9-2-2009

# Angioplasty vs. Cryoplasty for the Treatment of Symptomatic Peripheral Vascular Disease: a Retrospective Review Looking at Comparative Outcomes

Jordan Knepper

John Welker

# Angioplasty vs. Cryoplasty for the Treatment of Symptomatic Peripheral Vascular Disease: a Retrospective Review Looking at Comparative Outcomes.

Jordan Knepper MS4 John Welker MS4

## Background:

In 2007 it was reported that eight million Americans are affected by Peripheral Vascular Disease (PVD) and of these affected, around ten percent report being symptomatic (Mayo Clinic). With such a large percentage of Americans affected by this problem, many providers who care for these patients opt to treat with the least invasive option and then progress to more invasive means if necessary. To date, Percutaneous Transluminal Angioplasty (PTA) has been the preferred minimally invasive endovascular treatment option for symptomatic PVD. Though this option is preferred and used extensively, there are concerning short and long term potential consequence such as dissection and recoil of the arterial wall in the acute setting (Laird 2005), and, more importantly, re-stenosis of the affected area in the long term setting causing recurrent symptoms and the need for further treatment. There have been multiple reported results showing that the re-stenosis rates have been as high as 60% (Muradin 2001). Additionally, the Oxford trail showed that the quality of life in the long term setting was not improved and thus required additional therapy (Perkins 1996).

Studies examining PTA procedures have shown that restenosis is caused by three processes: immediate elastic recoil, late vascular remodeling, and importantly myointimal hyperplasia (McCaslin 2007). Myo-intimal hyperplasia results from the balloon dilation of the vessel wall causing proliferation of the vascular smooth muscle cells in the intimal layer of the vessel. This proliferation results in increased mass of smooth muscle and thus a restriction of blood flow through the affected lumen.

Due to the need for patency in the long term and the myointimal hyperplasia response of angioplasty, a technique building off of angioplasty called Cryoplasty is now offered. This method adds the dilation properties of angioplasty with an associated release of cold thermal energy to the arterial wall. The cold thermal energy is derived from the filling catheter containing nitrous oxide instead of the standard contrast and saline solution. The affect of this cooling process is thought to limit the variables such as myo-intimal hyperplasia and elastic recoil in the process of re-stenosis (Samson 2007). The success rate of cryoplasty has been promising with one study showing a 3-year patency rate of 75% (Laird 2006).

## Objectives:

A retrospective study assessing the immediate and long term outcomes using Angioplasty vs. Cryoplasty for the treatment of symptomatic peripheral artery disease.

## Methods:

IRB approval was obtained for a HIPPA waiver and review of records for a retrospective review. The records of 203 patients undergoing angioplasty and/or cryoplasty were reviewed and of these, 34 patients were found with complete records of one year and having a minimum follow-up in the

angioplasty group and 26 in the cryoplasty group. All procedures were done at UNMH from 2003 thru 2008 and were limited to lower extremity interventions with the indication of claudication and tissue loss.

This is a retrospective review study; the study design is to utilize the existing prospectively collected database in the division of vascular surgery that shows all cases performed from 2003 to present, e.g. Angioplasty and cryoplasty. Data was also collected from the existing medical records as to outcomes of these patients, including morbidity and mortality, recurrence of disease, co-morbid conditions and global health indicators. The date was made free of identifiers and statistical analyses was performed on the data to determine if the existing data support a superior technique. All the data was to be collected by two designated assessors .

The outcomes examined in our study were overall survival, subsequent need for surgical reintervention, limb salvage and graft patency.

Statistics: Chi-square test with continuity correction will be used. The differences in the numerical data were compared using independent t-test and differences in categorical variables were assessed using Fisher's Exact test. Data was analyzed using SAS 9.1 software (SAS, Inc, Cary, NC). P values $< 0.05$ were considered indicative of statistical significance.

Data protection – Data was input and analyzed on password protected workstation in a locked office in the UNMH department of surgery, the data was stored on this workstation as well as backed up on a password protected flash drive stored in a locked desk drawer in the same office.

Results:

34 patients undergoing lower extremity intervention meet criteria for follow-up ( 1 year) and had records complete enough for analyses from 2003-2008. 26 patient undergoing cryoplasty during the same time period also met these criteria. Demographic analyses on these group yielded similar and non-statistically different rate of smoking, diabetes mellitus and age and gender distribution was again similar.

