorar el efecto de diferentes tiempos de precalentamiento con aire caliente forzado (5 – 15 o 15 – 30 minutos) en la temperatura perioperatoria de pacientes sometidos a cirugía urológica laparoscópica.

- Evaluar la relación entre diferentes variables perioperatorias y presentar temperatura corporal menor al final de la cirugía.

- Valorar el impacto de estos tiempos de precalentamiento en la aparición de escalofríos postoperatorios, la estancia en la unidad de recuperación postanestésica, la aparición de complicaciones postoperatorias y la evolución del paciente.

Registro en Clinicaltrials.gov: NCT 03617809

Métodos: Estudio observacional prospectivo en varones consecutivos programados de forma electiva para prostatectomía o nefrectomía laparoscópica entre agosto de 2018 y octubre de 2019. Tras la medición de la temperatura timpánica, los pacientes eran precalentados en el antequirófano por enfermería. La duración del precalentamiento dependía del tiempo que el paciente iba a estar en el antequirófano: si se estimaba inferior a cinco minutos, el paciente no era precalentado (grupo P0); los demás pacientes eran precalentados de cinco a 15 minutos (P5–15) o durante 15 – 30 minutos (P > 15). El anestesiólogo responsable del manejo clínico del paciente desconocía la duración del precalentamiento. Tras el precalentamiento se medía de nuevo la temperatura timpánica y se realizaba la inducción anestésica. Todos los pacientes recibían calentamiento activo intraoperatorio mediante aire caliente forzado y se registraba la temperatura esofágica cada 15 minutos durante la primera hora intraoperatoria y luego cada 30 minutos hasta el final de la cirugía. Durante el postoperatorio, se registró la temperatura timpánica durante la primera hora, la presencia de escalofríos en el postoperatorio inmediato, la intensidad del dolor a los 30 minutos y la estancia en la unidad de recuperación postanestésica. Además, se registró la hemoglobina al primer día postoperatorio, los requerimientos transfusionales postoperatorios y la aparición de complicaciones postoperatorias, tales como infección de herida quirúrgica o íleo.

Resultados: Se incluyeron 99 pacientes, 33 en cada grupo. Las características de los pacientes eran similares en los tres grupos. Tras el precalentamiento la temperatura fue superior en los pacientes del grupo P > 15 (0,4ºC [IC 95% 0,14–0,69ºC], p = 0,004) que en el P0. Esta temperatura también fue superior en el grupo P 5 – 15 (0,2ºC [IC 95% 0,04 – 0,55ºC], pero no estadísticamente significativa (p = 0,093). Durante el intraoperatorio, ambos grupos de pacientes precalentados mostraron una temperatura superior al grupo no precalentado. Al final de la cirugía, la temperatura de los pacientes incluidos en el P0 fue 35,8 ± 0,8ºC, siendo esta temperatura superior en los grupos P 5 – 15 (0,5ºC [IC 95% 0,13–0,81ºC], p = 0,007) y P > 15 (0,9ºC [IC 95% 0,55 – 1,19ºC], p < 0,001). La temperatura de los pacientes precalentados fue superior durante la primera hora de su estancia en la unidad de recuperación postanestésica en comparación con los pacientes no precalentados (p < 0,0001).

Entre las variables relacionadas con la temperatura al final de la cirugía, se encontró una relación estadísticamente significativa directamente proporcional con el área de superficie corporal, el gasto metabólico basal, la hemoglobina preoperatoria, la temperatura preoperatoria, la temperatura ambiente del quirófano y la duración de la anestesia; e inversamente proporcional con la fluidoterapia administrada y el sangrado intraoperatorio.

A la llegada a la unidad de recuperación postanestésica, la hipotermia afectaba al 48,5% de los pacientes en P0, el 33% de los pacientes en P 5 – 15 (RR 1,88 [IC 95% 0,69–5,09], p = 0,211) y el 6% de los pacientes en P > 15 (RR 14,58 [IC 95% 2,99–71,15], p < 0,001). Además, los pacientes precalentados presentaron menor incidencia de escalofríos postoperatorios (p < 0,001) y menor intensidad de dolor (p = 0,001). Durante la estancia hospitalaria postoperatoria, los pacientes del grupo P > 15 recibieron menos transfusiones (p = 0,01) y presentaron una menor incidencia de infección de herida quirúrgica (p = 0,039). Sin embargo, no hubo diferencias entre los distintos grupos en cuanto al sangrado intraoperatorio, la hemoglobina postoperatoria, el descenso de la hemoglobina perioperatoria, la estancia en la unidad de recuperación postanestésica, la estancia hospitalaria o la presencia de otras complicaciones postoperatorias.

Conclusiones: El precalentamiento con aire caliente forzado durante 5 – 15 minutos y 15 – 30 minutos reduce la hipotermia intraoperatoria y este efecto se mantiene hasta la primera hora postoperatoria en pacientes sometidos a cirugía urológica laparoscópica. Además, el precalentamiento durante 15 – 30 minutos incrementó la temperatura corporal previo a la inducción y redujo la incidencia de hipotermia a la llegada a la unidad de recuperación postanestésica. Ambos periodos de precalentamiento de corta duración lograron disminuir la incidencia de escalofríos y la intensidad del dolor en la unidad de recuperación postanestésica, mientras que el precalentamiento durante 15 – 30 minutos logró disminuir la necesidad de transfusiones postoperatorias y la prevalencia de infección de herida quirúrgica. Por tanto, el precalentamiento durante menos de cinco minutos es ineficaz y cuanto mayor sea su duración (hasta 30 minutos), más efectos beneficiosos tiene.

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Effect of prewarming on body temperature in short-term bladder or prostatic transurethral resection under general anesthesia: A randomized, double-blind, controlled trial

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Título: Effect of prewarming on body temperature in short-term bladder or prostatic transurethral resection under general anesthesia: A randomized, double-blind, controlled trial.

Autores: Ángel Becerra, Lucía Valencia, Pedro Saavedra, Aurelio Rodríguez-Pérez, Jesús Villar.

Publicado el 21 de octubre de 2021 en Scientific Reports, Q1 (Journal Citation Reports), Factor de impacto: 4.380 (2020):

Sci Rep. 2021; 11: 20762. doi: 10.1038/s41598-021-00350-2.

Resumen en castellano:

Introducción: La mayoría de las investigaciones realizadas sobre hipotermia se han llevado a cabo en cirugías de larga duración, ya que la duración de la cirugía es uno de sus principales factores de riesgo. Sin embargo, los pacientes sometidos a cirugías cortas llegan frecuentemente hipotérmicos al final de la cirugía a pesar de recibir calentamiento activo intraoperatorio. No existen recomendaciones en las guías de práctica clínica actualmente vigentes sobre la aplicación del precalentamiento en cirugías de corta duración debido a la falta de evidencia.

Objetivos:

- Valorar el efecto de diferentes tiempos de precalentamiento con aire caliente forzado (15, 30 o 45 minutos) en la prevención del descenso de temperatura perioperatoria de pacientes intervenidos de resección transuretral bajo anestesia general.

- Valorar la prevalencia de hipotermia a la llegada a la unidad de recuperación postanestésica en los diferentes grupos y examinar el efecto del precalentamiento en la incidencia de escalofríos postoperatorios, la intensidad del dolor postoperatorio, la estancia en la unidad de recuperación postanestésica y las complicaciones postoperatorias.

Registro en Clinicaltrials.gov: NCT 03630887

Métodos: Ensayo clínico aleatorizado doble ciego controlado en pacientes sometidos a resección transuretral de vejiga o próstata de menos de una hora de duración bajo anestesia general entre agosto y octubre de 2018. La aleatorización fue realizada por un asistente no involucrado en el precalentamiento o en la recogida de datos, y el precalentamiento fue realizado por la enfermería del quirófano. Los pacientes fueron aleatorizados a recibir 0 minutos (Control), 15 minutos (15-min), 30 minutos (30-min) o 45 minutos (45-min) de precalentamiento mediante aire caliente forzado. Tras la medición de la temperatura timpánica, los pacientes fueron precalentados en el antequirófano el tiempo establecido por la secuencia de aleatorización, volviéndose a registrar la temperatura timpánica previo a la entrada en quirófano. Los pacientes correspondientes al grupo control fueron colocados bajo la manta, sin conectar al calentador. Ni los anestesiólogos a cargo del manejo clínico del paciente ni el paciente conocían la duración del precalentamiento. Todos los pacientes recibieron calentamiento activo intraoperatorio mediante aire caliente forzado y se registró la temperatura esofágica intraoperatoria cada 15 minutos. En el postoperatorio inmediato, se valoró la presencia de escalofríos a la llegada a la unidad de recuperación postanestésica, la intensidad del dolor 30 minutos después y la duración de la estancia en la unidad. Durante la estancia hospitalaria postoperatoria se recogieron la aparición de complicaciones cardiovasculares, la necesidad de reintervención por sangrado severo y el requerimiento de transfusiones.

Resultados: Se incluyeron 297 pacientes con la siguiente aleatorización: 76 pacientes en el grupo control, 74 pacientes en el grupo 15-min, 73 pacientes en el grupo 30-min y 74 pacientes en el grupo 45-min. El 16,5% de los pacientes presentaban hipotermia a la llegada al antequirófano. Tras el precalentamiento, la temperatura en los grupos 15-min y 30-min fue superior a la del grupo control (en el grupo 15-min 0,3ºC [IC 95% 0,1–0,4], p = 0,004; y en el grupo 30-min 0,2ºC [IC 95% 0,0–0,3], p = 0,041). Aunque el grupo 45-min también presentó una temperatura previa a la inducción anestésica superior al grupo control (0,1ºC [IC 95% 0,1–0,3]), esta diferencia no fue estadísticamente significativa (p = 0,203). Al final de la cirugía, la temperatura de los pacientes del grupo control fue 35,8 ± 0,6ºC. Esta temperatura fue superior en todos los grupos que recibieron precalentamiento (0,5ºC [IC 95% 0,3–0,7], p < 0,001). No se encontraron diferencias en la temperatura intraoperatoria entre los distintos grupos de precalentamiento. El modelo multivariable de medidas repetidas mostró que el efecto de la duración del precalentamiento y de la interacción tiempo-tratamiento fueron estadísticamente significativos (p < 0,001): La temperatura intraoperatoria se mantuvo significativamente superior en los grupos 30-min (0,4ºC [IC 95% 0,1–0,7], p = 0,01) y 45-min (0,4ºC [IC 95% 0,1–0,7], p = 0,003). Sin embargo, en el grupo 15-min la temperatura media durante la cirugía no alcanzó una diferencia significativa al compararla con el control (p = 0,099).

En el postoperatorio inmediato, los grupos precalentados mostraron menor incidencia de hipotermia (p < 0,001) y de escalofríos postoperatorios (p < 0,001), menor intensidad de dolor postoperatorio (p < 0,001) y menor estancia en la unidad de recuperación postanestésica (p = 0,001). Sin embargo, no hubo diferencias entre los tres grupos precalentados en cuanto a la estancia en la unidad de recuperación postanestésica (p = 0,8). Por tanto, cualquier tiempo de precalentamiento sirvió para reducir significativamente la estancia del paciente en la unidad de recuperación postanestésica. No se encontraron diferencias estadísticamente significativas entre los distintos grupos en cuanto a la aparición de complicaciones cardiacas (p = 0,119), necesidad de reintervención quirúrgica (p = 0,404) o transfusiones (p = 0,293) durante la estancia hospitalaria postoperatoria.

Conclusiones: En cirugías de menos de 60 minutos de duración bajo anestesia general, el precalentamiento activo mediante aire caliente forzado durante 15, 30 y 45 minutos sirve para reducir la hipotermia por redistribución, el descenso de la temperatura perioperatoria y la aparición de hipotermia al final de la cirugía. Al final de la cirugía todos los tiempos de precalentamiento son igualmente efectivos, logrando una temperatura 0,5ºC superior al control. Estos periodos de precalentamiento cortos también reducen la incidencia de escalofríos postoperatorios, la intensidad del dolor y la duración de la estancia en la unidad de recuperación postanestésica.

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Prospective observational study of the effectiveness of prewarming on perioperative hypothermia in surgical patients submitted to spinal anesthesia

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Prewarming has been shown to prevent intraoperative inadvertent hypothermia. Nevertheless, data about optimal prewarming-time from published clinical trials report contradictory results. We conducted this pilot study to evaluate routine clinical practice regarding prewarming and its effect on the prevalence of perioperative hypothermia in patients undergoing transurethral resection (TUR) under spinal anesthesia. This was a prospective, observational, pilot study to examine clinical practice in a tertiary hospital regarding prewarming in 140 consecutive patients. When prewarming (pw) was performed, forced-air warming was provided in the pre-anesthesia room for 15 (pw15), 30 (pw30), or 45 (pw45) min. Tympanic temperature was recorded upon entering the pre-anesthesia room, at the time of initiating surgery, and every 15 min intra-operatively. We also recorded duration of the surgical procedure and length of stay in the Post-Anesthesia Care Unit (PACU). Pw15 was performed in 34 patients, pw30 in 29 patients, and pw45 in 21 patients. Fifty-six patients did not receive pw and 96% of them developed hypothermia at the end of the surgical procedure, compared to 73% of patients in pw15 ($p=0.002$), 75% in pw30 ($p=0.006$) and 90% in pw45 ($p=0.3$). Length of stay in the PACU was markedly shorter in pw15 (131 ± 69 min) and pw30 (123 ± 60 min) than in the non-pw group (197 ± 105 min) ($p=0.015$ and $p=0.011$, respectively). This difference was not significant in pw45 (129 ± 56 min) compared to non-pw patients. In conclusion, prewarming for 15 or 30 min before TUR under spinal anesthesia prevents development of hypothermia at the end of the surgical procedure.

Hypothermia is a frequent complication during the perioperative period in surgical patients. Its appearance can lead to deleterious effects such as surgical site infection, myocardial ischemia or bleeding[1–3]. Most studies on perioperative hypothermia have focused on patients under general anesthesia. Few studies have examined the occurrence of hypothermia in patients under spinal anesthesia despite a body temperature drop during spinal anesthesia due to the loss of temperature autoregulation, to the vasodilation secondary to sympathetic block[4–8], and to the decrease in the shivering response[6]. Therefore, hypothermia can develop during neuraxial block, as frequently and deeply as during general anesthesia[6].

When the negative effects of spinal anesthesia on body temperature are aggravated by other factors occurring during surgery, such as by glycine infusion during transurethral resection (TUR), temperature can decrease more profoundly. Bladder irrigation with liquids at ambient temperature can cause a decrease in body temperature of one or two degrees centigrade[9]. Prewarming (pw) associated to intraoperative warming could be beneficial in this type of patients under spinal anesthesia. In fact, the most recent clinical practice guidelines advocate for active pw before induction of general anesthesia[10–14] (level A recommendation)[11]. However, pw in patients

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under spinal anesthesia is still a weak recommendation[12–14]. Most studies concerned with perioperative hypothermia in patients submitted to spinal anesthesia are focused on the importance of intraoperative active warming. Besides, those studies highlighting the importance of active prewarming do not compare different prewarming time-periods[15]. Findings of published clinical trials on this field are contradictory.

The aim of this study was to evaluate routine clinical practice and the effect of different time-periods of preoperative forced-air warming (15, 30 or 45 min) on perioperative temperature in patients submitted to TUR under spinal anesthesia. We also examined whether pw had an effect on the length of stay and the incidence of shivering in the Post-Anesthesia Care Unit (PACU) during the recovery period.

