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Temporary Targeted Hemostasis to Facilitate Bloodless Partial Nephrectomy

Niall J Harty^a, Alireza Moinzadeh^a, Sebastian Flacke^a, Jeffrey Pettit^c, James A. Benn^b, John A. Libertino^a, and Peter N Madras^{a,b}

^aThe Lahey Clinic, 41 Mall Road, Burlington, MA 01805

^bPluromed, Inc. 175 New Boston Street, Woburn, MA 01801

^cHarvard Center for Comparative Medicine, Harvard Medical School, Boston MA, 02115

Abstract

Purpose—LumagelTM, a non-toxic polymer may be administered intra-arterially under fluoroscopy to obtain a bloodless operative field during partial nephrectomy while maintaining normal circulation to uninvolved renal tissue. We extend previous robotic assisted techniques developed in the swine model to studies of laparoscopic and open partial nephrectomy conducted in pigs and calves, designed to encompass vessel diameters similar to those encountered in humans.

Materials and Methods—10 Animals (7 pigs, 3 calves) underwent flow interruption to the kidney, 2 with cross-clamping of the main renal artery, the remaining with Lumagel. Other than the first pig and calf, all animals then underwent partial nephrectomy.

Results and Conclusions—Using Lumagel, targeted blood flow interruption was achieved while circulation to uninvolved renal tissue was maintained. Hemostasis lasted for 30 minutes or more. Surgical resection averaged 11 minutes (range 10–13) and 23.3 (range 9–40) in the open and laparoscopic groups, respectively. Estimated blood loss was negligible with the exception of two cases, one in which an error in angiographic assessment lead to an unoccluded vessel near the resection site and a second case where a guide wire was inadvertently passed through a vessel. Time to complete flow return as determined by direct visualization of the kidney and its corresponding angiogram averaged 7 and 2.5 minutes for Lumagel and arterial clamping, respectively. Lumagel provides reliable and reproducible intraluminal blood flow interruption and flow restoration in both main and segmental renal arteries. By providing blood free resection, techniques described may facilitate partial nephrectomy without global renal ischemia.

Keywords

Partial Nephrectomy; Minimally Invasive; Warm Ischemia; Laparoscopy

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Corresponding Author Contact Information: Peter N. Madras, M.D., Lahey Clinic, Department of Urology, 41 Mall Road, Burlington, MA 01805; Peter.Madras@Lahey.org, Fax 781 744-7565, Phone 781 744-8328.

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INTRODUCTION

Nephron sparing surgery has assumed a more prominent role in the management of small, radiographically enhancing renal masses¹ and is gaining advocacy as standard of care for these lesions². While short ischemic times appear to have no early detrimental effects on the kidney^{3,4}, long-term harm to the spared renal tissue, caused by even short periods of renal ischemia has been recognized⁵. Reduction of overall renal function of the operated renal unit has been reported and prolonged ischemia time is associated with worse long-term renal function⁵. The ideal partial nephrectomy would allow for complete tumor resection while minimizing blood loss, maintaining blood flow to the untargeted portion of the kidney and maintaining good oncologic outcomes. A device that may take us closer to this ideal partial nephrectomy is LumagelTM (Pluromed Inc., Woburn, MA).

LumagelTM is a reverse thermosensitive polymer that may be administered fluoroscopically with great precision into segmental and sub-segmental renal artery branches to produce temporary blood flow interruption to renal tissue targeted for excision while maintaining normal flow to the spared nephrons⁶. Our previous work with LeGoo-XL gel polymer demonstrated temporary targeted renal segment occlusion is feasible⁷. Lumagel contains an FDA approved contrast agent differing it from LeGoo-XL. In the current work, we extend our early experience by including the techniques for open and minimally invasive partial nephrectomy with Lumagel. We compare the characteristics of flow interruption and flow return between Lumagel and standard arterial clamping. In this second feasibility study, we extend our techniques to encompass complex vascular configurations in which two or three sub-segmental branches of the renal artery require occlusion to ensure interruption of flow to the targeted renal area. Finally, experiments in calves are done to closer mimic arterial sizes (up to 8.5mm) likely to be encountered in clinical situations.

