

# **A comparative study on endovascular treatment of (sub)acute critical limb ischemia: mechanical thrombectomy vs. lysis**

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# Disclosure

Speaker name:

.....Dr. Mariya Kronlage.....

I have the following potential conflicts of interest to report:

- Consulting
- Employment in industry
- Stockholder of a healthcare company
- Owner of a healthcare company
- Other(s)
  
- I do not have any potential conflict of interest

# Background and Significance

- **Over the past decades, interventional treatment of critical limb ischemia (CLI) has gained significance over to state-of-the-art surgical procedures**
- **Besides local lysis there are also percutaneous mechanical thrombectomy methods available (Angiojet, Hydrolyser, Rotarex)**
- **Up-do-date, there are no systematic comparative studies that juxtapose different interventional techniques in terms of their safety and efficacy**

# Study features and aims

- **Aim:** to compare local lysis (rtPA) and Rotarex in terms of survival, amputation-free survival, and patency in the treatment of (sub)acute thrombotic lesions of the lower extremity
- **Design:** a retrospective, single-center study at the University Hospital Heidelberg (2006-2015)
- **Cohort:** 202 patients enrolled. 146 patients received Rotarex, 28 local lysis (rtPA) and 28 underwent a combination procedure
- **Timeline:** Follow-up of 12 and 24 months

# Study population

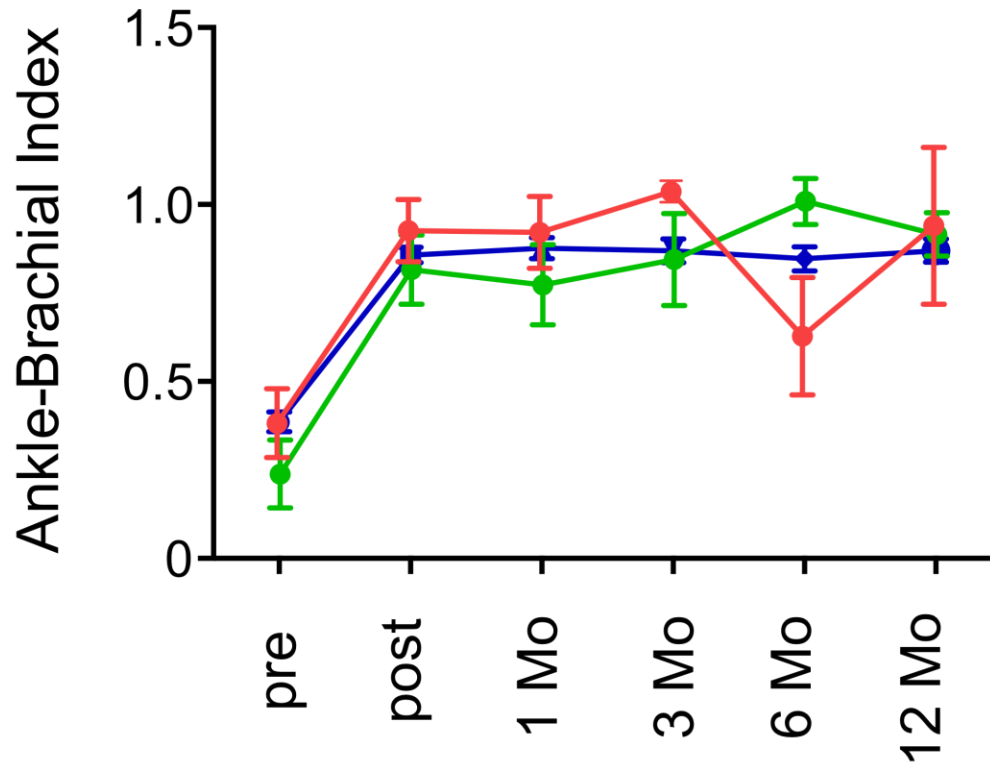
|             | ROTAREX              | Lysis               | ROTAREX+Lysis        | P-Value                                 |
|-------------|----------------------|---------------------|----------------------|---|
| Age (years) | 67,5 +/- 11,4        | 72,5 +/- 9,7        | 61,5 +/- 14,3        | R vs L *<br>R vs R+L ns<br>L vs R+L *** |
| Gender      | M 63,1 %<br>F 36,9 % | M 71,4%<br>F 29,4 % | M 64,3 %<br>F 35,7 % | R vs L **<br>R vs R+L ns<br>L vs R+L ** |
| Weight (kg) | 74,4 +/- 14,1        | 80,7 +/- 10,9       | 76,2 +/- 14          | ns                                      |
| Height (cm) | 170,7 +/- 11,1       | 174,8 +/- 6,4       | 167,4 +/- 5,5        | ns                                      |