Materials and Methods

This study was approved by the Ethics Committee at the Hospital Universitario de Gran Canaria Doctor Negrín, Las Palmas de Gran Canaria, Spain (#NAC120300) and registered at ClinicalTrials.gov (identifier NCT03527329). This is a non-randomized, pragmatic prospective study evaluating routine practice of prewarming in consecutive surgical male patients scheduled to undergo elective bladder or prostatic TUR under spinal anesthesia between March 2014 and April 2015. Exclusion criteria for enrolment into the study included: active infection, intake of antipyretics within 24 hours before surgery, neuropathy, thyroid disorders, peripheral vascular disease, skin lesions or history of hypersensitivity to skin contact devices. Female patients were also excluded in order to homogenize the sample regarding physiological and physical characteristics. Written informed consent was obtained from all patients. All methods were performed in accordance with the relevant guidelines and regulations, following good clinical practice. This manuscript adheres to the applicable STROBE guidelines.

Temperature monitoring. For the purpose of this study, we defined hypothermia as having a body temperature lower than 36 °C[10–14]. For measuring the temperature during the perioperative phase, we used a tympanic thermometer (Genius 2 Tympanic Thermometer and Base, Covidien Ltd, Mansfield, USA). This thermometer has an accuracy of ±0.1 °C[16]. Before starting the study, nurses in charge of temperature monitoring were trained to take correct measurements. In each patient, an otoscope was used to ensure that tympanic membrane could be visualized before measurements. After checking that the probe tip was clean, a cover was placed. The probe tip was then inserted into the ear canal without an ear tug and seated in the ear canal by rotating the handle a quarter turn toward the jaw[16]. To reduce the intra-observer variability in temperature measurements, we selected the mean value of three consecutive measurements in each ear. The average perioperative body temperature was defined as the mean temperature measured from the time the patient entered into the operating room until the patient was transferred to the PACU.

Study protocol. We collected and recorded patient's age, body weight and height, American Society of Anesthesiologist (ASA) physical status, type of TUR (prostatic or bladder), and baseline temperature upon admittance to the hospital. On arrival at the pre-anesthesia room, core temperature was measured at the tympanic membrane (Pre-T). After this first temperature measurement, patients were prewarmed using a forced-air blanket (WarmTouch lower body blanket, Covidien Ltd, Mansfield, USA) positioned over the body and connected to a forced-air warmer (WarmTouch Model WT-5900, Covidien Ltd, Mansfield, USA). Temperature output of the warmer was set at the maximum level (43 °C).

Prewarming was applied following routine clinical practice and time was not fixed to avoid a delay in induction. The prewarming time depended on the time the patient had to wait before entering the operating room. If the duration of stay in the pre-anesthetic room was less than 5 min, the patient was included in the non-prewarmed group. The rest of patients were classified in three groups: (i) pw15: patients on pw time $\leq$15 min; (ii) pw30: patients on pw time $\geq$15 and $\leq$30; (iii) pw45: patients on pw time $\geq$30 and $\leq$45. Attendant anesthesiologists responsible for clinical management of patients were blinded to group assignment and had no decision over duration of prewarming.

Patient's tympanic temperature was measured before transferring to the operating room (T0). Patients were premedicated with 1–3 mg of intravenous midazolam, at the discretion of the anesthesiologist. Once the patient entered the operating room, spinal anesthesia was performed in the sitting position using 10 mg of 0.5% hyperbaric bupivacaine intrathecally through spinous interspace L3/4 or L4/5, to reach a level of sensitive block at dermatome T10. During the surgical procedure, all patients were actively warmed using blankets over the upper part of the body. Tympanic temperature was measured at 15-min intervals from arrival into the operating room to the end of surgery (End-T). Operating room temperature during all surgical procedures was centrally controlled to be kept between 21.7–23.8 °C. Neither intravascular fluids nor bladder irrigation fluids were warmed following routine clinical practice. Room temperature, volume of intravenous fluids and volume of glycine infused were also recorded. During the surgical procedure, non-invasive arterial pressure, electrocardiography and peripheral arterial oxygen saturation were monitored in all patients.

After surgery, patients were transferred to the PACU, where the occurrence of shivering and the length of stay were recorded. Patients were treated by an independent clinician and transferred to a hospital ward once they recovered from spinal block, maintained adequate oxygen saturation, were hemodynamically stable and normothermic.

Statistical analysis. Based on historical data, the sample size for this study was calculated using power analysis to detect a difference higher than 0.3 °C (±0.05 °C) in core temperature at the end of surgery. Nineteen patients in each group were estimated to provide 80% power for detecting a statistically significant difference at an alpha-level of 0.05. Data were analyzed using the statistics program R Core Team (R Foundation for Statistical Computing, Vienna, Austria). Results of qualitative variables are expressed as frequency and percentage. Quantitative variables are expressed as mean (SD). The Shapiro-Wilk test was used to analyze the normality of the

Variable		Non-prewarmed group (n = 56)	pw15 group (n = 34)	pw30 group (n = 29)	pw45 group (n = 21)	*p*
Age (years)		69.8 (11.8)	68.7 (10.6)	72.8 (8.7)	72.4 (8.1)	0.34
Weight (kg)		79.9 (11.2)	77.8 (12.7)	80.5 (12.9)	74.8 (15.3)	0.34
BMI (kg·m^{-2})		27.6 (3.4)	26.8 (4.2)	28.3 (4.4)	26.2 (3.7)	0.21
ASA (%)	I	5.4	2.9	3.5	4.8	1
	II	35.7	29.4	34.5	38.1	
	III	48.2	58.8	55.1	47.6	
	IV	10.7	8.8	6.9	9.5	
Core temperature at hospital admission (%)	Unknown	37.5	47.0	55.2	61.9	—
	<36 °C	21.4	11.8	13.8	9.5	0.85
	>36 °C	41.1	41.2	31.0	28.6	
Operating room temperature (°C)		22.7 (0.5)	22.7 (0.4)	22.7 (0.5)	22.7 (0.3)	0.91
Duration of surgery (min)		32.9 (21.3)	32.4 (19.7)	36.2 (18.2)	40.7 (14.8)	0.37
Volume of intravenous fluids (ml)		571 (250)	589 (285)	563 (296)	657 (211)	0.59
Volume of Glycine infused (l)		9.6 (7.7)	9.9 (7.4)	9.4 (7.3)	11.8 (6.3)	0.66

Table 1. Patient characteristics and perioperative variables. Data are expressed as mean (SD) or percentage. BMI: Body Mass Index. ASA: American Society of Anesthesiologists. pw15: prewarmed for 15 min. pw30: prewarmed for 30 min. pw45: prewarmed for 45 min.

data. To compare quantitative variables between two groups, the Student-*t* test was used in cases of variables with normal distribution, and the Mann Whitney U test when the distribution of the variables could not be adjusted to normality. To compare quantitative variables among groups, ANOVA test was used in cases of normal variables and Kruskal-Wallis in cases where distribution was not adjusted to normality. Multiple lineal regression was used for paired data to detect differences in temperature when other variables were analyzed. A p-value <0.05 was considered statistically significant.

Study registration. Registered at ClinicalTrials.gov (Identifier: NCT03527329).

Implication statement. Prewarming in surgical interventions is not well-standardized. We evaluated routine clinical practice using different intervals of prewarming and their effect on temperature through the perioperative period. The present study helps clarify the importance of short time-periods of prewarming on the prevention of perioperative hypothermia in patients submitted to spinal anesthesia.

Results

A total of 140 patients were included in the study: 34 in the pw15 group, 29 in the pw30 group, 21 in the pw45 group and 56 in the non-pw group. Patient characteristics, temperature of the operating room, intravenous volume infused, duration of surgery, and amount of glycine instilled were similar in all groups (Table 1).

Average body temperature throughout the intraoperative period in non-pw patients was 35.35 ± 0.05 °C. Intraoperative temperature in pw15 and pw30 groups were 0.24 ± 0.08 °C and 0.36 ± 0.09 °C higher than in the non-pw group, being this difference statistically significant (p = 0.005 and p = 0.0001, respectively). Intraoperative temperature in pw45 was 0.06 ± 0.1 °C higher than in the non-pw group, but this difference did not reach statistical significance (p = 0.57). No significant relationships were found when performing the univariate analysis between average perioperative temperature and different variables, such as age (p = 0.56), BMI (p = 0.15), volume of glycine infused (p = 0.36), operating room temperature (p = 0.35) and duration of surgery (p = 0.52).

The evolution of temperature in each group is shown in Table 2 and Fig. 1. Baseline temperature of patients in the pre-anesthesia room (Pre-T) was similar in all groups. Mean body temperature of the non-pw group before entering into the operating room (T0) was 35.69 °C. After pw, T0 in pw15 and pw30 groups were 0.23 °C and 0.44 °C higher than in the non-pw group (p = 0.02 and p < 0.001, respectively). T0 in pw45 group was 0.03 °C higher than in the non-pw group, but this difference did not reach statistical significance (p = 0.83). The temperature at the end of the procedure (End-T) of the non-pw group was 35.04 °C. End-T in pw15 and pw30 were 0.49 °C and 0.59 °C higher (p < 0.001 and p < 0.001, respectively). End-T in pw45 was 0.29 °C higher than in the non-pw group, but it did not reach statistical difference (p = 0.055).

Most patients (96.4%) from the non-pw patients were hypothermic at the end of the procedure. This percentage decreased to 73.5% in the pw15 group (p = 0.002) and to 75.9% in the pw30 group (p = 0.006). However, hypothermia developed in 90.5% of patients in the pw45 group, without statistically significant difference from the non-pw group.

Upon admission to PACU, 42.9% of non-pw patients suffered shivering episodes. No shivering was observed in the pw15 and pw30 groups and it only affected 9.5% of patients in the pw45 group. These differences were significant in the three pw groups when compared to the non-pw group. Length of stay in PACU was shorter in the pw15 and pw30 groups when compared to the non-pw group (p = 0,015 and p = 0,011, respectively) (Table 3).

Temperature Measurement		Non-prewarmed (n = 56)	pw15 (n = 34)	pw30 (n = 29)	pw45 (n = 21)
Pre-T	<36 °C	55.4%	61.8%	65.5%	76.2%
	≥36 °C	44.6%	38.2%	34.5%	23.8%
End-T	<36 °C	96.4%	73.5%*	75.9%**	90.5%
	≥36 °C	3.6%	26.5%	24.1%	9.5%

Table 2. Percentage of hypothermia in the pre-anesthesia room and at the end of surgery. pw15: prewarmed for 15 min; pw30: prewarmed for 30 min; pw45: prewarmed for 45 min; Pre-T: temperature on the arrival at the pre-anesthesia room; End-T: temperature at the end of surgery. Data are expressed as mean (SD) or percentage. **P* = 0.002 versus non-prewarmed group. ***P* = 0.006 versus non-prewarmed group.

		Non-prewarmed (n = 56)	pw15 (n = 34)	pw30 (n = 29)	pw45 (n = 21)
Shivering (%)	No	57.1	100*	100*	90.5**
	Yes	42.9	0	0	9.5
Stay in PACU (min)		197 (105)	131 (69)$^{+}$	123 (60)$^{++}$	129 (56)

Table 3. Presence of shivering and length of stay in PACU in each group. pw15: prewarmed for 15 min; pw30: prewarmed for 30 min; pw45: prewarmed for 45 min; PACU (Post-Anesthetic Care Unit). Data are expressed as mean (SD) or percentage. **P* < 0.001 versus non-prewarmed group. ***P* = 0.006 versus non-prewarmed group. $^{+}P = 0.015$ versus non-prewarmed group. $^{++}P = 0.011$ versus non-prewarmed group.

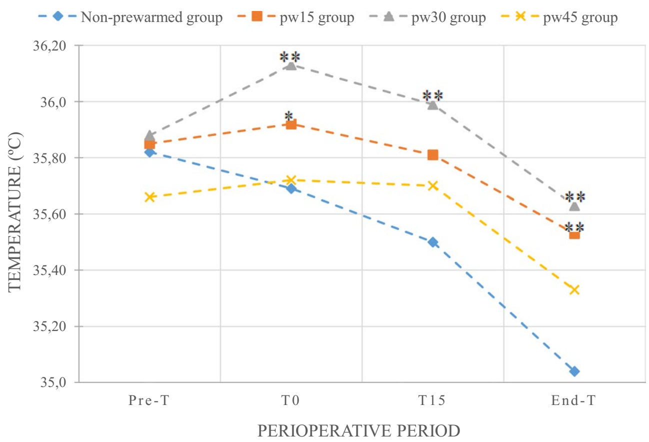

Figure 1. Mean perioperative temperatures (°C) in each group. pw15: prewarmed for 15 min; pw30: prewarmed for 30 min; pw45: prewarmed for 45 min; Pre-T: temperature on the arrival at the pre-anesthesia room; T0: temperature before entering the operating theatre; End-T: temperature at the end of surgery. *P = 0.02 versus non-prewarmed group. **P < 0.001 versus non-prewarmed group.

Discussion

To the best of our knowledge, this study is the first to report that 15 and 30 minutes of active pre-warming before TUR under spinal anesthesia decreases the prevalence of perioperative hypothermia. Our results also showed that this prewarming prevents postoperative shivering and reduces the length of stay in the PACU. Nevertheless, these benefits were not observed when prewarming lasted for 45 min.

Of note, we observed that 62.1% of patients who underwent TUR were already hypothermic upon arrival in the pre-anesthesia room, a prevalence that is higher than initially expected based on previous reports[17]. A possible explanation for a higher prevalence of preoperative hypothermia is that TUR patients are usually elderly. Moreover, males have a higher risk of developing hypothermia than women due to their physical characteristics and rate of metabolic heat production[18]. Preoperative hypothermia is a predictor for a more severe decrease in body temperature intraoperatively[12,19]. If the temperature is unknown before surgery, active measures for reversing hypothermia could be delayed. Once the temperature has decreased, its treatment is difficult since the application of heat to the body surface takes a long time to reach the core thermal compartment[20]. Intraoperative warming alone cannot avoid postoperative hypothermia[21], and the concept of prewarming in the surgical population has been established for a long time. Active prewarming prevents hypothermia by lowering the temperature gradient between core and peripheral compartments and by reducing thermal redistribution[15,22,23].

In our study, 15 or 30 min were able to markedly reduce the incidence of perioperative hypothermia. Our results are in agreement with other studies reporting the efficacy of prewarming in surgical procedures under neuraxial anesthesia. In elective caesarean section under epidural anesthesia, 15 min of forced-air prewarming accompanied by intraoperative active warming prevented hypothermia and shivering[24]. The same results were found applying 15 min of forced-air prewarming plus warming of intravenous fluids[25]. In contrast, a recent study showed that 20 min of prewarming plus warming of intravenous fluids was not effective at preventing hypothermia during caesarean delivery using intrathecal morphine[26]. Also, a study in a population similar to ours (men undergoing TUR under spinal anesthesia), reported that prewarming for 20 min did not reduce the incidence of hypothermia at the end of the procedure, although it reduced its severity[27]. These different results, when compared to ours, could be explained because patients with preoperative hypothermia (temperature <36 °C) were excluded in those studies. In our study, we showed that although more than 50% of patients were hypothermic at the time of arriving into the pre-anesthesia room, prewarming was effective in decreasing the incidence of hypothermia by more than 20%.