MATERIALS AND METHODS

Lumagel is a mixture of poloxamer 407 and Iohexol, an FDA approved contrast agent, in aqueous solution. Poloxamer is a commercially available triblock copolymer of polyethylene oxide, and polypropylene oxide and has been used in a variety of medical applications as a detergent or solubilizing agent for cosmetics and certain medications⁸. The fact that it is highly resistant to biochemical interaction in the body makes it particularly suitable for these applications and other medical applications. It was long appreciated that this polymer increased viscosity on warming, but this property was ignored until the publication, in 2004, by Raymond et al describing its ability to form a reversible, intraluminal vascular plug, capable of temporary interruption of blood flow without deleterious effects in a canine renal artery model⁸. The product used in this and subsequent work is a highly purified fraction of poloxamer 407 which was renamed “LeGoo”. In 2005, Boodwani et al described the use of LeGoo in swine coronary artery reconstruction⁹ followed shortly thereafter with studies showing no effect on vascular endothelium¹⁰. More recently, there has been increasing use of Legoo for temporary artery occlusion in patients undergoing off-pump coronary artery bypass with successful occlusion in 81 out of 89 vessels (91%)¹¹. The polymer proved to be atraumatic, safe, and effective¹².

Lumagel exists as a low viscosity liquid when cool (about 20°C) temperature, and rapidly increases in viscosity, by a factor of approximately 10⁶, on warming. This liquid, in its high viscosity state, has the “look and feel” of a gel. On the molecular level, the increase in temperature causes a conformational change in the polymer molecule which increases hydrogen bonding between proximate polymer molecules. This change occurs over a fraction of a degree. On intra-vascular injection, body temperature causes the injected polymer to suddenly form a hemostatic, intra-luminal “plug”. On re-cooling, the Lumagel

reverts to its low viscosity state, dissolves in the flowing blood and is excreted unmetabolised in the urine. Our earlier work in a porcine model demonstrated that this change of viscosity allows deposition of polymer in selected renal artery branches creating a bloodless operative field while maintaining intact blood flow to the rest of the kidney^{6,7}.

The Institutional Animal Care and Use Committees of Lahey Clinic (Burlington, MA) and DaVinci Biomedical Inc, (South Lancaster, MA - where the calf experiments were performed) approved this study. Seven farm pigs and three calves were included in this study. Of the seven pigs, the Lumagel group consisted of 5 pigs, 1 of which underwent open radical nephrectomy (ORN), 2 pigs underwent laparoscopic partial nephrectomy (LPN) and 2 open partial nephrectomy (OPN) (Table 1A). The other two pigs underwent main renal artery clamping for comparison with Lumagel. One pig in the clamping group had a LPN, the other, an OPN. All 3 calves underwent vascular occlusion of the main renal artery with Lumagel. One ORN and 2 LPNs were performed in this group (Table 1B).

The first calf experiment was performed to optimize techniques for deploying Lumagel to plug a large artery. The main renal artery of the calf, measuring 8.5mm was the largest vessel to be occluded to date. Accordingly, it underwent many cycles of plug deposition and lysis as we gained confidence in the ability of Lumagel to maintain a plug for 30 minutes in the larger 8.5 mm artery. This vessel was reliably plugged with a rapid injection of 5 ml of Lumagel. All occlusions were reversed using iced saline infusion injected through an intra-arterial catheter placed to the site of the polymer. Catheter placement and dissolution of the plaques was directly visualized using fluoroscopy. We operated on both the upper and lower pole without regards to laterality.

Our operative technique consisted of placing the animal in a supine position following the induction of general anesthesia. A central venous catheter was placed in the internal jugular vein for venous access. The animals in the Lumagel group underwent percutaneous femoral artery access using Seldinger technique for angiography. Advancing the catheters to the targeted vessel was accomplished under C-arm fluoroscopy using a 7Fr guiding catheter and 5Fr injection catheter (Renal Access Cobra Catheter, Cook, Bloomington, Indiana). The diameter of the vessels was estimated by measuring the angiographic image on the screen with a ruler. In open cases, the kidney was dissected in a retroperitoneal fashion with hilar dissection completed only in those animals undergoing renal artery clamping. In animals undergoing LPN, the animal was repositioned in flank position. A transperitoneal approach was employed with standard 4-port placement. Following renal mobilization, the angiographic catheter tip was guided into position under fluoroscopy to lie 2 to 5 mm proximal to the center of the intended Lumagel plug (Fig 1A). The polymer was injected under fluoroscopy, and was easily seen filling vessels as small as 1.3 mm in diameter (Fig. 1B). The location and extent of the resultant plug was controlled by real-time fluoroscopic observation. Accurate injection of the polymer, in increments of 0.05 ml, was performed with a hand-held, power injector specifically designed for this application. Duration of selective ischemia was recorded and location of vascular occlusion was noted both angiographically and visually. Following blood flow interruption, the targeted portion of the kidney was sharply resected without regard for bleeding or underlying structure. The size of the resected tissue specimen varied from a small segment of tissue to a complete polar resection which required repair of the collecting system. Hemostasis was not attempted until the entire resection was complete to allow accurate measurement of blood loss. The collecting system was closed with a running suture, and large, obvious vessels were suture ligated. A hemostatic bolster consisting only of rolled gauze soaked in thrombin was then sewn over the defect. Reliability of polymer reversal from a solid back to a liquid state with iced saline allowing reperfusion was evaluated by visually inspecting the kidney and angiographically observing dissolution of the radio-opaque polymer. A post-surgical