An anaylsis of both groups yielded indications for the procedures as: Claudication 33% and 68% for limb threatening ischemia ( rest pain, tissue loss and non-healing wounds). The mean pre-operative ABI in the angioplasty group was 0.6 and 0.52 in the cryoplasty group; the difference did not reach statistical significance.

The 30-day mortality in the angioplasty group was 5.88% and 3.48% in the cryoplasty group with a p-value of 0.43, thus not reaching statistical significance for differences.

The one year primary patency of the angioplasty group was 50% ( 17/34) and 73% (19/26) in the cryoplasty group with a p-value of 0.0629, thus not meeting statistical significance.

Finally primary assisted patency in the angioplasty group was 15% (5/34) and 12% (3/26) in the cryoplasty group. Limb amputation was 21% (7/34) in the angioplasty group and 15% (4/26) in the cryoplasty group. Both comparisons had a p-value of greater than 0.05.

Conclusion:

Cryoplasty remains a relatively new technology with limited comparative data to establish whether a benefit exists over traditional balloon angioplasty in the lower extremity. Our series attempts to begin to examine this issue with a follow-up greater than many of the published 30-day outcomes. The majority of the patients treated in our center were treated for limb threatening ischemia and as the majority of patients seen at UNMH have advanced stages of disease and many possessing co-morbidities making other interventions have a risk to benefit ratio.

This is a small review with a relatively limited follow-up period due to both the short duration of this technology being available and many of our rural patients being lost to follow-up. But with all of our patients having post-operative flow monitoring we are able to establish a patency rate as well as show trends even though our N is small.

Our data indicates no statistically significant differences between cryopasty and traditional plain balloon angioplasty. Our primary patency rates do trend toward superior outcomes with the cryoplasty, but this difference was not statistically significant, but our small N makes it possible to see if a true difference exists.

From our trends and patient outcome experience with cryoplasty and the cost of this technology in equivalent pooled data, it does not appear that there is data to support the use of this technology over balloon-angioplasty. As time progresses, the data pool increases, and sub-group separation can be examined, for certain disease processes and anatomy some patient groups may be better served with cryoplasty.

References:

Mayo Clinic – Peripheral Arterial Disease. http://www.mayoclinic.com/health/peripheral-arterial-disease/DS00537/DSECTION=7. Accessed 4/11/2008.

Samson RH, Showalter DP, Lepore Jr. MR, Ames, S. CryoPlasty Therapy of the Superficial Femoral and Popliteal Arteries: A Single Center Experience. Vascular and Endovascular Surgery 2007; 6(40):446-450.

Laird J, Jaff MR, Biamino G, McNamara T, Scheinert D, Zetterlund P, Moen E, Joye JD. Cryoplasty for the Treatment of Femoropopliteal Arterial Disease: Results of a Prospective, Multicenter Registry. Journal of Vascular Interventional Radiology 2005; 16:1067-1073.

Murphy KD, Encarnacion CE, Le VA, Palmaz JC. Iliac artery stent placement with the Palmaz stent: follow-up study. Journal of Vascular and Interventional Radiology 1995; 6(3):321-9.

Muradin G, Bosch J, Stijnen T, et al. Balloon dilation and stent implantation for treatment of femoropopliteal arterial disease: Meta-analysis. Radiology 2001; 221:137-145.

Perkins JMT, Collin J, Creasy TS, Fletcher EWL, Morris PJ. Exercise training versus angioplasty for stable claudication. Long and medium term results of a prospective, randomized trial. European Journal of Vascular and Endovascular Surgery 1996; 11:409-13.

McCaslin JE, Macdonald S, Stansby G. Cryoplasty for peripheral vascular disease. Cochrane Database of Systematic Reviews 2007, Issue 4. Art. No.: CD005507. DOI: 10.1002/14651858.CD005507.pub2.

Laird JR, Biamino G, McNamara T, Scheinert D, Zetterlund P, Moen E, et al. Cryoplasty for the treatment of femoropopliteal arterial disease: extended follow-up results. Journal of Endovascular Therapy 2006; 13 Suppl 2:ii52-9.