Paradoxically, we observed that the increase in body temperature was not proportional to the amount of time the prewarming was performed, since patients prewarmed during 45 min suffered more hypothermia at the end of the surgery. Our findings are consistent with other study, which show that an increased duration of prewarming beyond the 30 min in patients submitted to general anesthesia may not result in better preservation of normothermia[28]. This finding might be explained by the fact that the long time while the patient is in contact with the hot-air device could lead to excessive vasodilation, facilitating the conductance of heat to the environment[20]. Nevertheless, other factors could have influenced on having a lower temperature at the end of surgery in the pw45 group in our study. Although there were not statistically significant differences, pw45 group were submitted to a longer surgery, receiving a higher amount of Glycine and more intravenous fluid.

Prewarming for less than 30 min also decreased the length of stay in the PACU, suggesting that prewarmed patients required less time to recover their baseline temperature and could be transferred earlier to the hospital ward. The optimization of postoperative time speeds up the process of patient turnover and improves quality of care. It is important to highlight that postoperative shivering increases oxygen consumption, postoperative pain, and is one of the main causes of postoperative discomfort[4,29].

The ideal prewarming time has long been investigated. Early studies established that a prewarming of at least 60 min was needed to prevent intraoperative hypothermia[30–34]. It was also observed that, although prewarming during 60 min did not completely prevent hypothermia, it attenuated the temperature drop[35]. Due to the inefficiency of long-time prewarming in short-term surgical procedures, studies were conducted to find out the optimal prewarming time. It was observed that in patients undergoing general anesthesia, hypothermia was reduced by using active forced-air warming for only 30 min prior to induction of anaesthesia[28,36,37], and that even 10 min of prewarming could be effective in reducing the temperature drop and postoperative shivering[38]. These results have been confirmed in patients receiving combined general and regional anesthesia[8].

In contrast to other studies, we did not find a relationship between hypothermia and any relevant variable, such as duration of surgery or the operating-room temperature[4,12]. The short duration of the surgery and the exposure to low room temperature during a short period of time could explain the lack of association.

Despite the strengths of our study, we acknowledge some potential limitations. First, our study was not designed as a randomized controlled trial. Dividing participants into groups depending on the time they were going to wait in the pre-anesthetic room before entering the operating room, could be the main limitation in this study, since it does not allow to ensure that the characteristics of different groups are comparable. The prewarming-time group was selected arbitrarily. However, no significant differences were found among different groups in the subsequent analysis regarding the main characteristics that may affect the thermal evolution during the perioperative period. However, we think that the main strength of this pilot study was to be able to examine different approaches regarding temperature control according to individual routine clinical practice in a Department of Anesthesia in a University Tertiary Hospital. Besides, the fact that the anesthesiologist responsible for clinical management in each participating patient did not control the prewarming time, findings are not influenced by the decision of the attending clinician. In addition, the sample size is large enough for the results to be generalizable. As it was a prospective observational study, temperature of some patients at admission was unknown and they could be already hypothermic at the beginning of the study. Because of this, clinical relevance of this study is also increased. Having only male patients as an inclusion criterion makes the sample more homogeneous in terms of physical characteristics of patients. However, the results obtained cannot be extrapolated to the general or the female population. Second, we did not measure the sensory level of the neuraxial block and, as a result, the level of sympathetic block. Considering that one of the main predictors of hypothermia during spinal anesthesia is the level of the block[5], this variable could have conditioned the severity of hypothermia. Although all patients received intrathecally the same dose of local anesthetic, there is a possibility that other factors, such as patient's age, spinal curvature, intra-abdominal pressure or height, could influence the level reached during spinal anesthesia. Third, the use of the non-invasive, easy accessible, and comfortable tympanic thermometer to monitor temperature could show an incidence of hypothermia different from the real measured with the gold standard of core temperature monitoring, which is through a pulmonary artery catheter. However, and following the method used in many previous studies[5,7,8,17,24–27,33,35–38], we did not consider alternative techniques as this was a pragmatic study and temperature was measured in awake conditions.

Conclusions

Short prewarming before TUR under spinal anesthesia reduces hypothermia appearance at the end of the surgical procedure and decreases PACU length of stay and the incidence of postoperative shivering. We encourage the implementation of actions to combat hypothermia immediately upon admission and monitoring temperature in all patients during the perioperative period.

Received: 7 May 2019; Accepted: 27 October 2019;
Published online: 11 November 2019

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Acknowledgements

This research did not receive any specific grant from funding agencies in the public, private, or not-for-profit sectors.

Author contributions

A.B. and A.R.P.: study conception and design, acquisition, analysis and interpretation of data, writing and finalizing the manuscript; L.V.: acquisition and interpretation of data, writing and finalizing the manuscript; C.F. and J.V.: finalizing the manuscript and critical revision; All authors read and approved the final manuscript.

Competing interests

The authors declare no competing interests.

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Journal of
Clinical Medicine

MDPI

Article

Short-Periods of Pre-Warming in Laparoscopic Surgery. A Non-Randomized Clinical Trial Evaluating Current Clinical Practice

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Citation: Becerra, Á.; Valencia, L.; Villar, J.; Rodríguez-Pérez, A. Short-Periods of Pre-Warming in Laparoscopic Surgery. A Non-Randomized Clinical Trial Evaluating Current Clinical Practice. *J. Clin. Med.* **2021**, *10*, 1047. https://doi.org/10.3390/jcm10051047

Academic Editor: Benedikt Preckel

Received: 1 February 2021
Accepted: 28 February 2021
Published: 3 March 2021

Abstract: Background: Pre-warming prevents perioperative hypothermia. We evaluated the current clinical practice of pre-warming and its effects on temperature drop and postoperative complications; Methods: This prospective, observational pilot study examines clinical practice in a tertiary hospital on 99 patients undergoing laparoscopic urological surgery. Pre-warming was performed in the pre-anesthesia room. Patients were classified into three groups: P 0 (non-prewarmed), P 5–15 (pre-warming 5–15 min) and P > 15 (pre-warming 15–30 min). Tympanic temperature was recorded in the pre-anesthesia room, prior to anesthesia induction, and in the PACU. Esophageal temperature was recorded intraoperatively. The occurrence of shivering, pain intensity, length of stay in PACU, and postoperative complications during hospital stay were also recorded; Results: After pre-warming, between-group difference in body temperature was higher in P > 15 than in P 0 (0.4 °C, 95% CI 0.14–0.69, $p = 0.004$). Between P 5–15 and P 0 difference was 0.2 °C (95% CI 0.04–0.55, $p = 0.093$). Temperature at the end of surgery was higher in pre-warmed groups [mean between-group difference 0.5 °C (95% CI 0.13–0.81, $p = 0.007$) for P 5–15; 0.9 °C (95% CI 0.55–1.19, $p < 0.001$) for P > 15]. Pain and shivering was less common in pre-warmed groups. Postoperative transfusions and surgical site infections were lower in P > 15; Conclusion: Short-term pre-warming prior to laparoscopic urological surgery decreased temperature perioperative drop and postoperative complications.

Keywords: active warming; body temperature; hypothermia; laparoscopic surgery; perioperative complications; pre-warming; urology

1. Introduction

The laparoscopic approach for urological abdominal surgery decreases serious complications, such as surgical stress [1], perioperative bleeding [2], surgical wound infection [3], and hospital stay [4]. However, it has not been reported whether it could also decrease the rate of perioperative hypothermia when compared to an open approach [5]. Inadvertent hypothermia is common in the perioperative period, affecting 50–90% of patients undergoing surgery [6–9]. Perioperative hypothermia can increase intraoperative bleeding [10], surgical wound infection [11], discomfort, and length of hospital stay [12]. Thus, hypothermia throughout laparoscopic surgery can offset the expected benefits of this technique, and prevention of temperature drop during laparoscopic surgery should be mandatory.

Preoperative forced-air warming (pre-warming) is the most effective tool for preventing hypothermia. Its use is recommended in high-risk patients undergoing surgeries longer than 30 min [13–17], and it has been incorporated into routine clinical practice. However, trials examining the impact of pre-warming for preventing complications associated with hypothermia show conflicting results [18]. Despite the fact that laparoscopic surgeries are widespread nowadays, much is still unknown about the effect of pre-warming on these surgeries due to the lack of studies. In patients at risk for hypothermia undergoing laparoscopic surgery, pre-warming has been shown to prevent temperature drop [19]. However, the duration of prewarming and its effect on reducing complications have not yet been clarified.

We evaluated the effects of different time-periods of pre-warming on perioperative body temperature in patients undergoing urological laparoscopic surgery. As secondary objectives, we evaluated the relationship between a lower core temperature at the end of surgery and perioperative risk factors. We also tested the impact of pre-warming on the rate of postoperative shivering, pain, length of stay in Post-Anesthesia Care Unit (PACU), complications, and evolution of the patient.

2. Materials and Methods

This pragmatic, nonrandomized, prospective study evaluated routine clinical practice in 99 consecutive male patients scheduled to undergo laparoscopic prostatectomy or nephrectomy in a university hospital from August 2018 to October 2019. The study was conducted in accordance with the Declaration of Helsinki, and the protocol was approved by the Ethics Committee of Hospital Universitario de Gran Canaria Dr. Negrín, Las Palmas de Gran Canaria, Spain (IRB approval #2018-089-1), and prospectively registered at ClinicalTrials.gov (NCT03617809). All methods were carried out following good clinical practice. The manuscript follows the STROBE guidelines [20]. Patients were excluded if they met any of the following criteria: active infection, antipyretic consumption during the hospital stay, neuropathy, hyper or hypothyroidism, peripheral vascular disease, skin lesion, immunosuppression, insulin-dependent or poorly controlled diabetes mellitus, bleeding disorders, or intake of antiplatelet or anticoagulation agents. Written informed consent from each patient was obtained before enrollment.

2.1. Outcomes

For assessing the effect of different time-periods of pre-warming on perioperative body temperature, we selected as the primary outcome the difference in temperature between groups throughout the perioperative period and the first postoperative hour. Secondary objectives included the relationship between temperature at the end of surgery and perioperative risk factors, and the impact of pre-warming on the postoperative evolution of the patient.

2.2. Study Protocol

Upon hospital admission, the patient's age, weight, height, American Society of Anesthesiologists (ASA) physical status, hemoglobin, and surgery (prostatectomy or nephrectomy) were recorded. Body mass index (BMI), body surface area (BSA), and basal metabolic rate (BMR) were calculated. Core temperature was measured using a tympanic thermometer (Genius-2 Tympanic Thermometer and Base, Covidien Ltd., Mansfield, MA, USA) at hospital admission and upon arrival at the pre-anesthesia room (PreT). Prior to initiating the study, nurses-in-charge of temperature monitoring were trained for temperature measurements [9]. To reduce intra-observer variability, the mean value of three consecutive measurements was selected.

Patients were pre-warmed at the pre-anesthesia room following routine clinical practice covering the entire body with a forced-air blanket (WarmTouch total body blanket, Covidien). The temperature output of the warmer (WarmTouch Model WT-5900, Covidien) was set at maximum level (43 °C). The duration of pre-warming depended on the time the patient had to wait in the pre-anesthesia room before surgery. Patients with a waiting time < 5 min were not pre-warmed (P 0 group). Patients pre-warmed for 5–15 min were included in the P 5–15 group, and those pre-warmed for 15–30 min were included in the P > 15 group. Anesthesiologists responsible for clinical intraoperative management made no decisions on the duration of pre-warming and were not aware of its duration.

After pre-warming, the tympanic temperature was measured (T0). Then, patients were pre-medicated (intravenous midazolam, 1–2 mg) and monitored using non-invasive arterial pressure, electrocardiogram, peripheral oxygen saturation, and bispectral index (BIS, Covidien). General anesthesia was performed using remifentanil and propofol with effect-site target-controlled infusion (TCI, B.Braun, Melsungen, Germany) to maintain BIS 40–60 and intraoperative hemodynamic stability. Cisatracurium was administered in bolus (0.2 mg·kg^{-1}) to allow orotracheal intubation and in continuous infusion during surgery to ensure a low intraperitoneal pressure during laparoscopy. Patients were actively warmed intraoperatively using a forced-air blanket over the upper part of the body. Temperature was measured intraoperatively using an esophageal thermometer (Mon-a-Therm, Covidien). Intraoperative core temperature was recorded at 15-min intervals (T15, T30, T45) during the first hour of anesthesia (T60), then at 30-min intervals (T90, T120, T150, T180, T210, T240, T270, T300) until the end of surgery (EndT). Intravascular fluids were not warmed. CO2 used for pneumoperitoneum was not heated or humidified. Volume of administered intravenous fluids, and intraoperative bleeding were registered.

At the end of surgery, the neuromuscular blockade was reversed and the tracheal tube was removed. Patients were transferred to the PACU, where an independent clinician was in-charge. Postoperative temperature during the first hour using tympanic thermometer, presence of shivering at arrival (using a dichotomous scale, positive when it was visible), pain intensity at 30 min after arrival (using a numerical rating scale, NRS), and length of stay in PACU were logged. Patients were transferred to the hospital ward once core temperature was above 36.0 °C and Aldrete modified score [21] was higher than 8. On the first postoperative morning, we measured hemoglobin for calculating the difference with the preoperative value. During postoperative hospital stay, blood transfusion requirements (as decided by an independent clinician) and presence of postoperative complications were recorded. Surgical site infection and postoperative ileus were clinically defined, assessed by an independent clinician. Follow-up ended once the patient was discharged from the hospital.

2.3. Statistical Analysis

The sample size was estimated based on a previous observational study [9], with a power analysis to detect a difference of 0.3 °C in core temperature. Ninety patients (n = 30 in each group) provided an 80% power for detecting a difference at an alpha-level of 0.05.

Data were analyzed using SPSS 24.0 (Statistical Package for Social Sciences, IBM). Data on categorical variables are expressed as frequency and percentage. A Chi-square test was used to compare frequency data among groups. Quantitative variables are expressed as mean ± SD. We used Shapiro–Wilk's test to analyze the normality of data. To compare quantitative variables between the two groups, a t-test for independent samples was used in cases of variables with normal distribution, and Mann–Whitney U-test when the distribution of variables could not be adjusted to normality. To compare temperature (continuously scaled variable) among groups, one-way analysis of variance (ANOVA) test for independent samples was used in variables with normal distribution, and Kruskal-Wallis test where distribution was not adjusted to normality. Pearson's correlation coefficient was used to detect relationships between quantitative perioperative variables and temperature at the end of surgery. Differences among groups regarding pain intensity, length of stay in PACU, postoperative hemoglobin, and hospital length of stay were analyzed using one-way ANOVA test for independent samples. A Chi-square test was used to compare the frequency of shivering and postoperative complications among groups. A p-value < 0.05 was considered statistically significant.

3. Results

Ninety-nine patients were included (n = 33 patients in each group). Patient characteristics, body temperature upon arrival at pre-anesthesia room (PreT), and perioperative characteristics were similar among groups (Table 1). After pre-warming, core temperature before entering the operating room (T0) was higher in P > 15 than in P 0 (between-groups difference 0.4 °C, 95% CI 0.14–0.69, p = 0.004). Between P 5–15—P 0 difference was 0.2 °C (95% CI 0.04–0.55, p = 0.093). Pre-warmed patients had a significantly higher temperature throughout the intraoperative period compared to non-pre-warmed patients (Table 2, Figure 1). The temperature at the end of the procedure (EndT) in P 0 was 35.8 ± 0.8 °C. EndT was higher in pre-warmed groups (between P 5–15—P 0 difference 0.5 °C, 95% CI 0.13–0.81, p = 0.007; between P > 15—P 0 difference 0.9 °C, 95% CI 0.55–1.19, p < 0.001). No secondary effects due to pre-warming, such as sweating or thermal discomfort were observed.