|                          | ROTAREX                    | Lysis                    | ROTAREX+Lysis            | P-Value |
|--------------------------|----------------------------|--------------------------|--------------------------|---------|
| Ischemic cardiac disease | 46% (65/146)               | 46,4% (13/28)            | 39,3 % (11/28)           | ns      |
| Arterial Hypertension    | 78%(110/146)               | 78,6% (22/28)            | 78,6 % (22/28)           | ns      |
| Diabetes Mellitus        | 33,3 (47/146)              | 50% (14/28)              | 28,6% (8/28)             | ns      |
| Smoking                  | 66% (93/146)               | 67,9% (19/28)            | 60,7% (17/28)            | ns      |
| Kidney failure           | Stadium III 18,4% (26/146) | Stadium III 10,7% (3/28) | Stadium III 21,4% (6/28) | ns      |
|                          | Stadium IV 3,5% ( 5/146)   | Stadium IV 10,7% (3/28)  | Stadium IV 3,6% (1/28)   | ns      |
|                          | Stadium V 2,1 % (3/146)    | Stadium V 0              | Stadium V 0              | ns      |

# Lesions` characteristics

|                            | <b>ROTAREX</b>    | <b>Lysis</b>   | <b>ROTAREX+Lysis</b> |
|----------------------------|-------------------|----------------|----------------------|
| Native Vessel              | 68,5% (100/146)   | 71,4% (20/28)  | 78,6%(22/28)         |
| Bypass                     | 1,4 % (2/146)*    | 10,7 % (3/28)  | 3,6 % (1/28)         |
| Calcification grade<br>low | 70,55 % (103/146) | 71,42% (20/28) | 78,57% (22/28)       |
| moderate-severe            | 29,45 % (43/146)  | 28,57 % (8/28) | 21,43 % (6/28)       |
| Thrombotic burden<br>Low   | 32,25 % (50/146)* | 28,57% (8/28)  | 10,71% (3/28)        |
| moderate-severe            | 65,75 % (96/146)* | 71,73% (20/28) | 89,28% (25/28)       |

