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Original research

Elimination of warm ischemia using the Ice Bag Technique does not decrease delayed graft function

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ABSTRACT

Background: Warm ischemic time (WIT) in kidney transplantation has significant effects on graft survival, function, and postoperative morbidity. We utilized the Ice Bag Technique (IBT) to determine if eliminating WIT would decrease the incidence and length of delayed graft function (DGF) in our cohort.
Methods: We conducted a prospective study of 150 kidney transplants. We compared the elimination of WIT with IBT to traditional methods. Data was analyzed using non-parametric statistical tests.
Results: 66 of the 134 patients underwent transplantation using IBT. 28 right kidneys, 34 left kidneys, and 4 dual kidneys were implanted successfully. Patients with a body mass index (BMI) as high as 41 were transplanted. Kidneys with up to three arteries and two veins, and kidneys up to 15.5 by 9 cm in size were safely transplanted into either iliac fossa. Despite the complete elimination of WIT, there was no difference in DGF, length of DGF, length of stay graft rejection, graft survival, patient survival, or wound or urologic complications between groups ($p > 0.05$).
Conclusions: The elimination of warm ischemic time using the IBT does not appear to reduce the incidence or length of DGF in this cohort. The technique may be useful for cases with prolonged anastomosis time (AT), but further studies with larger cohorts are required to determine whether it decreases DGF.
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1. Introduction

It is impossible to transplant an organ without causing ischemia and microcirculatory disturbance. These insults are established causes of reperfusion injury and functional impairment [1–3]. Ischemia and reperfusion injury (IRI) are associated with an increased rate of acute rejection, primary non-function (PNF), delayed graft function (DGF), initial poor graft function (IPGF), and late graft failure [1–4].

WIT refers to the time necessary to perform the vascular anastamoses during kidney transplantation [1,4]. While WIT is an accepted risk factor for DGF, we do not know the safe upper limit. DGF is defined as the requirement of dialysis within seven days of transplantation. It is a negative prognostic indicator for long-term allograft survival and is also associated with significant costs. Attempts to minimize WIT include wrapping the kidney in an ice-soaked laparotomy pad. Other techniques include using an RAY-TEC sponge (Johnson & Johnson, New Brunswick, NJ, USA), stockinette, cooling jacket, or clear sterilized bag [5]. Some surgeons eschew this technique, preferring to simply suture the vessels as quickly as possible. However, this approach may lead to technical errors, excessive bleeding, worse long-term outcomes, and a poor learning experience for the resident staff [1]. The ice bag technique is a method developed in the 1990's to reduce WIT that was largely abandoned before being studied in the literature. This technique may potentially lead to less DGF. The aim of this study was to evaluate the effect of the IBT on incidence and length of DGF. We also sought to determine its effect on wound and urologic complications as well as patient and graft survival.

2. Materials and methods

We conducted an Institutional Review Board – approved prospective study of renal transplants performed between January 2010 and June 2011. 150 renal transplants were identified after excluding allografts from living or infant donors. These were excluded to provide uniformity to our cohort and because they comprised an extremely small proportion of transplants. We also wanted to show that the technique is safe with longer vessels,

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which are more likely found in deceased donors than living donors. We divided subjects into three arms: IBT, non-IBT due to surgeon preference, and non-IBT for anatomic reasons. Informed consent was waived by the local ethics committee. Cases performed by the surgeon who preferred not to use the IBT served as the control group. Patients in the anatomic limitation group were excluded from statistical analysis. Reasons for exclusion from the IBT included cut or short renal arteries or veins, difficult arterial course, duplicate arteries, recipient BMI, and limited operative space (Table 1). The follow-up for these patients was one year, which was chosen because our primary endpoint, DGF, would manifest within that time frame.

Donor variables recorded include donor type (donation after cardiac death or DCD, donors after neurologic determination of death or DND, expanded criteria donors or ECD, and combined ECD/DCD donors), donor gender, donor age, kidney side, size, number of vessels, terminal creatinine and use of the machine perfusion pump. We classified donor type by the Organ Procurement and Transplantation Network (OPTN) definitions. We also examined recipient demographics including body mass index (BMI), comorbidities such as diabetes and hypertension, and primary renal disease. Intraoperative parameters included WIT, cold ischemic time (CIT), and operative site. We defined WIT, also referred to as AT, as time from removal of the kidney from storage to reperfusion with or without IBT. It is important to note that WIT was eliminated with the IBT. Primary endpoints included incidence and length of DGF. The length of DGF was defined as the duration between transplant date and last dialysis session. Secondary endpoints included creatinine levels on postoperative days 10 and 365, graft rejection, graft and patient survival, length of hospital stay (LOS), wound complications and urologic complications. Creatinine levels at postoperative day 10 were chosen as this is the usual postoperative nadir value. We also collected data on postoperative day 365 creatinine as it is routinely collected by UNOS and is an excellent predictor of long-term allograft outcome. Renal allograft loss was defined as death with a functioning graft, allograft nephrectomy or resumption of dialysis. Wound complications included fascial dehiscences, wound dehiscences, and wound infections. Wound infection was defined as infection of the skin or subcutaneous tissues surrounding the surgical wound. Urologic complications examined include urosepsis and urine leaks. Results were compiled into a series of Excel databases to be analyzed at the end of the specified time period. Due to the small size of the group, patients in the anatomical exclusion cohort were unable to be statistically compared to the patients in the IBT and non-IBT cohort and were thus excluded from statistical analysis.