Table 1. Patient characteristics and perioperative variables.

	P 0 (n = 33)	P 5–15 (n = 33)	P > 15 (n = 33)	p
Age (years)	59.7 ± 9.2	59.2 ± 12.2	60.5 ± 8.1	0.895
BMI (kg·m^{-2})	27.9 ± 5.6	27.2 ± 3.7	28.2 ± 3.5	0.581
BSA (m^2)	1.9 ± 0.3	1.9 ± 0.2	1.9 ± 0.2	0.451
BMR (kcal)	1641 ± 273	1587 ± 232	1667 ± 203	0.516
ASA II (%)	60.6	57.6	60.6	0.959
Core temperature at admission (°C)	36.5 ± 0.5	36.4 ± 0.5	36.4 ± 0.5	0.274
Hypothermia (<36 °C) upon arrival at pre-anesthesia room (%)	21.2	36.4	12.1	0.062
Laparoscopic Surgery (Prostatectomy, %)	57.6	51.5	66. 7	0.399
Hemoglobin at admission (g·dL^{-1})	14.3 ± 2.1	14.3 ± 2.2	14.5 ± 1.9	0.890
Duration of anesthesia (min)	280 ± 60	291 ± 66	302 ± 57	0.444
Operating room temperature (°C)	22.6 ± 0. 6	22.6 ± 0.6	22.7 ± 0.6	0.714
Fluid therapy (mL)	2042 ± 1070	1795 ± 688	1759 ± 563	0.654

Data are expressed as mean ± SD and percentage. BMI: body mass index; BSA: body surface area; BMR: basal metabolic rate; ASA: American Society of Anesthesiologists; P 0: non-pre-warmed; P 5–15: pre-warmed for 5–15 min; P > 15: pre-warmed for 15–30 min.

Table 2. Perioperative core temperature evolution.

	P 0 (n = 33)	P 5–15 (n = 33)	P > 15 (n = 33)	p
PreT	36.3 ± 0.6	36.2 ± 0.5	36.3 ± 0.4	0.73
T0	36.2 ± 0.7	36.5 ± 0.5	36.6 ± 0.4	0.009
T15	36.0 ± 0.6	36.2 ± 0.4	36.4 ± 0.4	0.003
T30	35.8 ± 0.6	36.1 ± 0.5	36.2 ± 0.4	0.002
T45	35.7 ± 0.6	35.9 ± 0.5	36.1 ± 0.4	0.007
T60	35.7 ± 0.6	35.9 ± 0.4	35.9 ± 0.4	0.014
T90	35.7 ± 0.6	35.9 ± 0.5	36.1 ± 0.5	0.009
T120	35.7 ± 0.6	36.0 ± 0.5	36.2 ± 0.5	0.001
T150	35.8 ± 0.6	36.1 ± 0.5	36.3 ± 0.5	<0.001
T180	35.8 ± 0.7	36.2 ± 0.5	36.4 ± 0.4	<0.001
T210	35.8 ± 0.8	36.2 ± 0.5	36.5 ± 0.5	<0.001
T240	35.8 ± 0.8	36.3 ± 0.5	36.6 ± 0.5	<0.001
T270	35.8 ± 0.8	36.3 ± 0.6	36.6 ± 0.5	0.0001
T300	35.7 ± 0.9	36.4 ± 0.5	36.8 ± 0.5	0.0001
EndT	35.8 ± 0.8	36.2 ± 0.6	36.6 ± 0.5	<0.0001

Data are expressed as mean ± SD. PreT: temperature upon arrival at the pre-anesthesia room; T0: temperature after pre-warming; T15: temperature 15 min after induction; T30: temperature 30 min after induction; T45: temperature 45 min after induction; T60: temperature 60 min after induction; T90: temperature 90 min after induction; T120: temperature 120 min after induction; T150: temperature 150 min after induction; T180: temperature 180 min after induction; T210: temperature 210 min after induction; T240: temperature 240 min after induction; T270: temperature 270 min after induction; T300: temperature 300 min after induction; EndT: temperature at the end of surgery; P 0: non-pre-warmed; P 5–15: pre-warmed for 5–15 min; P > 15: pre-warmed for 15–30 min.

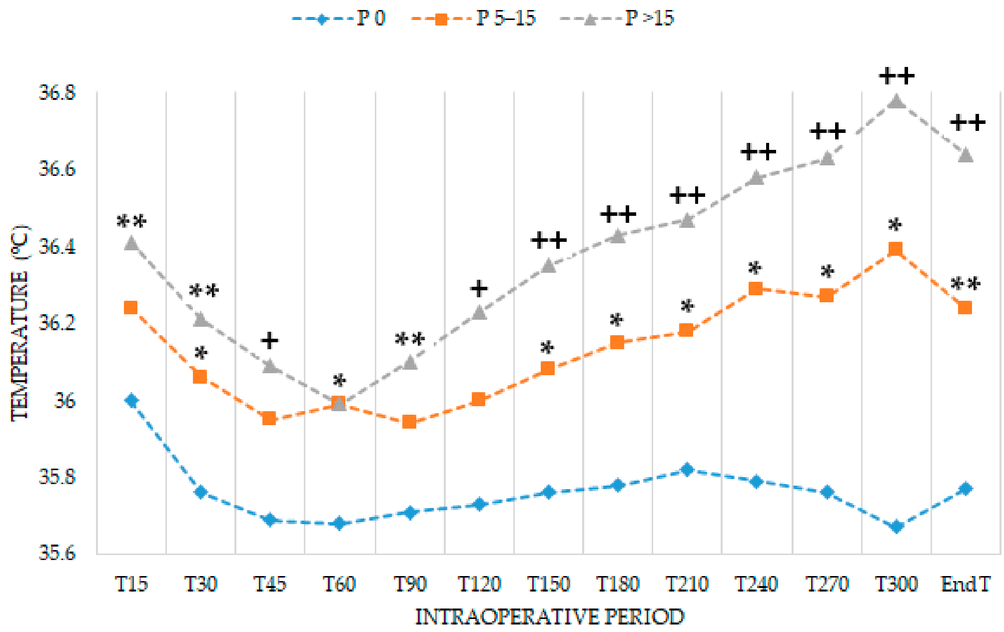

Figure 1. Mean perioperative temperature (°C) in each group. PreT: temperature upon arrival at the pre-anesthesia room; EndT: temperature at the end of surgery; P 0: non-pre-warmed; P 5–15: pre-warmed for 5–15 min; P > 15: pre-warmed for 15–30 min. * $p < 0.05$ vs. P 0; ** $p < 0.01$ vs. P 0; + $p < 0.001$ vs. P 0; ++ $p \leq 0.0001$ vs. P 0.

We found a direct proportional relationship among temperature and BSA, BMR, preoperative hemoglobin, operating room temperature, length of anesthesia, and temperature upon arrival at the pre-anesthesia room. We also found an inverse proportional relationship between EndT and volume of intravenous fluid therapy and intraoperative bleeding (Table 3).

Table 3. Correlation between EndT and characteristics of patients and perioperative variables.

	Age	BMI	BSA	BMR	Pre Hb	OR Temp	Length Anesthesia	Fluid Therapy	PreT	Bleeding
Pearson correlation	−0.19	0.14	0.22	0.24	0.28	0.32	0.27	−0.31	0.24	−0.22
p	0.065	0.162	0.030	0.018	0.005	0.001	0.006	0.002	0.018	0.031

BMI: body mass index; BSA: body surface area; BMR: basal metabolic rate; Pre Hb: preoperative hemoglobin; OR Temp: operating room temperature; PreT: core temperature upon arrival at the pre-anesthesia room.

Hypothermia upon the arrival at PACU occurred in 48.5% (16/33) of patients in P 0, 33% (11/33) in P 5–15 (RR 1.88, 95%CI 0.69–5.09, $p = 0.211$), and 6% (2/33) in P > 15 (RR 14.58, 95%CI 2.99–71.15, $p < 0.001$). Figure 2 shows the postoperative evolution of temperature throughout the first postoperative hour in PACU. Moreover, pre-warmed patients suffered from less postoperative pain and shivering (Table 4).

The estimated intraoperative bleeding was 377 ± 301 mL in P 0, 325 ± 257 mL in P 5–15, and 264 ± 189 mL in P > 15 ($p = 0.204$). No differences were found in postoperative hemoglobin or in the decrease in hemoglobin among groups (Table 4). However, we found statistically significant differences regarding the percentage of patients receiving postoperative transfusions: 18.2% (6/33) in P 0, 6.1% (2/33) in P 5–15 (RR 0.29, 95% CI 0.05–1.56, $p = 0.131$), and 0% in P > 15 ($p = 0.010$). Surgical site infection occurred in 12.1% (4/33) in P 0, 9.1% (3/33) in P 5–15 (RR 0.73 95% CI 0.15–3.53, $p = 0.689$), and 0% in P > 15 ($p = 0.039$). Postoperative ileus developed during the postoperative period in 15.2% (5/33) in P 0, and 9.1% (3/33) in both pre-warmed groups (RR 0.56, 95% CI 0.12–2.56, $p = 0.451$). No differences were found regarding PACU or hospital length of stay (Table 4).

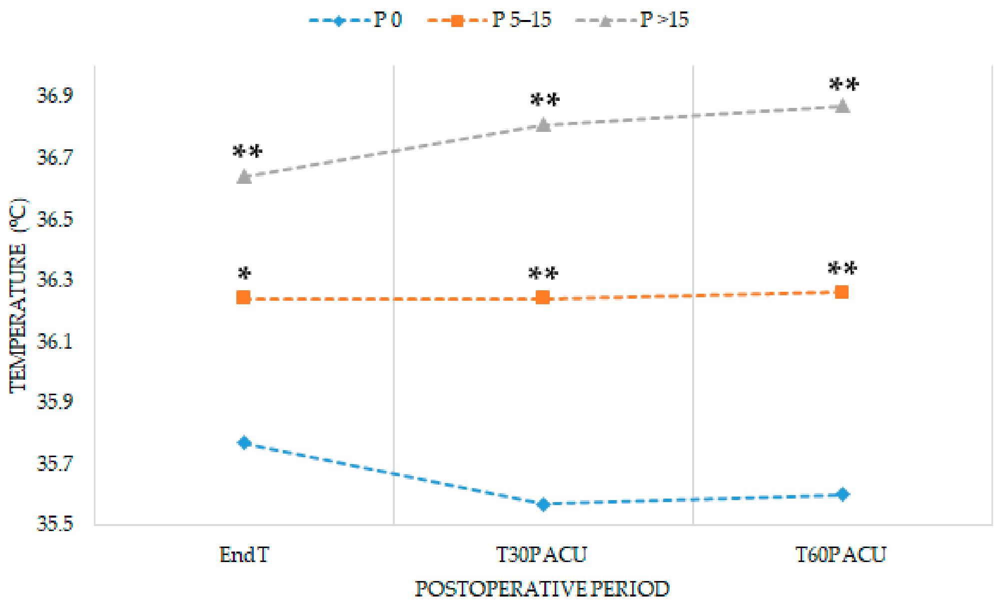

Figure 2. Mean perioperative temperature (°C) in the PACU in each group. PACU: Post-Anesthetic Care Unit; EndT: temperature at the end of surgery; T30PACU: temperature 30 min after admission to PACU; T60PACU: temperature 60 min after admission to PACU; P 0: non-pre-warmed; P 5–15: pre-warmed for 5–15 min; P > 15: pre-warmed for 15–30 min. * $p < 0.01$ vs. P 0; ** $p < 0.0001$ vs. P 0.

Table 4. Postoperative evolution of patients in PACU, postoperative lab test, and complications throughout hospital stay and length of hospital stay.

	P 0 (n = 33)	P 5–15 (n = 33)	P > 15 (n = 33)	p
NRS in PACU	3.06 ± 2.2	1.79 ± 1.2 *	1.58 ± 1.3 **	0.001
Shivering in PACU (%)	39.39	3.03	3.03	<0.001
Length of stay in PACU (min)	531 ± 443	482 ± 375	449 ± 331	0.69
Postoperative Hemoglobin (g·dL^{-1})	11.36 ± 1.6	11.73 ± 1.9	11.84 ± 1.8	0.52
Hemoglobin drop (g·dL^{-1})	2.93 ± 1.4	2.60 ± 1.7	2.67 ± 1.7	0.67
Hospital length of stay (days)	4.5 ± 3	3.7 ± 3	3.4 ± 2.4	0.24

Data are expressed as mean ± SD and percentage. NRS: numerical rating scale; PACU: Post-Anesthetic Care Unit; P 0: non-pre-warmed; P 5–15: pre-warmed for 5–15 min; P > 15: pre-warmed for 15–30 min. * $p = 0.005$ vs. P 0; ** $p = 0.001$ vs. P 0.

4. Discussion

In this trial examining routine clinical practice regarding pre-warming, short-time periods of pre-warming (P 5–15 or P > 15) prior to urological laparoscopic surgery was able to increase core temperature intraoperatively and during the first postoperative hour. These short-time periods of pre-warming decreased the rate of hypothermia, the occurrence of shivering, the intensity of pain, and the need for transfusions postoperatively.

It could be argued that there is a low risk of hypothermia during laparoscopic surgery because no heat loss occurs from exposure of surgical wounds and abdominal organs to the environment. However, in our study, up to 29.3% of patients developed hypothermia due to internal heat redistribution, despite preventive measures, and intraoperative hypothermia is also observed during laparoscopic procedures [22]. The mechanism underlying hypothermia in laparoscopic procedures has not been well elucidated. One of main reasons could be the prolonged surgical time and the increased heat loss via exposure to cold/dry CO_2 insufflation during pneumoperitoneum [23]. In non-laparoscopic surgeries, pre-warming for less than an hour has been shown to decrease the occurrence of intraoperative hypothermia [9,24–28]. However, few studies have examined the effect of pre-warming in laparoscopic surgery. In a small randomized clinical trial in laparoscopic cholecystectomy, patients pre-warmed for one hour showed a lower rate of hypothermia during the first intraoperative hour [29]. However, pre-warming for an hour might be too long to be included in routine clinical practice.

Pre-warming prevents hypothermia by decreasing the temperature gradient between peripheral and central compartments, not by increasing core temperature [30]. However, in our study, pre-warming for 15–30 min increased the body temperature prior to anesthetic induction. During the first intraoperative hour, body temperature dropped sharply in all groups, as expected [31]. Afterward, the temperature remained constant until the end of surgery in non-pre-warmed patients, probably due to intraoperative active warming. Nevertheless, pre-warmed patients showed an exponential increase in temperature from the first intraoperative hour to the end of surgery and this effect persisted up to the first postoperative hour [32]. Therefore, pre-warming could enhance the effectiveness of intraoperative warming, increasing perioperative body temperature. In short-term surgeries, pre-warming diminishes the incidence of hypothermia in PACU and shortens length of stay [9]. Although pre-warming prevents against shivering and postoperative pain [9,33], we found no differences in the length of stay in PACU. Duration of recovery after long-term surgeries may depend on several factors, such as the need for postoperative care (control of drainage or diuresis), or the routine institutional protocol [27,34].