# Results



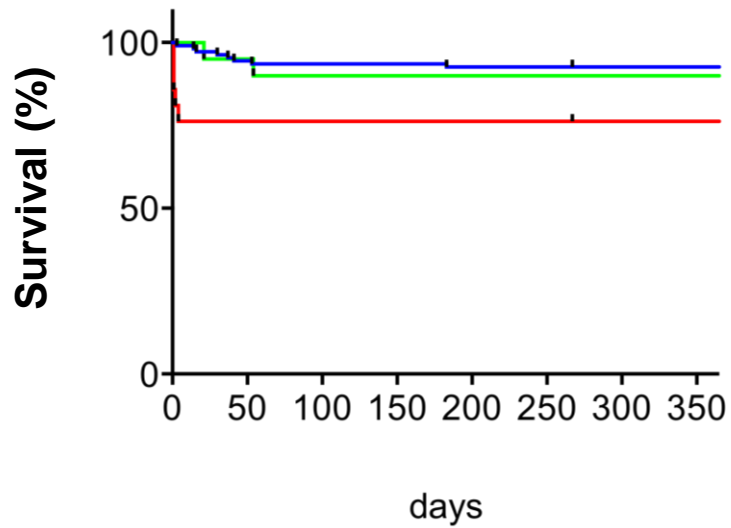
-Rotarex

-Lysis

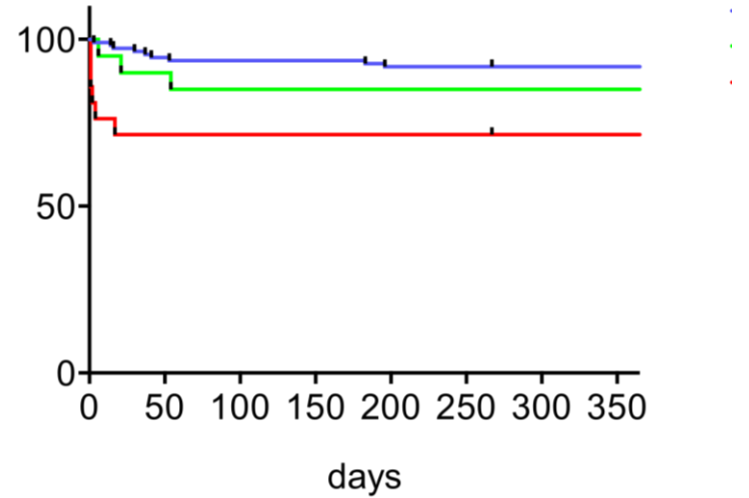
-Rotarex+Lysis

# Results

## Overall survival



## Amputation-free survival

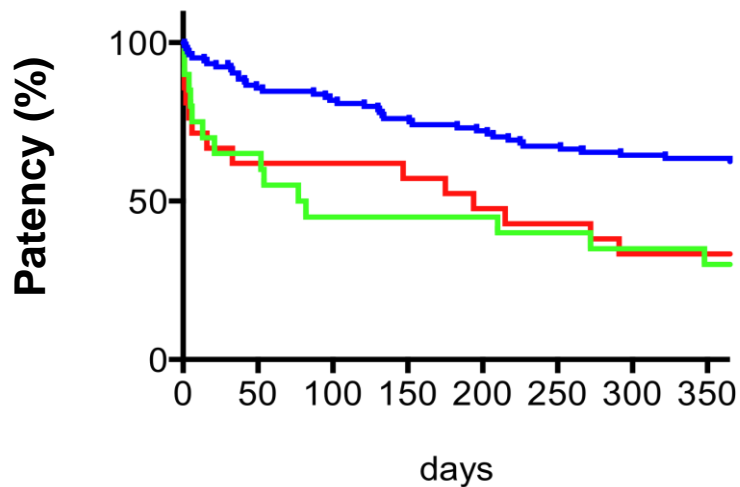


- Rotarex
- Lysis
- Rotarex+Lysis

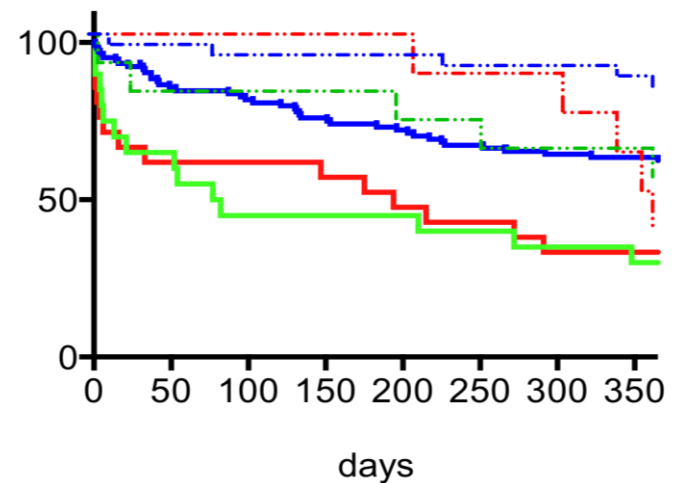


# Results: Patency

## Primary Patency



## Secondary Patency



- Rotarex
- Lysis
- Rotarex+Lysis

# Results: Complications

|  | ROTAREX       | Lysis         | ROTAREX+Lysis |
|--|---------------|---------------|---------------|
| Bleeding<br>(Hb decrease > 2 mg/dl)            | 3,4 % (5/146) | 17,9% (5/28)* | 7,1% (2/28)   |
| Aneurysma spurium                              | 2,7% (4/146)  | 0             | 3,6% (1/28)   |
| AV-Fistula                                     | 0,7 % (1/146) | 0             | 0             |
| Compartment                                    | 0             | 0             | 3,6% (1/28) * |
| Mean hospital length stay (non-critically ill) | 1,4+/-0,9***  | 4,6+/-3       | 4,36+/-1,8    |
| Mean hospital length stay (critically ill)     | 21,7+/-34,4   | 13,33+/-4,5   | 18,25+/-9,36  |

# Summary

- Excellent primary revascularization results in all 3 groups
- Overall survival 12 months upon intervention was  $> 90\%$  in both Rotarex and lysis group ( $p>0.05$ ), and  $>70\%$  in the Rotarex+lysis group ( $p=0.01$  and  $p=0.2$ )
- Amputation-free survival reached up to  $91.8\%$  in the Rotarex,  $90\%$  in the lysis , and  $76.19\%$  in the Rotarex+lysis group ( $p<0.05$ )
- In terms of primary and secondary patency, Rotarex-treated group was significantly better off than both the lysis and Rotarex+lysis group ( $p<0.0001$ ) and ( $p<0.05$ )

# Conclusion

- **Interventional treatment of thrombotic occlusions of the peripheral arteries proved to be effective in all cases**
- **Rotarex thrombectomy was a safe alternative to lysis**
- **Future prospective, randomized studies are necessary to further evaluate the advantages and disadvantages of both procedures in clinical practice**

# Thank you

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**Dr. Felicitas Stoll**

**Prof. Dr. Hugo A. Katus**



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