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Evaluation of a minimally invasive renal cooling device using heat transfer analysis and an *in vivo* porcine model

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ABSTRACT

Partial nephrectomy is the gold standard treatment for renal cell carcinoma. This procedure requires temporary occlusion of the renal artery, which can cause irreversible damage due to warm ischemia after 30 min. Open surgical procedures use crushed ice to induce a mild hypothermia of 20 °C in the kidney, which can increase allowable ischemia time up to 2.5 h. The Kidney Cooler device was developed previously by the authors to achieve renal cooling using a minimally invasive approach. In the present study an analytical model of kidney cooling *in situ* was developed using heat transfer equations to determine the effect of kidney thickness on cooling time. *In vivo* porcine testing was conducted to evaluate the cooling performance of this device and to identify opportunities for improved surgical handling. Renal temperature was measured continuously at 6 points using probes placed orthogonally to each other within the kidney. Results showed that the device can cool the core of the kidney to 20 °C in 10–20 min. Design enhancements were made based on surgeon feedback; it was determined that the addition of an insulating air layer below the device increased difficulty of positioning the device around the kidney and did not significantly enhance cooling performance. The Kidney Cooler has been shown to effectively induce mild renal hypothermia of 20 °C in an *in vivo* porcine model.

1. Introduction

Renal cell carcinoma, or kidney cancer, affects over 58,000 people per year in the United States alone [1]. There are several treatment options, including radical nephrectomy and tumor ablation, but the gold standard for treatment of T1a (<4 cm) tumors is the partial nephrectomy [2]. In this procedure the tumor is excised while leaving the rest of the kidney intact, saving much of the organ's functionality.

During a partial nephrectomy procedure, blood flow to the kidney is occluded by clamping the renal artery to prevent excessive bleeding. This technique, however, prevents kidney tissues from receiving oxygen, a condition called warm ischemia. Permanent damage can occur to the kidney if this condition lasts for more than 30 min [3].

A mild hypothermia can mitigate the effects of warm ischemia. If the core of the kidney can be cooled to 20 °C then ischemic time can be extended up to 2.5 h [4]. In open surgery this is accomplished by packing crushed saline ice around the kidney for 10 min [3]. Upon completion of cooling the ice can be removed with the aid of suction. In some cases, the ice is left in the body during the procedure to prevent rewarming of the kidney. This method is effective and has been adopted as standard practice by most surgeons.

Minimally invasive surgery has become an increasingly popular surgical option with advances in equipment and techniques. Studies in the literature have shown that with an experienced surgeon, minimally invasive surgery can provide equal oncologic results to open surgery but with improved patient recovery times [5]. Partial nephrectomy procedures are sometimes performed using this approach; however, there is currently no effective solution for inducing renal hypothermia with a minimally invasive approach. Thus, minimally invasive partial nephrectomies can only be performed safely in patients with small tumors in easily accessible locations.

Various strategies have previously been developed to attempt minimally invasive renal cooling, though none have been adopted for use. A cooling element inserted through an artery has been developed, but is intended for localized cooling rather than whole-organ cooling. Surface cooling devices that surround the kidney have been designed and patented that circulate a chilled liquid to act as a heat exchanger. This approach necessarily utilizes secondary equipment to recirculate and remove heat from the fluid.

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Nomenclature

Roman symbols

A	surface area, top of kidney [m^2]
c_p	specific heat capacity [J/kg °C]
D	distance of capillary from muscle surface [m]
d	thickness
Fo	Fourier number
g	acceleration of gravity [m/s^2]
h	heat transfer coefficient [W/m^2 °C]
k	thermal conductivity [W/m °C]
l	length [m]
l_i	characteristic length [m]
$\dot{m}$	mass flow rate [kg/s]
m	mass [kg]
NTU	number of transfer units
Nu	Nusselt number
$\dot{Q}$	heat transfer rate [W]
Q	thermal energy [J]
R	thermal resistance [°C/W]
r	radius [m]
Ra	Rayleigh number
S	geometric shape factor [m]
t	time [s]
UA	overall heat transfer coefficient [W/°C]
w	width [m]
x	distance [m]
z	non-dimensional distance

Greek symbols

α	thermal diffusivity [m^2/s]
β	thermal expansion coefficient of air [1/K]
ΔT	temperature difference from bag surface [°C]
ϵ	effectiveness
ν	kinematic viscosity [m^2/s]
θ	non-dimensional temperature

Subscripts

air	air in body cavity
av	average
b	blood
cap	capillary in muscle
ins	insulating air layer
k	kidney
m	muscle
s	bag surface

Additionally, long tubing lengths (2 m) are required to extract sufficient thermal energy, which adds bulk to the devices. Phase change cooling has been attempted by placing ice slurry into a plastic bag that is cinched around the renal hilum [3]. This approach can achieve successful cooling but increases risk to the patient due to increased activity around the delicate renal hilum.