Hypothermia is known to increase perioperative bleeding by causing alterations in platelet and coagulation enzyme function [10,35,36], and intraoperative normothermia reduces perioperative bleeding [2,37]. However, these hematological alterations may not have a clinical impact on increasing intraoperative bleeding [38,39]. Improvement in surgical techniques and less invasiveness in laparoscopic surgery imply a decrease in intraoperative bleeding, making it more difficult to detect intergroup differences. Of note, we did not find a reduction in intraoperative bleeding or a lower drop in hemoglobin values in pre-warmed patients, but we found a decrease in the requirement of postoperative transfusions in patients pre-warmed for 15–30 min. Hypothermia also causes an impairment in immune function and vasoconstriction, increasing the risk of surgical wound infection [12]. In our study, pre-warming for 15–30 min reduced the incidence of surgical wound infection, as previously demonstrated [40]. However, pre-warming for 5–15 min was not efficiently enough to reach statistical significance, likely because core temperature in P 5–15 group was lower than in the P > 15 group. On the other hand, hypothermia is not an independent risk factor for postoperative ileus, but its appearance delays the onset of oral tolerance [41]. We found no influence of pre-warming on decreasing the rate of postoperative ileus, probably due to its low prevalence in laparoscopic urological surgery.

We acknowledge some potential limitations and strengths. First, since this is an observational study, we can only report associations. Patients were not randomized into different pre-warmed groups, and pre-warming time was selected arbitrarily. However, its design faithfully reflects the true relevance of short pre-warming on routine clinical practice in laparoscopic urological surgery. Secondly, since the study only included males, results cannot be generalized to the female population. Third, we used non-invasive tympanic and esophageal thermometers to monitor temperature depending on the moment of measurement (tympanic when the patient was awake, esophageal intraoperatively). However, we believe that our results are valid since comparison among groups at each measurement was performed using the same thermometer.

5. Conclusions

Pre-warming for 5–15 min and 15–30 min prior to laparoscopic urological surgery reduces the occurrence of hypothermia during the intraoperative period and during the first postoperative hour. Pre-warming for 15–30 min increased core temperature before induction and reduced occurrence of hypothermia upon arrival at PACU. Both short-time periods of pre-warming decreased the rate of shivering and the intensity of pain in PACU. Pre-warming for 15–30 min reduced the need for postoperative transfusions and the prevalence of surgical site infections. Thus, the take-home message is that less than 5 min of pre-warming is useless and more than 15 min is better than less.

Author Contributions: Conceptualization, Á.B. and A.R.-P.; methodology, Á.B., L.V. and A.R.-P.; software, Á.B.; validation, L.V. and A.R.-P.; formal analysis, Á.B.; investigation, Á.B. and L.V.; resources, A.R.-P. and J.V.; data curation, L.V. and A.R.-P.; writing—original draft preparation, Á.B. and L.V.; writing—review and editing, Á.B., A.R.-P. and J.V.; visualization, Á.B.; supervision, J.V.; project administration, A.R.-P. and J.V.; funding acquisition, A.R.-P. and J.V. All authors have read and agreed to the published version of the manuscript.

Funding: This research received no external funding.

Institutional Review Board Statement: The study was conducted according to the guidelines of the Declaration of Helsinki, and approved by the Ethics Committee of Hospital Universitario de Gran Canaria Dr. Negrín, Las Palmas de Gran Canaria, Spain (EC approval #2018-089-1) on 26 April 2018.

Informed Consent Statement: Informed consent was obtained from all subjects involved in the study.

Data Availability Statement: Data presented in this study are available on request from the corresponding author.

Acknowledgments: We thank Aída Sánchez, Estefanía Maldonado, and Yurena Cardona for their extraordinary role in the application of pre-warming and measuring temperature. We also thank Reinaldo Marrero, Pablo Jiménez, and Nicolás Jorge for their collaboration.

Conflicts of Interest: The authors declare no conflict of interest.

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Effect of prewarming on body temperature in short-term bladder or prostatic transurethral resection under general anesthesia: A randomized, double-blind, controlled trial

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Perioperative hypothermia causes postoperative complications. Prewarming reduces body temperature decrease in long-term surgeries. We aimed to assess the effect of different time-periods of prewarming on perioperative temperature in short-term transurethral resection under general anesthesia. Randomized, double-blind, controlled trial in patients scheduled for bladder or prostatic transurethral resection under general anesthesia. Eligible patients were randomly assigned to receive no-prewarming or prewarming during 15, 30, or 45 min using a forced-air blanket in the pre-anesthesia period. Tympanic temperature was used prior to induction of anesthesia and esophageal temperature intraoperatively. Primary outcome was the difference in core temperature among groups from the induction of general anesthesia until the end of surgery. Repeated measures multivariate analysis of covariance modeled the temperature response at each observation time according to prewarming. We examined modeled contrasts between temperature variables in subjects according to prophylaxis. We enrolled 297 patients and randomly assigned 76 patients to control group, 74 patients to 15-min group, 73 patients to 30-min group, and 74 patients to the 45-min group. Temperature in the control group before induction was 36.5 ± 0.5 °C. After prewarming, core temperature was significantly higher in 15- and 30-min groups (36.8 ± 0.5 °C, $p = 0.004$; 36.7 ± 0.5 °C, $p = 0.041$, respectively). Body temperature at the end of surgery was significantly lower in the control group (35.8 ± 0.6 °C) than in the three prewarmed groups (36.3 ± 0.6 °C in 15-min, 36.3 ± 0.5 °C in 30-min, and 36.3 ± 0.6 °C in 45-min group) ($p < 0.001$). Prewarming prior to short-term transurethral resection under general anesthesia reduced the body temperature drop during the perioperative period. These time-periods of prewarming also reduced the rate of postoperative complications.

Study Registration Registered at ClinicalTrials.gov (Identifier: NCT03630887).

Perioperative hypothermia is common in patients under general anesthesia[1]. Its appearance could lead to cardiovascular and hemorrhagic complications[1,2]. Since duration of surgery is one of the main risk factors for intraoperative temperature decrease[3], most reported studies dealing with anesthesia-associated hypothermia have focused on long-term surgical procedures. However, the decrease in body temperature starts just after anesthesia

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induction due to impaired thermal regulation, loss of compensatory mechanisms by anesthetic-induced vasodilation, and redistribution of heat from core to peripheral compartments. Patients are usually normothermic at the end of surgery when intraoperative active warming is applied. However, patients undergoing short-term surgeries are usually hypothermic at the end of surgery, even with intraoperative warming, due to redistribution hypothermia[4].

During the first 30 min after anesthetic induction, an abrupt decrease in temperature from 0.5 to 1.5 °C occurs[4]. One of the most effective tools for preventing perioperative hypothermia is the application of active prewarming using forced-air devices. Most recent guidelines recommend its application before anesthetic induction[5–7]. However, it is surprising that this recommendation applies only to long surgeries[6], since the fastest temperature decrease occurs just after anesthesia induction[8]. There are no prewarming recommendations for short-term surgical procedures due to lack of evidence.

We hypothesized that short-time periods of preoperative forced-air warming (for 15, 30 or 45 min) will prevent the decrease of body temperature in patients undergoing transurethral resection under general anesthesia, when compared to non-prewarmed patients. As secondary objectives, we assessed the prevalence of hypothermia among different groups upon arrival at Post-Anesthesia Care Unit (PACU) and examined the effects of these prewarming times for decreasing the rate of postoperative shivering, postoperative pain, length of stay in the PACU, and development of other postoperative complications.

Materials and methods

Study design and patients. This study was approved by the Hospital's Institutional Review Board (CEI/CEIm Provincial Las Palmas, approval number 2018-153-1). Written informed consent was obtained from all subjects participating in the trial. The trial was registered prior to patient enrollment at clinicaltrials.gov (NCT03630887) on 15/08/2018. This manuscript adheres to the Consolidated Standards of Reporting Trials (CONSORT) guidelines for reporting randomized clinical trials[9]. The trial was designed in accordance with the Declaration of Helsinki[10]. This trial was conducted in compliance with the original protocol. The full protocol of the study is available by request to the corresponding author.

This trial was a randomized, double-blinded, controlled trial. Eligible patients were those scheduled for elective bladder or prostatic transurethral resection under general anesthesia from August 2018 to October 2018 at the Hospital Universitario de Gran Canaria Dr. Negrín, Las Palmas de Gran Canaria, Spain. We excluded patients with current infections, those taking antipyretics within 24 h before surgery, patients with neuropathy, thyroid disorders, marked peripheral vascular diseases, skin lesions, or history of hypersensitivity to skin contact devices. Patients expected to have a transurethral resection lasting longer than one hour, and those who declined consent were also excluded.

Intervention. Prewarming was performed in the pre-anesthesia room using a forced-air blanket (WarmTouch total body blanket, Covidien, Mansfield, USA) covering the entire body. Temperature output of the warmer (WarmTouch Model WT-5900, Covidien) was set at maximum level (43.0 °C).

Outcomes. For assessing hypothermia, we selected as the primary outcome the difference in core temperature among treatment groups from the time of arrival to the pre-anesthesia room to the end of surgery. Secondary outcomes included the incidence of postoperative hypothermia, shivering, pain intensity 30 min upon arrival at the PACU, length of PACU stay, and postoperative complications.

Sample size. We estimated the sample size based on data from our previous observational study in 56 patients receiving spinal anesthesia, in which hypothermia developed in 96% of non-prewarmed patients[11]. We performed a power analysis to detect a temperature difference of 0.15 °C (± 0.05 °C) at the end of surgery. To detect differences in the esophageal temperature, 40 patients in each group were estimated to provide 80% power at an alpha level of 0.05. Surgery lasted less than 60 min and several temperature measurements were recorded intraoperatively (at 15, 30, and 45 min). Since in some patients the surgical procedure lasted less than 30 min, temperature at 30 or 45 min could not be measured. Under the expectation of missing data at 30 or 45 min in many patients, the sample size was increased to at least 293 patients. No interim analysis was performed.

Enrolment, randomization, and masking. Eligible patients were approached the day before surgery after ensuring they met inclusion criteria and none of exclusion criteria. Subsequently, informed consent was obtained. Randomization was performed by an assistant (not involved in enrollment or data collection) using a computer-generated randomization approach with a 1:1 ratio without blocks or stratification to one of the following four groups: three prewarming groups (15, 30, or 45 min) and a control group (non-prewarming group). The computer-generated allocation sequence was done by a statistician not involved in the rest of the trial. The assistant was the only person with access to documents indicating the randomization group in which each patient was allocated. After randomizing each patient, the assistant reported the duration of prewarming by a phone call to the nurse-in-charge of patient care in the pre-anesthesia room. Patients were unaware of the duration of prewarming. In patients allocated to the control group, the same blanket was placed over the body without connecting it to the warmer. The attending intraoperative anesthesiologist, the anesthesiologist in-charge of care in the PACU, and the assistant reviewing postoperative data were blinded to patient's allocation.

Procedures. Before starting the trial, nurses in-charge of temperature monitoring in the pre-anesthesia room were trained for correct measurements using tympanic thermometers. An otoscope was used in each patient to ensure that tympanic membrane could be visualized. After checking that the probe tip was clean, a cover was placed. Then, the probe tip was inserted into the ear canal without an ear tug and seated in the ear canal by rotating the handle a quarter turn toward the jaw. To reduce intra-observer variability in temperature measurements, we selected the mean value of three consecutive measurements in each patient[11]. Hypothermia was defined as a body temperature < 36.0 °C.

Preoperative phase. Patient's age, gender, body weight and height, American Society of Anesthesiologists (ASA) physical status, and surgical indication of transurethral resection (prostatic or bladder) were recorded. Upon arrival at the pre-anesthesia room, temperature was measured using a tympanic thermometer (Genius 2 Tympanic Thermometer and Base, Covidien, Mansfield, USA). Patients were prewarmed as established in randomization sequence. To avoid delays between the intervention and the induction of anesthesia, prewarming started before the end of surgery in the previous patient, and induction of anesthesia of prewarmed patient was performed once prewarming time finished. After prewarming and before transferring the patient to the operating room, temperature was measured again.

Intraoperative phase. Patients were actively warmed intraoperatively using a forced-air body blanket (WarmTouch upper body blanket, Covidien) positioned over the upper part of the body. Patients were pre-medicated with intravenous midazolam (1–3 mg) at the discretion of the attending anesthesiologist. Intraoperative monitoring included non-invasive arterial pressure, heart rate, electrocardiography, peripheral arterial oxygen saturation, and bispectral index (BIS, Covidien). General anesthesia was performed using fentanyl (1–2 mcg kg^{-1}) and propofol with effect-site target-controlled infusion (TCI, B.Braun, Melsungen, Germany) to maintain BIS 40–60. A laryngeal mask (Ambu AuraGain, Ballerup, Denmark) was used to provide mechanical ventilation. After anesthetic induction, temperature was measured using an esophageal thermometer (Mon-a-Therm, Covidien) placed through the drainage tube of the laryngeal mask, and recorded at 15-min intervals from anesthesia induction to the end of surgery. Neither intravascular fluids nor bladder irrigating fluids were warmed. Room temperature, volume of intravenous fluids, and volume of infused glycine were also recorded.

Postoperative phase. Patients were transferred to the PACU after surgery, where an independent clinician was in-charge of care. The presence of shivering upon arrival (as defined as been visible by an observer), pain intensity at 30 min after arrival at PACU (using a numerical rating scale, NRS), and length of PACU stay were recorded. Patients were transferred to the hospital ward once the Aldrete modified scale[12] was higher than 8. During the postoperative hospital stay, a trial investigator recorded the presence of cardiovascular complications (cardiac arrest, myocardial infarction, unstable angina, arrhythmias), as assessed by an independent clinician (when a patient had cardiovascular symptoms, appropriate complementary tests were performed). Postoperative analgesic requirements were controlled by the clinician responsible for managing the patient (not involved in the trial). These analgesic requirements were not recorded for the study, since due to the characteristics of the surgeries, it was assumed that it would consist only of non-opioid analgesics. The need for re-operation due to severe postoperative bleeding, and blood transfusion requirements (defined by the need of ≥ 1 red blood cell package) were also recorded. Due to the characteristics of the surgery, surgical wound infection was not recorded.

Statistical analysis. Categorical variables are expressed as frequency and percentages and continuous as mean and standard deviation (SD) when data followed a normal distribution, or as median and interquartile range (IQR 25th–75th percentiles) when distribution departed from normality. Percentages were compared using the Chi-square test, means by the t-test, and distributions by the Kruskal–Wallis test for independent data.

To assess the effects of prewarming on temperature evolution throughout the surgery, we fitted a repeated measure multivariate analysis of covariance (MANCOVA) model to the temperature response vector (On arrival at the pre-anesthesia room, Before entering the operating room, 15 min after induction, 30 min after induction, 45 min after induction, At the end of surgery), using the prewarming time as the categorical main effect. The effects of each time-periods of prewarming and the prewarming-time interaction were contrasted using the corresponding F-tests. The model framework allowed us to estimate the marginal means of temperature according time and prophylaxis type directly from parameters of the fitted model. Mean temperatures throughout the surgery according to each treatment group were estimated using 95% confidence intervals and multiple comparisons of these means were made between the control group and each prewarmed group using the test of Dunnet.

Length of stay in PACU among groups was analyzed using one-way ANOVA for independent samples. For each prewarmed group, the survival functions corresponding to the length of stay in the PACU were estimated using the Kaplan–Meier method. Comparisons between groups were made using the log rank test.

Statistical significance was set at $p < 0.05$. Data were analyzed using the R Core Team (2016), version 3.3.1 (R: A language and environment for statistical computing. R Foundation for Statistical Computing, Vienna, Austria. URL: https://www.R-project.org/).