arteriogram was performed to assess perfusion following resection. Following surgery, all animals were euthanized according to IACUC approved protocols.

The sequence of images shown in Figures 1 to 3 demonstrates the steps in Lumagel plug deposition. The vessel or vessels requiring flow interruption are selected based on a subtraction, selective renal angiogram. In Fig 1A an excellent location is identified, just proximal to the termination of a segmental renal branch to the lower pole. This location allows the plug to form first in the terminal branches of the lower segmental branch which stabilize the occluding plug. Under fluoroscopy, growth of the plug may be observed and controlled using a specially designed power injector. In Fig 1B, the final plug is observed, with extensions into the terminal branches, and retrograde growth back to a more proximal branch which is intentionally left open as it does not feed the targeted region. The total volume injected is approximately 1 ml, of which 0.9 ml is the priming volume of the catheter system, and 0.1cc is actual polymer based on the vessel diameter of 2.3 mm. Figure 1C demonstrates clearly the Lumagel plug on a subtraction image. Prior to dissolving the plug with cold saline, the catheter is removed, flushed with saline to remove the residual Lumagel and replaced.

Figure 2 shows the most difficult situation for obtaining complete flow interruption to a targeted region. In this case, two arteries were identified by angiography as needing occlusion, but when this was achieved, inspection of the renal surface showed that there was still residual circulation. Accordingly, the last vessel leading to the upper pole was plugged. The two smaller vessels undergoing Lumagel plugging were 1.3 and 1.6 mm diameter, and these were readily plugged and unplugged in the planned manner. The color changes on the renal surface corresponding to the occlusions are shown in Figure 2.

In Figure 3, the solitary lower pole artery is occluded, the lower pole resected and the flow restored showing the typical sequence allowing blood free targeted resection.

RESULTS

Selective renal ischemia was achieved in all cases using Lumagel plugs in segmental arteries. Global ischemia occurred in all pig and calf cases in which the main renal artery was targeted for occlusion with Lumagel. All plugs remained stable for both the duration of the partial nephrectomy and for a minimum of 30 minutes without requiring a subsequent Lumagel injection. Surgical resection time averaged 11 minutes (range 10–13) and 23.3 (range 9–40) in the open and laparoscopic groups, respectively. Estimated blood loss during PN was negligible in all cases except two where technical problems became apparent. One laparoscopic partial nephrectomy was complicated by 900 cc blood loss secondary to neglecting to identify an accessory renal artery which was readily plugged after recognition. In another open procedure, we encountered excess bleeding following dissolution of the plug as a guide wire had inadvertently been advanced through the resection margin, maintaining an open artery. This was readily controlled with a suture ligature.

The correlation of radiographic and visual assessment of vascular occlusion was consistent. Reversal of the polymer to a liquid state by irrigation with iced saline was assessed both angiographically and visually in all 10 cases. The time to complete flow return averaged 7 and 2.5 minutes for Lumagel and vascular clamping, respectively (Table 1C).

All kidneys were grossly inspected following euthanasia, and no pathology was seen on gross examination in the Lumagel animals. In the clamp experiments, residual indentations of the clamp on the wall of the vessel were observed grossly, though no pathologic analysis of the tissue was performed. In previous studies, we performed pathologic examination of

other organs (lung, heart) and did not identify any distant embolization. We did not repeat that in this study.