All procedures were in accordance with the Helsinki Declaration of 1975.

2.1. The Ice Bag Technique

After back table preparation, the allograft was placed in an ice-filled bag with an outlet for the renal artery and vein. A Kelly clamp was employed to maintain the fluid and ice in place and to function as a handle (Fig. 1). The handle was always placed on the inferior (ureteral) side of the graft for orientation. A penetrating towel clamp affixed the kidney to one side of the wound while the anastomoses were performed (Fig. 2). After completion of the anastomoses, the vascular clamps were removed and the bag was cut and passed off the field. At no time was there evidence of loss of the cooling properties of the ice bags or frostbite leading to injured kidney parenchyma in the IBT group.

Table 1
Reasons for anatomic exclusion.

Anatomic reasons for exclusion	Number (n)
Arteries cut	1 (6%)
Short arteries	3 (18%)
Difficult arterial course	1 (6%)
Ice bag failure	3 (18%)
Short renal vein	1 (6%)
Duplicate arteries	2 (12%)
Too small space	1 (6%)
BMI	3 (18%)

2.2. Patient management protocols

All patients were immunosuppressed with Prograf (Tacrolimus, Astellas Pharma, Deerfield IL), Cellcept (Mycophenolate Mofetil, Roche, Nutley NJ) and prednisone. Anti-thymocyte globulin (ATG, Genzyme) was the most common agent used for induction therapy, followed by the IL-2 receptor antibody (Daclizumab). ATG was dosed at 1.5 mg/kg per day for 4–7 days starting intraoperatively through a central line and titrated for leukopenia, thrombocytopenia or other side effects attributed to the induction. The goal dose ranged between 5 and 6 mg/kg. Acetaminophen, diphenhydramine and steroids were given before all infusions. All patients were started on Mycophenolate Mofetil with doses ranging from 1 to 2 g per day. The dosage was titrated for gastrointestinal side effects and leukopenia. Patients received methylprednisolone 400–500 mg IV intraoperatively followed by a prednisone taper to 30 mg daily by day 7, 20 mg daily by day 30 and 5 mg daily by day 90. Tacrolimus was started by day 4. Target trough levels ranged between 5 and 12 ng/ml. For Pneumocystis jiroveci pneumonia prophylaxis, all patients received one single strength trimethoprim/sulfamethoxazole daily for at least 6 months post transplant, and 3 months after

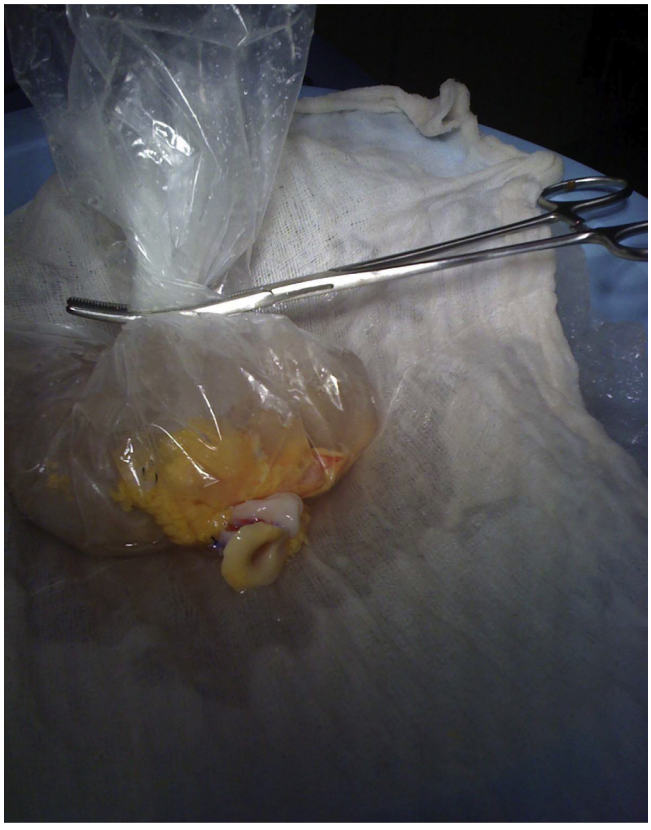

Fig. 1. Ice Bag Technique: The kidney is introduced into the bag with ice and a small hole was made near the hilum through which the renal artery and vein were passed. A Kelly clamp was used to maintain the fluid and ice in place as a handle.

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