Results

Between August and October 2018, we enrolled 297 patients and randomly assigned 76 patients to the control group, 74 patients to the 15-min prewarming group, 73 patients to the 30-min prewarming group, and 74 patients to the 45-min prewarming group (Fig. 1). Patient characteristics, temperature of the operating room, intravenous volume infused, duration of surgery, and amount of glycine instilled were similar in all groups (Tables 1 and 2). In the pre-anesthesia room, 16.5% (49/297) of patients had a temperature lower than 36 °C, while the rest of patients were normothermic. We did not find differences among groups regarding the core body temperature upon arrival at the pre-anesthesia room (Table 3).

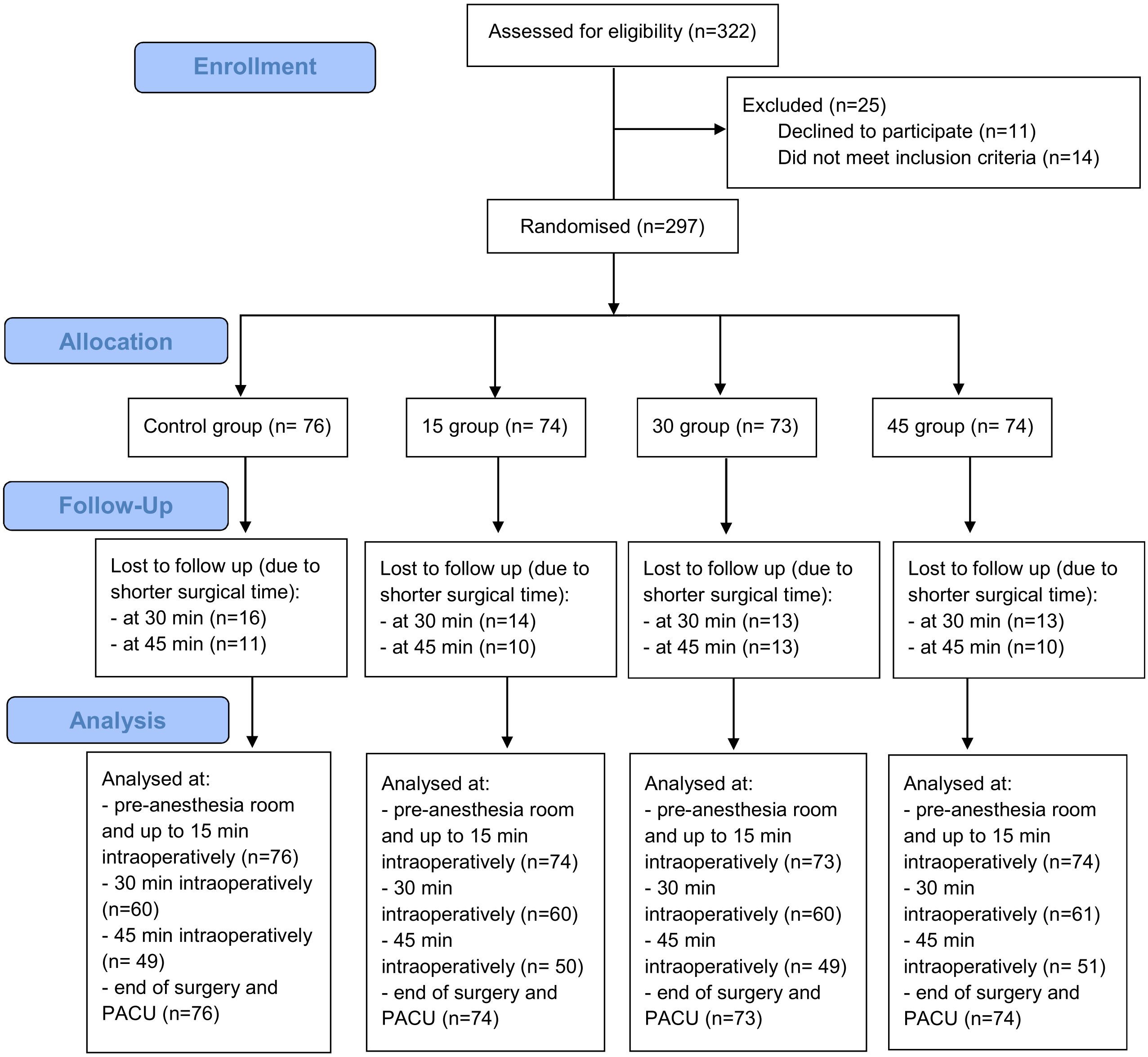

Figure 1. Flow chart diagram.

Mean body temperature of control group before entering into the operating room was 36.5 ± 0.5 °C. After prewarming, body temperature was higher in two prewarmed groups (between 15-min—control difference 0.3 °C, 95% CI 0.1–0.4, p = 0.004; between 30-min—control difference 0.2 °C, 95% CI 0.0–0.3, p = 0.041). Between 45-min—control difference was 0.1 °C (95% CI 0.1–0.3, p = 0.203). Temperature in the control group at the end of surgery was 35.8 ± 0.6 °C. At the end of surgery, temperature was higher in prewarmed groups than in the control group (between 15-min—control group difference 0.5 °C, 95% CI 0.3–0.7, p < 0.001; between 30-min—control group difference 0.5 °C, 95% CI 0.3–0.7, p < 0.001; and between 45-min—control group difference 0.5 °C, 95% CI 0.3–0.7, p < 0.001). No differences were found in intraoperative temperature among prewarmed groups.

The repeated measures multivariate model shows that the effects of duration of prewarming were statistically significant (p < 0.001) and also, the effects of interaction time-treatment (p < 0.001). Table 3 show the marginal means of perioperative temperatures adjusted by the model according the duration of prewarming and time elapsed after induction. Figure 2 shows the trajectories of the temperatures throughout the surgery in each group. Prewarming for 30 min maintained mean temperature throughout the surgery 0.4 °C (95% CI 0.1–0.7) above the control group (p = 0.010) and prewarming for 45 min maintained mean temperature 0.4 °C (95% CI 0.1–0.7) above the control group (p = 0.003). However, when prewarming lasted only 15 min, mean perioperative temperature throughout the surgery did not reach a significant difference when compared to the control group (p = 0.099) (Table 4).

At the end of surgery, 54% (41/76) of patients in the control group, 23% (17/74) in the 15-min group, 25% (18/73) in the 30-min group, and 30% (22/74) in the 45-min group developed hypothermia (p < 0.001). Upon admission to PACU, 42% (32/76) of patients in the control group had shivering episodes. No shivering was observed in the 30-min group, and it only affected 4% (3/74) of patients in the 15-min and the 45-min groups

	Control (n = 76)	15-min (n = 74)	30-min (n = 73)	45-min (n = 74)
Age, years	70 ± 13	73 ± 11	70 ± 12	71 ± 11
Male gender, No. (%)	66 (87)	64 (86)	49 (67)	67 (91)
Body mass index, kg m^{-2}	27.5 ± 4.6	27.7 ± 4.1	27.5 ± 4.3	28.0 ± 4.5
Body surface area, m^2	1.9 ± 0.2	1.9 ± 0.2	1.9 ± 0.2	2.0 ± 0.2
Type of transurethral resection, No. (%)				
Bladder	61 (80)	67 (90)	63 (86)	56 (76)
Prostatic	15 (20)	7 (10)	10 (14)	18 (24)
ASA physical status, No. (%)				
I	3 (4)	0 (0)	3 (4)	1 (1)
II	27 (35)	32 (43)	31 (43)	30 (41)
III	44 (58)	38 (51)	38 (52)	41 (55)
IV	2 (3)	4 (5)	1 (1)	2 (3)

Table 1. Characteristics of patient preoperative variables. Data are expressed as mean ± SD or frequency and percentage. ASA, American Society of Anesthesiologists; 15-min, prewarmed for 15 min; 30-min, prewarmed for 30 min; 45-min, prewarmed for 45 min. Body Surface Area equation: Square root of (Weight (kg) × height (cm)/3600).

	Control (n = 76)	15-min (n = 74)	30-min (n = 73)	45-min (n = 74)	*P* Value
Duration of surgery (min)	30 [20–45]	20 [15–35]	25 [20–40]	25 [15–39]	0.209
Operating room temperature (°C)	23.0 [22.6–23.1]	22.9 [22.5–23.1]	22.8 [22.3–23.1]	23.0 [22.7–23.2]	0.260
Fluid therapy (ml)	300 [200–500]	300 [200–400]	300 [200–500]	300 [200–500]	0.116
Glycine (l)	5 [3–10]	4 [3–7]	5 [3–9]	3 [3–10]	0.460

Table 2. Characteristics of intraoperative variables. Data are expressed as median [IQR]. 15-min: prewarmed for 15 min. 30-min: prewarmed for 30 min. 45-min: prewarmed for 45 min.

Time	Control (n = 76)	15-min (n = 74)	30-min (n = 73)	45-min (n = 74)
On arrival at the pre-anesthesia room	36.6 [36.4; 36.8]	36.5 [36.3;36.7]	36.5 [36.3; 36.7]	36.5 [36.3; 36.7]
Before entering the operating room	36.5 [36.3; 36.7]	36.7 [36.5; 36.9]	36.8 [36.7; 37.0]	36.9 [36.7; 37.1]
15 min after induction	36.4 [36.2; 36.6]	36.6 [36.4; 36.9]	36.7 [36.5; 36.9]	36.8 [36.6; 36.9]
30 min after induction	36.1 [35.9; 36.2]	36.4 [36.2; 36.6]	36.5 [36.3; 36.7]	36.6 [36.4; 36.8]
45 min after induction	35.8 [35.6; 36.0]	36.2 [36.0; 36.4]	36.4 [36.2; 36.6]	36.4 [36.2; 36.6]
At the end of surgery	35.5 [35.2; 35.7]	36.1 [35.9; 36.4]	36.2 [35.9; 36.4]	36.3 [36.1; 36.5]

Table 3. Perioperative temperature in each group (°C) estimated from the repeated measures model. Data are expressed as marginal means [95% CI]. 15-min: prewarmed for 15 min; 30-min: prewarmed for 30 min; 45-min: prewarmed for 45 min.

(OR 0.058, 95% CI 0.017–0.201). Prewarmed groups also showed a lower NRS (between-group difference for 15-min—control 1.0, 95% CI 0.8–1.2, $p < 0.001$; between-group difference for 30-min—control 1.2, 95% CI 0.9–1.4, $p < 0.001$; between-group difference for 45-min—control 1.1, 95% CI 0.9–1.3, $p < 0.001$) and a shorter length of stay in PACU (between-group difference for 15-min—control 34 min, 95% CI 13–55, $p = 0.002$; between-group difference for 30-min—control 42 min, 95% CI 21–63, $p < 0.001$; between-group difference for 45-min—control 38 min, 95% CI 16–60, $p = 0.001$) (Table 5). The length of stay in the PACU showed statistically significant differences among groups ($p = 0.001$). However, there were no significant differences between the three prewarmed groups ($p = 0.800$). Therefore, in order to reduce the time that the patient spends in the PACU, any prewarming duration (15, 30 and 45 min) is superior to the control (Fig. 3).

In the control group, two patients suffered from post-surgical cardiac complications (atrial fibrillation and thoracic pain) and one patient needed re-operation due to post-surgical bleeding. No patients in prewarmed groups suffered from cardiac complications or needed re-operation. These differences were not statistically significant ($p = 0.119$ and $p = 0.4040$, respectively). Of the two patients developing cardiac complications, only one patient had postoperative shivering. One patient in the 15-min group and two patients in the 45-min group needed perioperative blood transfusions. In control group and in the 30-min group, no patients needed

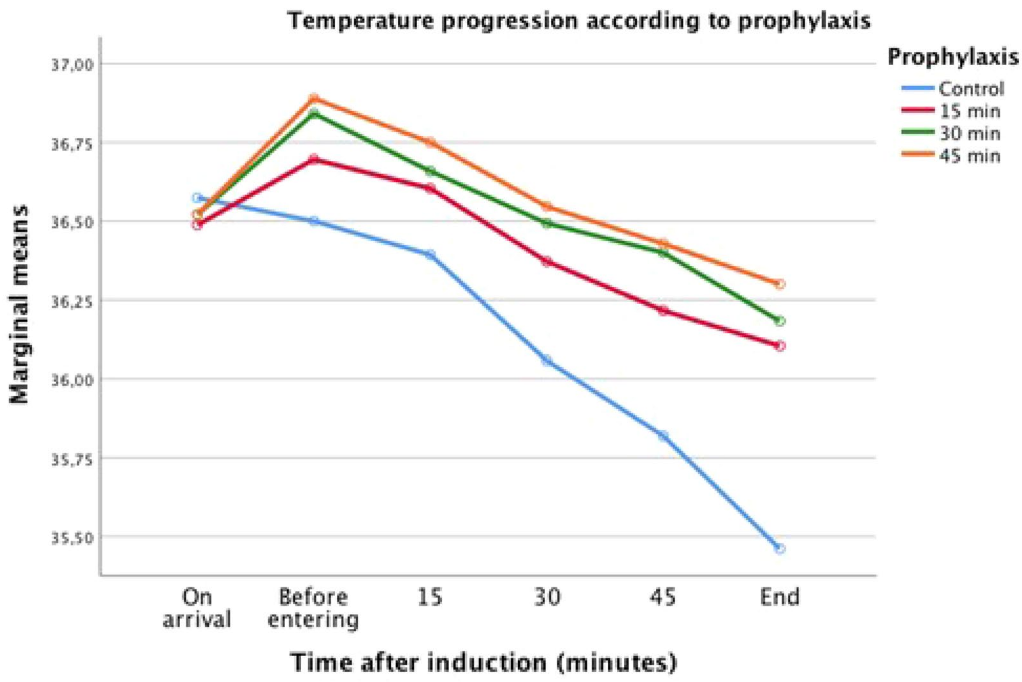

Figure 2. Repeated measures model for perioperative temperatures according to the prewarming duration: estimated marginal means (°C). 15-min: prewarmed for 15 min; 30-min: prewarmed for 30 min; 45-min: prewarmed for 45 min. The effects on temperature of the prewarming for 15 min did not show a statistically significant difference with the control group (p = 0.099). However, the effects showed statistically significant differences with the groups prewarmed for 30 min (p = 0.010) and for 45 min (p = 0.003).

Prewarming	Difference of temperature means [95% CI]*	P-value
Control		
15 min	0.3 [− 0.0; 0.6]	0.099
30 min	0.4 [0.1; 0.7]	0.010
45 min	0.4 [0.1; 0.7]	0.003

Table 4. Comparison of mean temperatures throughout surgery between each prewarmed group with the control using the Dunnett test. (*) Differences are between the control group minus each prewarmed group.

	Control (n = 76)	15-min (n = 74)	30-min (n = 73)	45-min (n = 74)	P Value
Presence of shivering, No. (%)	32 (42)	3 (4)	0 (0)	3 (4)	< 0.001
NRS, No. (%)					
1	8 (11)	49 (66)	55 (75)	52 (70)	< 0.001
2	33 (43)	17 (23)	17 (23)	18 (24)	
3 / 4	35 (46)	8 (11)	1 (1)	4 (5)	
Length of stay in PACU (min)	156 ± 72	122 ± 58	114 ± 56	118 ± 64	0.001

Table 5. Presence of shivering, pain (NRS) and length of stay in PACU in each group. PACU: Post-Anesthetic Care Unit; NRS: numerical rating scale; 15-min: prewarmed for 15 min; 30-min: prewarmed for 30 min; 45-min: prewarmed for 45 min. Data are expressed as percentage and frequency or mean ± SD.

postoperative blood transfusions, but this difference was not statistically significant (p = 0.293). No complications due to prewarming were observed.