DISCUSSION

Recognition of the negative renal consequences of even short interruptions of circulation has resulted in methods for performing PN without flow interruption. These include renal arterial balloon catheterization with hypothermic perfusion of the renal parenchyma during LPN¹³. Ice slush for renal hypothermia during renal artery and vein occlusion has been advocated for improving nephron protection during blood flow interruption¹⁴. Recently, in a small series of patients, robotic assisted laparoscopic partial nephrectomy (RPN) without renal hilar occlusion has been reported¹⁵. This study, from a high volume, minimally invasive institute, with a select patient population, may not be generally applicable. More recently, a “zero ischemia” laparoscopic and robotic technique in 15 patients has been described requiring pharmacologically induced hypotension during tumor resection¹⁵. This use of this technique is complex with unique anesthetic requirements but underscores the negative effect of ischemia on kidneys.

In comparison to release of arterial clamps, dissolution of Lumagel is associated with more gradual return of flow to the targeted region upon flow restoration. The mechanism behind this gradual return remains poorly understood, but appears to have no measurable ill effect, and, we speculate, may account for the secure hemostasis that seems to occur with Lumagel use. We did, in later experiments; to be published shortly, observe that reformulation of Lumagel such that the viscosity of the plug was reduced from 10^6 centipoise to about 7×10^5 centipoise led to more rapid reperfusion and no apparent decrease in plug efficacy or duration. Nevertheless, we emphasize that all animals showed complete return of blood flow and that this phenomenon affects only the targeted region which is largely resected, contrasting with the use of hilar clamping which affects the entire kidney. In an ongoing survival study there was no significant effect on renal function 6 weeks following the operation with Lumagel (in preparation).

Our study is both a feasibility study as well as a comparison study between Lumagel and vascular clamping. It does have some limitations. Although no problems were encountered with femoral cannulation in the swine, the risk associated with percutaneous access to the femoral artery in humans was recently reported at about estimated at about 1/1000¹⁶. Secondly, we do not have a method to quantify the true amount of renal function preserved in the Lumagel group compared to those animals in the vascular clamping group. A survival study comparing the preoperative and postoperative renal function is in progress. Our technique requires intravascular manipulation which could potentially cause vessel injury or existing plaque disruption, also a small but recognized risk. Because of possible error in intraoperative angiography, any clinical application would have pre-operative 3D angiographic reconstructions of CT data. Finally, the use of contrast is not without its inherent nephrotoxicity. Our cumulative dose of contrast used is less than 100cc which is less than the dose used for a typical aortogram (300cc).

The use of Lumagel requires a specially designed power injector for two reasons. First, the long angiographic catheter which lies within the body warms to body temperature. Therefore, the Lumagel emerging from the catheter is already in its higher viscosity state, requiring very high pressures to induce flow. Of equal importance is that very fine control of small volumes is not possible with a hand injection. Occluding vessels of less than 2 mm requires amounts of Lumagel under one tenth of a milliliter. It is remarkable how readily these minute injections are seen on the fluoroscope. In the above experiments, all injections were performed with a “breadboard” version of the injector which was undergoing

simultaneous development and will reduced to final form as a light-weight unit, operated with a single hand by the interventional radiologist during the process of catheter placement and manipulation. While the entire process of plug formation adds time to the operation, it is offset by obviating the need for hilar dissection.

With increasing experience it became clear that certain anatomic considerations are highly amenable to creation of a blood free field, while other situations carry greater challenges. Polar lesions, fed by a single segmental branch, are readily rendered ischemic and resection may proceed with confidence. When 2 or more vessels supply a region, they must both be plugged. A flush aortogram to rule out accessory arteries is always needed. These considerations mandate that any contemplated clinical application of this technology be preceded by full angiographic evaluation of the kidney. Since any clinical candidate for partial nephrectomy would have had preceding CT or MR imaging, reformatted, three - dimensional angiography of those studies would not constitute an additional invasive procedure to the standard work-up.

Transition of this technique to humans would require some alterations. Initial cases may require dissection of the hilar vessels prior to tissue resection. This would be advantageous in the case that unexpected bleeding was encountered requiring hilar control with clamps. However, dissection of the renal hilum is not without inherent risks. We have demonstrated that Lumagel can occlude the main renal artery for 30 minutes. If bleeding was encountered at time of resection, another option would be to provide occlusion with Lumagel at the level of the renal artery rather than a more selective vessel.

We were able to perform open experiments with the animals in the supine position. This would not be the case as it is standard to operate in a flank position in humans. Femoral artery access could be achieved in the supine position with subsequent transfer to a lateral decubitus position. However, there is the risk of possible dislodgement of the femoral access during transfer. We have had no issues with space for the surgeon(s), interventionalist, and equipment needed in the operating room. The requirement for fluoroscopy adds to complexity of the proposed procedure.