Recently, a new device for achieving renal hypothermia during minimally invasive surgery was developed by the authors utilizing a phase change cooling approach [6]. An *ex vivo* model was used for preliminary evaluation of its cooling capabilities. The present study describes the development of an analytical model of kidney heat transfer *in situ* to determine the effect of kidney thickness on cooling time. *In vivo* porcine testing of the device was conducted to evaluate cooling performance and identify opportunities for improved surgical handling.

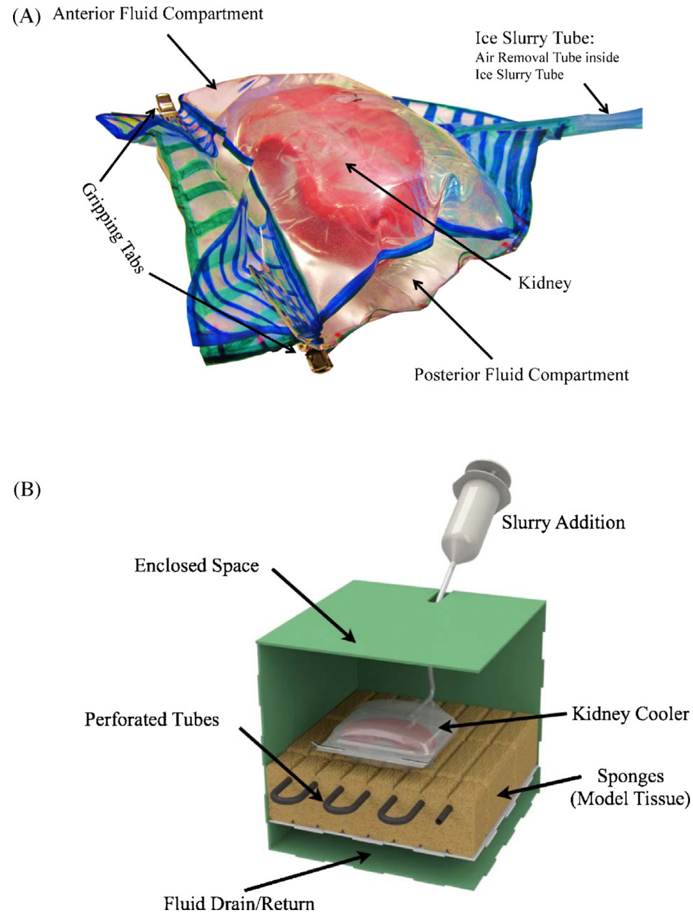

Fig. 1. (A) The Kidney Cooler device filled with fluid and wrapped around a model kidney. Ice slurry fills the anterior and posterior fluid compartments through the attached slurry tube. An embedded air removal tube allows venting while filing. Bulldog clamps (represented by clips) are placed along the gripping tabs to keep the device in position around the kidney. Color-coding of different faces improve visualization in the minimally invasive environment. (B) *Ex vivo* abdominal cavity environment to evaluate kidney cooling time. Perforated tubing is embedded within a sponge layer housed within a plexiglass container. Water is heated to 37 °C and circulated through the tubing to model blood profusion through abdominal tissue. (For interpretation of the references to color in this figure legend, the reader is referred to the web version of the article.)

2. Methods

2.1. The Kidney Cooler

The Kidney Cooler, shown in Fig. 1(A), was previously described by the authors [6]. Briefly, it is a device that is inserted through a 15 mm trocar, surrounds the kidney with ice slurry, and is removed upon completion of cooling. Two fluid-filled compartments are in contact with the anterior and posterior surfaces of the kidney, covering nearly 100% of the organ's surface area. Ice slurry is added through a urethane tube with an embedded vent to equalize pressure. The device is made with 0.051–0.127 mm thick urethane film that can be manipulated with standard laparoscopic instruments without tearing. Tabs located at the end of the bag provide accessible gripping points that do not interfere with the renal hilum and are secured with bulldog clamps once the device is situated. Select devices were manufactured with a thin inflatable air layer on the outer posterior compartment of the device. This air layer insulates the ice slurry in the posterior compartment from heat generated by the abdomen. The added stiffness from this air layer facilitates handling by the surgeon. The design process and additional features of