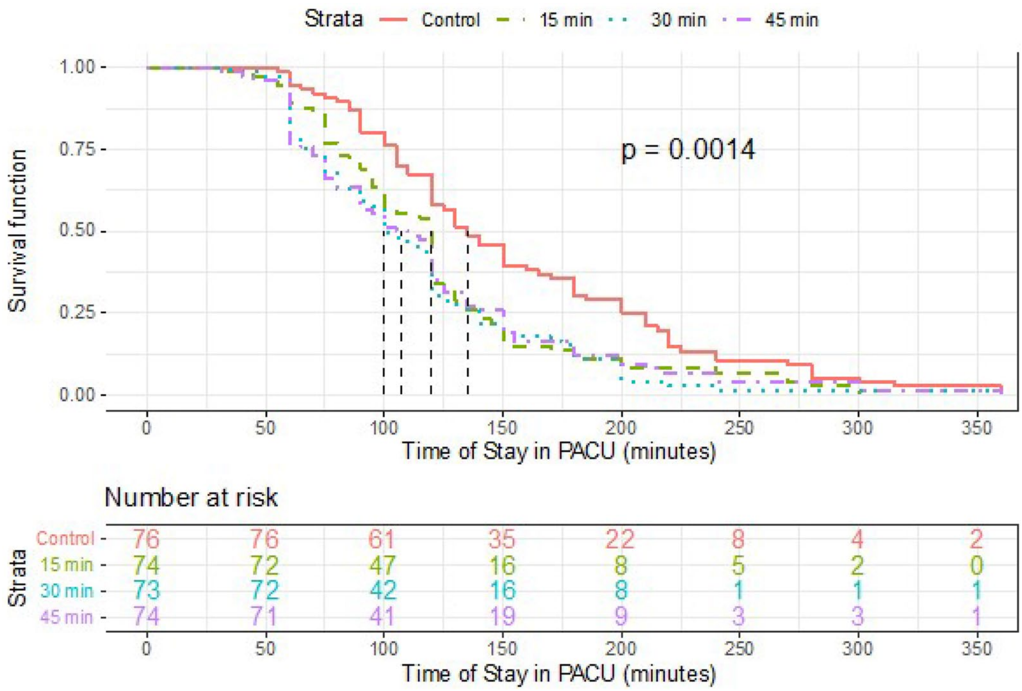

Figure 3. Survival function for the length of stay in PACU according to the prewarming duration. The median length of stay obtained in each group were as follows: in the control group, 135 min; in the group prewarmed for 15 min, 120 min; in the group prewarmed for 30 min, 100 min; and in the group prewarmed for 45 min, 108 min.

Discussion

In this randomized, double-blind, controlled trial, the application of short-time periods of active prewarming before bladder or prostatic transurethral resection reduced the prevalence of redistribution hypothermia. Prewarming also reduced postoperative shivering, postoperative pain intensity, and length of stay in the PACU.

Perioperative hypothermia affects up to 20–50% of patients undergoing general anesthesia[13]. Once the temperature has decreased, treatment of redistribution hypothermia is difficult, since the application of heat to the superficial compartment takes a long time to reach the core compartment. There are two reasons why redistribution hypothermia occurs. First, general anesthetic agents impair autonomic thermoregulatory control, decreasing the vasoconstriction threshold 2–4 °C. The second major factor is the degree of temperature gradient between the core and peripheral compartments[4]. Peripheral compartments (legs and arms) represents approximately 48% of the total body mass, and redistribution hypothermia contributes 81% to the temperature drop, corresponding to a redistribution of 46 kcal during the first hour after general anesthesia induction[14]. The application of warming only during the intraoperative period would not be sufficient to compensate this problem. The prevention of perioperative hypothermia by intraoperative warming using forced air devices seems to be more effective when a greater body surface area of the patient is covered[15]. Forced-air warming increases peripheral heat content (69 kcal) during the first 30 min of warming[16]. During the lithotomy position necessary to perform transurethral resection, large areas of patient's surface are uncovered. Therefore, intraoperative warming alone is insufficient to maintain normothermia in this type of surgery, and prewarming could diminish the redistribution from the core to the peripheral tissues. In our study, short-time periods of active prewarming reduced redistribution hypothermia by 0.5 °C and reduced the prevalence of hypothermia at the end of surgery by 24–31%.

We observed a lower prevalence of preoperative hypothermia than expected[11,17]. The main factors related to perioperative temperature decrease include the preoperative hypothermia[18,19], or the duration of surgery[20]. Although most of these risk factors are not modifiable, there are some modifiable factors, such as prewarming. Active prewarming using forced air devices does not increase core body temperature but reduces core-to-peripheral redistribution of heat[21]. It was initially established that prewarming for 60 min was required to prevent intraoperative hypothermia[21–25]. In other studies, prewarming for 60 min did not prevent the occurrence of hypothermia, but it attenuated redistribution hypothermia[26]. In patients under general anesthesia, 30 min of prewarming appeared to reduce hypothermia[16,27,28], and even 10–15 min reduced temperature decrease and postoperative shivering[29–31]. However, these studies were performed on surgeries lasting more than 60 min. Studies conducted on surgeries shorter than 60 min also showed that prewarming decreased the prevalence of perioperative hypothermia[32–34], but results cannot be extrapolated to our population because they were obtained from pregnant women with the inherent physiological implications. In a previous study performed on men submitted to transurethral resection under spinal anesthesia, short prewarming (15–30 min) reduced the prevalence of hypothermia at the end of the procedure[11].

In our trial, prewarming for 45 min also succeeded in reducing the occurrence of hypothermia at the end of surgery. Our results are consistent with a meta-analysis of previous prewarming trials[35]. We also observed that prewarming for less than 45 min reduced the prevalence of postoperative shivering, the intensity of postoperative pain, and the length of stay in the PACU. Postoperative shivering is one of the most important causes of patient's discomfort and prewarming can increase patient comfort[11,35]. Most post-anesthetic shivering-like tremors are presumably thermoregulatory responses to hypothermia. Nevertheless, shivering can appear in normothermic patients, triggered by the presence of pain[36]. Therefore, patients in the control group might present more episodes of shivering, not only because they were hypothermic, but also because they had more pain. Despite that transurethral resection is a type of surgery associated with mild pain, we found differences in postoperative pain among groups. It could be argued that suffering greater discomfort leads to more complaints of pain. However, temperature and pain signals travel together through the same nerve fibers, synapsing in the dorsal horn of the spinal cord. Thermoregulatory response to the increase in temperature could inhibit the response to pain. There are few studies evaluating the relationship between hypothermia and pain in the postoperative period with contradictory results[29,37–39].

We acknowledge some limitations of our study. First, the gold standard for central temperature monitoring is via a catheter in the pulmonary artery[4,40]. Esophageal thermometers are less invasive, but it is not feasible to place them prior to induction. In the pre-anesthesia room, tympanic temperature measurement is easily accessible and comfortable, with a reported accuracy of ± 0.1°C[40]. We could have obviated data collection of preoperative temperature, but this information allows us to know the preoperative core temperature and how prewarming modifies it. Therefore, since comparison among groups at each time-period was performed using the same thermometer, we believe that our results are valid. Second, we analyzed each time-point without considering temperature progression in each patient. Third, the study was performed on transurethral resection, where bladder irrigation with glycine in the operating room temperature is used. Bladder irrigation produces trivial cooling[41], and is therefore unlikely to have influenced our conclusions.

Conclusions

This randomized controlled trial on surgeries lasting less than 60 min under general anesthesia shows that active prewarming for at least 15 min reduces redistribution hypothermia, the decrease of body temperature throughout perioperative period, and the prevalence of hypothermia at the end of surgery. However, at the end of the surgery, each of the prewarming time-periods (15, 30 or 45 min) are comparably effective, and about 0.5 °C higher than no prewarming. One of our most clinically relevant findings is that these prewarming time-periods also reduced postoperative shivering, postoperative pain intensity, and length of stay in PACU.

Received: 21 June 2021; Accepted: 11 October 2021
Published online: 21 October 2021

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Acknowledgements

We would like to thank Aida Sánchez-Morales, Raquel Gutiérrez-Rodríguez, and Mar Alonso-Fuentes, nurses at Hospital Universitario de Gran Canaria Dr. Negrín for being in-charge of prewarming and measurements of temperature. We also would like to thank the Urology department at Hospital Universitario de Gran Canaria Dr. Negrín for their help in carrying out this trial.

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Funding

This research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors. Aurelio Rodríguez-Pérez is supported by the Canary Islands Health Service, Las Palmas de Gran Canaria, Spain, and by Fundación Canaria Instituto de Investigación Sanitaria de Canarias, Las Palmas de Gran Canaria, Spain. Jesús Villar is supported by Instituto de Salud Carlos III, Madrid, Spain (CB06/061088), PI16/00049, PI19/00141), The European Regional Development's Funds (FEDER), and Fundación Canaria Instituto de Investigación Sanitaria de Canarias.

Competing interests

The authors declare no competing interests.

Additional information

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V. CONCLUSIONES

- La hipotermia perioperatoria es una complicación frecuente en los pacientes intervenidos de cirugía urológica.
- A pesar de las recomendaciones actuales, muchos pacientes llegan al área quirúrgica con una temperatura inferior a 36ºC: el 62,1% de los pacientes programados para ser intervenidos de resección transuretral bajo anestesia espinal; el 23,2% de los pacientes programados para cirugía urológica laparoscópica y el 16,5% de los pacientes programados para resección transuretral de corta duración bajo anestesia general.
- En los tres estudios se aprecia un incremento de la temperatura corporal central tras el precalentamiento con aire caliente forzado y previo a la inducción anestésica.
- El 85,7% de los pacientes sometidos a resección transuretral bajo anestesia espinal sufrieron hipotermia postoperatoria a pesar del uso de medidas activas preoperatorias para evitar su aparición en el 60% de ellos.
- En los pacientes sometidos a resección transuretral bajo anestesia espinal, el precalentamiento durante menos de 15 minutos y durante 15 – 30 minutos de duración resultó útil para incrementar la temperatura intraoperatoria, disminuir la hipotermia por redistribución, la incidencia de hipotermia postoperatoria y la estancia en la unidad de recuperación postanestésica. El precalentamiento activo durante 30 – 45 minutos no

fue tan eficaz en la prevención de la hipotermia como tiempos más cortos.

- El precalentamiento durante menos de 45 minutos de duración disminuye la incidencia de escalofríos postoperatorios tras resección transuretral bajo anestesia espinal.
- En cirugía urológica laparoscópica, el precalentamiento durante 5 – 15 minutos y durante más de 15 minutos logra que los pacientes tengan una mayor temperatura intraoperatoria, disminuye el descenso intraoperatorio de temperatura y la incidencia de hipotermia postoperatoria. Este efecto perdura en el tiempo hasta, al menos, la primera hora postoperatoria. Además, estos tiempos de precalentamiento disminuyen la aparición de escalofríos postoperatorios y la intensidad del dolor a los 30 minutos de la llegada a la unidad de recuperación postanestésica.
- En el estudio presentado, los pacientes con mayor área de superficie corporal, tasa metabólica basal, temperatura preoperatoria y hemoglobina preoperatoria tienen una mayor temperatura corporal central al final de la cirugía urológica laparoscópica.
- Aquellos pacientes que presentaron una menor temperatura corporal central al final de la cirugía urológica laparoscópica habían recibido mayor fluidoterapia intraoperatoria y sufrido mayor sangrado intraoperatorio.
- El efecto del precalentamiento no afecta a la duración de la estancia en la unidad de recuperación postanestésica en cirugía urológica laparoscópica.

- A pesar de la baja necesidad de transfusiones y la baja tasa de infección de herida quirúrgica encontradas, el precalentamiento durante más de 15 minutos logró disminuir los requerimientos de transfusión postoperatoria y el porcentaje de pacientes que sufrió infección de herida quirúrgica en pacientes intervenidos de cirugía urológica laparoscópica.
- En los pacientes sometidos a resección transuretral bajo anestesia general, el precalentamiento durante 15, 30 y 45 minutos incrementaron la temperatura al final de la cirugía. Sin embargo, solo los precalentamientos durante 30 y 45 minutos lograron mantener la temperatura intraoperatoria significativamente superior a la del grupo control.
- El precalentamiento durante 15, 30 y 45 minutos previo a la resección transuretral bajo anestesia general disminuye la incidencia de hipotermia postoperatoria, la aparición de escalofríos postoperatorios, la intensidad del dolor a los 30 minutos de la llegada a la unidad de recuperación postanestésica y la duración de la estancia en la unidad de recuperación postanestésica.
- El precalentamiento durante 15, 30 y 45 minutos no disminuye las complicaciones postoperatorias en pacientes sometidos a resección transuretral bajo anestesia general.

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VII. ANEXOS:

Dictámenes del Comité de Ética:

- Dictamen del Comité de Ética para la realización del estudio prospectivo observacional del precalentamiento en pacientes sometidos a resección transuretral bajo anestesia espinal
- Dictamen del Comité de Ética para la realización del estudio prospectivo observacional del precalentamiento en pacientes sometidos a cirugía urológica laparoscópica
- Dictamen del Comité de Ética para la realización del ensayo clínico sobre el precalentamiento en pacientes sometidos a resección transuretral bajo anestesia general

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INFORME DEL COMITÉ ÉTICO DE INVESTIGACIÓN CLÍNICA/COMITÉ DE LA ÉTICA EN LA INVESTIGACIÓN

Dª MARÍA DOLORES FIUZA PÉREZ, Secretaria del Comité Ético de Investigación Clínica-Comité de Ética en la Investigación del Hospital Universitario de Gran Canaria Doctor Negrín.

C E R T I F I C A:

Que este Comité ha evaluado en la reunión correspondiente al **Acta 9/2011** la propuesta del promotor: **Investigación Independiente** para que se realice el Proyecto de Investigación: **"Efecto del aire caliente forzado en la prevención de la hipotermia perioperatoria en pacientes sometidos a RTU en el Hospital Universitario de Gran Canaria Dr. Negrín".**

Protocolo.
Hoja de información al paciente y consentimiento informado.

Y considera que:

Se cumplen los requisitos necesarios de idoneidad del protocolo en relación con los objetivos del estudio y están justificados los riesgos y molestias previsibles para el sujeto.

La capacidad del investigador y los medios disponibles son apropiados para llevar a cabo el Estudio Observacional.

Es adecuado el procedimiento para obtener el consentimiento informado y el modo de reclutamiento previsto para el Estudio Observacional.

El investigador y su equipo se comprometen a cumplir las recomendaciones y directrices de Buena Práctica Clínica aplicables a este tipo de estudios y la Declaración de Helsinki actualizada.

El alcance de las compensaciones económicas previstas no interfiere con el respeto a los postulados éticos.

Asimismo, este Comité acepta que dicho **Proyecto de Investigación** sea realizado en el Hospital Universitario de Gran Canaria Doctor Negrín por el **Dr. Ángel Becerra Bolaños** del **Servicio de Anestesia y Reanimación** como investigador principal.