CONCLUSIONS

We have developed a reliable and reproducible technique for the delivery and dissolution of Lumagel for temporary, targeted vascular occlusion in main, segmental and subsegmental renal arteries, ranging from 1.3 to 8.5 mm diameter. Lumagel was as effective as vascular clamping in producing bloodless operative field. The time to complete flow return to the kidney is greater after Lumagel than after vascular clamping but full flow inevitably returned within minutes. Unlike clamping, Lumagel allows normal perfusion to uninvolved portions of the ipsilateral renal parenchyma. Chronic survival animal studies are underway to explore both long term effects on renal function and pathology, as well as local arterial wall effects of the Lumagel plug.

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ABBREVIATIONS

LPN Laparoscopic Partial Nephrectomy

RPN	Robotic Partial Nephrectomy
OPN	Open Partial Nephrectomy
ml	Milliliter
CT	Computerized Tomography
Fr	French

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Figure 1.

Steps in the Formation of the Intraluminal Arterial Plug

A: Subtraction arteriographic view of targeted site for flow interruption is selected. In this case it was the branch to the lower pole of the kidney (arrow).

B: Unsubtracted radiographic view of final configuration of the Lumagel plug lying within the selected vessel. The tip of the catheter used to administer the Lumagel was placed just proximal to the “trifurcation” of the selected branch, very close to the tip of the arrow. The operator was then able observe formation of the plug. Where possible, formation near a major branch or bifurcation is a preferred site, since the terminal branches serve to stabilize the plug reducing the possibility of migration. The Lumagel plug is visible since this is a non-subtracted view of the kidney.

C: Subtraction image shows the Lumagel plug (white) and the normal arteriographic perfusion pattern for the remaining renal tissue. The point of arterial occlusion is seen to correspond to the proximal extent of the Lumagel plug B.

Fig. 2.

Selective Occlusion of Multiple Small Segmental Branches

A: Normal Kidney, No obstructed vessels. B: Three Vessels ascending to upper pole of a left kidney. Note that 2 of these originate from the lower segmental branch of the renal artery. C: Segmental Branch to upper pole occluded leaving significant perfusion to upper pole. D: occlusion of 1.3 mm branch to upper pole. Note that the origin of this vessel was in spasm at the time of Lumagel plug deposition. The occlusion of this vessel still did not provide adequate flow interruption in this case. E: All branches to the upper pole blocked producing the appearance shown in F with demarcation. The final branches from the lower pole measured 1.6. After 30 minutes of occlusion all vessels were reopened readily with iced saline and the kidney resumed normal perfusion (Fig 3).

Figure 3.

Bloodless Resection of Lower Pole, Right Kidney

A: Kidney demonstrating occlusion of the lower segmental branch.

B: Bloodless resection performed followed by restoration of flow. A small subcapsular hematoma is seen in the midportion of the kidney.

C: Final angiogram showing restoration of flow to the kidney and truncation of the lower pole branches as seen in Fig 3 above. The truncated appearance is secondary to amputation of the lower pole. Note the normal appearance of the arterial “blush” in panels A and C following the occlusion and flow restoration to the three upper pole vessels.

Table 1A

Swine experiments.

ORN = Open Radical Nephrectomy

LPN = Laparoscopic Partial Nephrectomy

OPN = Open Partial Nephrectomy

Table 1B

Calf experiments.

ORN = Open Radical Nephrectomy

LPN = Laparoscopic Partial Nephrectomy

OPN = Open Partial Nephrectomy

ANIMAL EXPERIMENTS

Table 1C

No.	Species	Approach	Occlusion	Duration of Occlusion	Site of Occlusion	Pole Resection	Time to Dissolution
1	Swine	Open	Lumagel	30	Segmental	None	NA
2	Swine	Lap	Lumagel	33	Segmental	Right Upper	6
3	Swine	Open	Lumagel	30	Segmental	Left Lower	7
4	Swine	Open	Lumagel	37	Segmental	Left Upper	25
5	Swine	Lap	Lumagel	45	Main	Left Lower	20
6	Swine	Open	Clamp	30	Main	Right Lower	Immediate
7	Swine	Lap	Clamp	30	Main	Left Lower	Immediate
8	Calf	Open	Lumagel	30	Main	None	15
9	Calf	Lap	Lumagel	30	Main	Right Lower	15
10	Calf	Lap	Lumagel	30	Main	Left Lower	15