Lo que firmo en Las Palmas de Gran Canaria, a 29 de septiembre de 2011

La Secretaria

Fdo.: Dª. María Dolores Fiuza Pérez

Comité Ético de Investigación Clínica CEIC/CEI
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CONFORMIDAD DE LA DIRECCIÓN DEL CENTRO

Don **JOSE MIGUEL SANCHEZ HERNANDEZ** Director Gerente del **HOSPITAL UNIVERSITARIO DE GRAN CANARIA DOCTOR NEGRÍN**, al amparo de la Orden SAS/3470/2009) y vistas las autorizaciones del Comité Ético de Investigación Clínica-Comité de Ética en la Investigación de este Hospital **(Acta 9/2011).**

CERTIFICA:

Que conoce la propuesta realizada por el promotor: **Investigación Independiente** para que sea realizado en este centro el Proyecto de Investigación:

TITULO: **"Efecto del aire caliente forzado en la prevención de la hipotermia perioperatoria en pacientes sometidos a RTU en el Hospital Universitario de Gran Canaria Dr. Negrín".**

Protocolo.

Hoja de información al paciente y consentimiento informado.

Y, que será realizado por el **Dr. Ángel Becerra Bolaños** del **Servicio de Anestesia y Reanimación** como investigador principal.

Que acepta la realización de dicho **Proyecto de Investigación**, en este Centro.

Lo que firma en Las Palmas de Gran Canaria, a 29 de septiembre de 2011.

El Director Gerente

SERVICIO CANARIO DE LA SALUD GERENCIA LAS PALMAS

Fdo: D. José Miguel Sánchez Hernández

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COMITÉ ÉTICO DE INVESTIGACIÓN CON
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DICTAMEN DEL COMITÉ DE ÉTICA DE LA INVESTIGACIÓN/COMITÉ DE ÉTICA DE LA INVESTIGACIÓN CON MEDICAMENTOS

Dña Mª DOLORES FIUZA PEREZ, Secretaria Técnica del Comité de Ética de la Investigación/Comité de Ética de la Investigación con Medicamentos (CEI/CEIm) Hospital Universitario de Gran Canaria Dr. Negrín.

CERTIFICA:

Que este Comité, según consta en el Acta 3/2018 de fecha 26/04/2018 ha evaluado la propuesta del promotor: ANGEL BECERRA BOLAÑOS, para que se realice el **ESTUDIO OBSERVACIONAL - No-EPA**. Titulado:

"Efecto del aire caliente forzado en la prevención de la hipotermiaperioperatoria en pacientes sometidos a cirugía urológica en el Hospital Universitario de Gran Canaria Dr. Negrín".

Promotor: ANGEL BECERRA BOLAÑOS
Código CEIm HUGCDN: 2018-089-1

Docs. con versiones:

Protocolo	Versión abril 2018
HIP y DCI	V. HUGC D. Negrín, abril 2018

CEIC de Referencia: CEI/CEIM Hospital Universitario de Gran Canaria Dr. Negrín.
Investigador Principal: **Dr. ANGEL BECERRA BOLAÑOS del Hospital Universitario de Gran Canaria Dr Negrín, Servicio de Anestesiología y Reanimación.**

Y considera que:

Se cumplen los requisitos necesarios de idoneidad del protocolo en relación con los objetivos del estudio y están justificados los riesgos y molestias previsibles para el sujeto.

La capacidad del investigador y los medios disponibles son apropiados para llevar a cabo el ESTUDIO OBSERVACIONAL - No-EPA

Es adecuado el procedimiento para obtener el consentimiento informado y el modo de reclutamiento.

El investigador y su equipo se comprometen a cumplir las recomendaciones y directrices de Buena Práctica Clínica aplicables a este tipo de estudios y la Declaración de Helsinki actualizada.

El alcance de las compensaciones económicas previstas no interfiere con el respeto a los postulados éticos.

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Asimismo, este Comité **APRUEBA** que dicho ESTUDIO OBSERVACIONAL - No-EPA sea realizado en el Hospital Universitario de Gran Canaria Dr. Negrín por D. ANGEL BECERRA BOLAÑOS como Investigador Principal.

Que este Comité, tanto en su composición como en los PNTs, cumple con las normas de BPC (CPMP/ICH/135/95).

Con la elevación de este Dictamen a la Dirección Gerencia de este Centro para valoración de su Conformidad, terminan las acciones competencia de este CEI/CEIm sobre su estudio.

Que en dicha reunión se cumplió el quórum preceptivo legalmente.

Que, en el caso de que se evalúe algún proyecto del que un miembro sea investigador/colaborador, dicho miembro no participa en la evaluación ni el dictamen del propio protocolo.

Lo que firmo en Las Palmas de Gran Canaria, a 14 de mayo de 2018

La Secretaria Técnica

Fdo.: DÑA. Mª DOLORES FIUZA PEREZ

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COMITÉ ÉTICO DE INVESTIGACIÓN CON
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ANEXO I:

La Composición actual del Comité es la siguiente:

PRESIDENTE:
Dr. D. Vicente Olmo Quintana Resp. Servicio Farmacia de Atención Primaria

VICEPRESIDENTE:
Dr. D. Antonio García Quintana Jefe Servicio Cardiología. F.E.A. Servicio de Cardiologia HUGCDN

SECRETARIA TECNICA:
Dra. Dª. Mª Dolores Fiuza Pérez. F.E.A. Epidemiología Clínica HUGCDN. Conocimientos acreditados en Bioética

VOCALES:
Dr. D. Daniel López Fernández . Fisioterapéuta del Servicio de Rehabilitación HUGCDN
Dr. D. Antonio Tugores Cester. Responsable Unidad de Investigación CHUIMI
Dra. Dª. Attenya Álamo Medina. F.E.A. Servicio de Farmacia Hospitalaria CHUIMI
Dr. D. José L. Alonso Bilbao. F.E.A. Técnico Salud Pública AP
Dr. D. Mauro Boronat Cortés. F.E.A. Servicio Endocrinología CHUIMI
Dr. D. David Aguiar Bujanda. F.E.A. Servicio Oncología Médica HUGCDN
Dra. Dª. Elisabet Guerra Hernández F.E.A. Anestesiología y Reanimación HUGCDN
Dª. Elisabeth Cheneau. D.U.E. Docencia, Salud Mental CHUIMI
Dr. D. Félix Isidro López Blanco. Farmacólogo Clínico, Dpto. Farmacología ULPGC – CHUIMI
Dr. D. Francisco J. Navarro Vázquez. F.E.A. Técnico salud Pública AP
Dr. D. Jordi López García. F.E.A. Servicio de Neumología CHUIMI
Dña. Fuensanta León Amador. Presidenta de la Asociación de Enfermos de Crohn y colitis ulcerosa de Canarias- Personal ajeno a las Instituciones Sanitarias
Dr. D. Jesús María González Martín. Estadístico Unidad de Investigación HUGCDN
D. José Juan Morales Castro. D.U.E. Área de Quirófano CHUIMI
Dr. D. Octavio Ramírez García. Presidente Comité Ética Asistencial CHUIMI. Conocimientos demostrados en Bioética
Dr. D. Jorge Arencibia Borrego. F.E.A. Servicio de Medicina Interna HUGCDN
Dra. Dª. Beatriz Sánchez Lerma. F.E.A. Servicio Farmacia Hospitalaria CHUIMI
Dr. D. Jorge Solé Violán. F.E.A. Servicio de Medicina Interna HUGCDN
D. Julio Ángel de Santiago Angulo. Lcdo. en Derecho, Asesor Jurídico CHUIMI
Dra. Dª. Mª. Asunción Acosta Mérida. F.E.A. Servicio de Cirugia General y Digestiva HUGCDN
Dra. Dª. Blanca Valenciano Fuente. F.E.A. Pediatra, Servicio de Pediatría CHUIMI
Dña. Rita del Carmen Gutiérrez Gil. Lcda. en Derecho, Asesora Jurídica HUGCDN
Dra. Dª. Silvia de la Iglesia Iñigo F.E.A. Servicio de Hematología HUGCDN
Dra. Dª. Juana Teresa Rodríguez Sosa. F.E.A. Servicio de Psiquiatría HUGCDN
Dª. Mª. Dolores Jarillo López-Mora. D.U.E. Enfermería HUGCDN
Dra. Dª. Mireya Amat López. F.E.A. Servicio de Farmacia Hospitalaria HUGCDN
Dra. Dª. Ana Aldea Perona. Farmacólogo Clínica HUC
Dª. Mª. Del Pino Fierro Ferreyra. Periodista personal ajeno a las Instituciones Sanitarias

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ANEXO II:

Investigadores Colaboradores:

Mar Alonso Fuentes. Enfermería Área Quirúrgica.
Aida Sánchez Morales. Enfermería Área Quirúrgica.
Aurelio E. Rodríguez Pérez. FEA Anestesiología y Reanimación.
Raquel Gutiérrez Rodríguez. Enfermería Área Quirúrgica.
Hector Trujillo Morales. FEA Anestesiología y Reanimación.

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DICTAMEN DEL COMITÉ DE ÉTICA DE LA INVESTIGACIÓN/COMITÉ DE ÉTICA DE LA INVESTIGACIÓN CON MEDICAMENTOS

D/ Dña Mª DOLORES FIUZA PEREZ**,** Secretaria Técnica del Comité de Ética de la Investigación/Comité de Ética de la Investigación con Medicamentos (CEI/CEIm) Provincial de Las Palmas

C E R T I F I C A:

Que este Comité, según consta en el Acta 5/2018 de fecha 19/07/2018 ha evaluado la propuesta del promotor: AURELIO E. RODRÍGUEZ PÉREZ, para que se realice el **ENSAYO CLÍNICO** - **EC Otros**. Titulado:

"Efecto del aire caliente forzado en la prevención de la hipotermia perioperatoria en pacientes sometidos a RTU".

Promotor: AURELIO E. RODRÍGUEZ PÉREZ
Código CEIm LAS PALMAS: 2018-153-1
Docs. con versiones:

Protocolo		V.O. de 15 de junio de 2018
HIP y DCI		V. HUGC D. Negrín

CEIC de Referencia: CEI/CEIM HOSPITAL UNIVERSITARIO DE GRAN CANARIA DR. NEGRIN.
Investigador Principal: **D ANGEL BECERRA BOLAÑOS, del Hospital Universitario de Gran Canaria Dr Negrín, Servicio Anestesiología y Reanimación**

Y considera que:

Se cumplen los requisitos necesarios de idoneidad del protocolo en relación con los objetivos del estudio y están justificados los riesgos y molestias previsibles para el sujeto.

La capacidad del investigador y los medios disponibles son apropiados para llevar a cabo el ENSAYO CLÍNICO - EC Otros

Es adecuado el procedimiento para obtener el consentimiento informado y el modo de reclutamiento.

El investigador y su equipo se comprometen a cumplir las recomendaciones y directrices de Buena Práctica Clínica aplicables a este tipo de estudios y la Declaración de Helsinki actualizada.

El alcance de las compensaciones económicas previstas no interfiere con el respeto a los postulados éticos.

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Asimismo, este Comité **APRUEBA** que dicho ENSAYO CLÍNICO - EC Otros sea realizado en el Hospital Universitario de Gran Canaria Dr. Negrín por D ANGEL BECERRA BOLAÑOS como Investigador Principal.

Que este Comité, tanto en su composición como en los PNTs, cumple con las normas 0de BPC (CPMP/ICH/135/95).

Con la elevación de este Dictamen a la Dirección Gerencia de este Centro para valoración de su Conformidad, terminan las acciones competencia de este CEI/CEIm sobre su estudio.

Que en dicha reunión se cumplió el quórum preceptivo legalmente.

Que, en el caso de que se evalúe algún proyecto del que un miembro sea investigador/colaborador, dicho miembro no participa en la evaluación ni el dictamen del propio protocolo.

Lo que firmo en Las Palmas de Gran Canaria, a 1 de agosto de 2018

La Secretaria Técnica

Fdo.: Dra Mª DOLORES FIUZA PEREZ

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COMITÉ ÉTICO DE INVESTIGACIÓN CON
MEDICAMENTOS PROVINCIAL LAS PALMAS.
CEI/CEIm.

Gobierno
de Canarias

ANEXO I:

La Composición actual del Comité es la siguiente:

PRESIDENTE:
Dr. D. Vicente Olmo Quintana. Responsable Servicio Farmacia de Atención Primaria

VICEPRESIDENTE:
Dr. D. Antonio García Quintana. F.E.A. Servicio de Cardiología HUGCDN

SECRETARIA TECNICA:
Dra. Dª. Mª Dolores Fiuza Pérez. F.E.A. Epidemiología Clínica HUGCDN

VOCALES:
Dr. D. Daniel López Fernández . Fisioterapéuta del Servicio de Rehabilitación HUGCDN
Dr. D. Antonio Tugores Cester. Unidad de Investigación CHUIMI
Dra. Dª. Attenya Álamo Medina. F.E.A. Servicio de Farmacia Hospitalaria CHUIMI
Dr. D. José L. Alonso Bilbao. F.E.A. Técnico Salud Pública AP
Dr. D. Mauro Boronat Cortés. F.E.A. Servicio Endocrinología CHUIMI
Dr. D. David Aguiar Bujanda. F.E.A. Servicio Oncología Médica HUGCDN
Dra. Dª. Elisabet Guerra Hernández F.E.A. Anestesiología y Reanimación HUGCDN
Dª. Elisabeth Cheneau. D.U.E. Docencia, Salud Mental CHUIMI
Dr. D. Félix Isidro López Blanco. Dpto. Farmacología ULPGC – CHUIMI
Dr. D. Francisco J. Navarro Vázquez. F.E.A. Técnico salud Pública AP
Dr. D. Jordi López García. F.E.A. Servicio de Neumología CHUIMI
Dña. Fuensanta León Amador. Presidenta de la Asociación de Enfermos de Crohn y colitis ulcerosa de Canarias. Personal ajeno a las Instituciones Sanitarias
Dr. D. Jesús María González Martín. Estadístico Unidad de Investigación HUGCDN
D. José Juan Morales Castro. D.U.E. Área de Quirófano CHUIMI
Dr. D. Octavio Ramírez García. Presidente Comité Ética Asistencial CHUIMI
Dr. D. Jorge Arencibia Borrego. F.E.A. Servicio de Medicina Interna HUGCDN
Dra. Dª. Beatriz Sánchez Lerma. F.E.A. Servicio Farmacia Hospitalaria CHUIMI
Dr. D. Jorge Solé Violán. F.E.A. Servicio de Medicina Interna HUGCDN
D. Julio Ángel de Santiago Angulo. Lcdo. en Derecho, Asesor Jurídico CHUIMI
Dra. Dª. Mª. Asunción Acosta Mérida. F.E.A. Servicio de Cirugia General y Digestiva HUGCDN
Dra. Dª. Blanca Valenciano Fuente. F.E.A. Pediatra, Servicio de Pediatría CHUIMI
Dra. Dª. Silvia de la Iglesia Iñigo F.E.A. Servicio de Hematología HUGCDN
Dra. Dª. Juana Teresa Rodríguez Sosa. Representante Comité Ética Asistencial HUGCDN
Dª. Mª. Dolores Jarillo López-Mora. D.U.E. Enfermería HUGCDN
Dra. Dª. Mireya Amat López. F.E.A. Servicio de Farmacia Hospitalaria HUGCDN
Dª. Mª. Del Pino Fierro Ferreyra. Periodista. Personal ajeno a las Instituciones Sanitarias

Servicio
Canario de la Salud

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ANEXO II:

Centros colaboradores:

Investigadores:

Angel Becerra Bolaños	Anestesiología y Reanimación	HUGCDN
Aurelio E. Rodríguez Pérez	Anestesiología y Reanimación	HUGCDN
Lucia Valencia Sola	Anestesiología y Reanimación	HUGCDN
María Bermejo guillén	Anestesiología y Reanimación	HUGCDN
Aída Sánchez Morales		HUGCDN
Mar Alonso Fuentes		HUGCDN