ATTRACT Study: A Multicenter Randomized Trial to Evaluate Pharmacomechanical Catheter Directed Thrombolysis

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INTRODUCTION

Deep vein thrombosis is a common condition with a significant socioeconomic burden, particularly in the setting of PT and ulceration. The current standard of treatment remains anticoagulation in the absence of trial data. PMT is an emerging technology that offers promising results as an adjunct to CDT. Early reports suggest that PMT is safe and may be cost-effective with an acceptable safety profile and encouraging mid-term results.

METHODS

The ATTRACT trial was a randomized, double-blind, placebo-controlled, multicenter trial comparing CDT alone to CDT plus intravenous low molecular weight heparin (LMWH) in patients with acute DVT.

RESULTS

The primary endpoint was the development of post-thrombotic syndrome (PTS) at 24 months. The study showed a significant reduction in PTS in the CDT group compared to the anticoagulation group. The absolute risk reduction was 14.4% (number needed to treat was 7).

CONCLUSION

CDT should be considered as an alternative to anticoagulation in patients with acute DVT and low risk of bleeding.

Chest Guidelines 2012

Recommendation

2.9. In patients with acute proximal DVT of the leg, we suggest anticoagulant therapy alone over CDT (Grade C).

Remarks: Patients who are most likely to benefit from CDT (see text) and attach a high value to prevention of PTS and a lower value to the initial complexity, cost, and risk of bleeding with CDT are likely to choose CDT over anticoagulation alone.

Patients who are most likely to benefit from CDT have iliofemoral DVT; symptoms less than 14 days, good functional status, and low risk of bleeding.
The Open Vein Hypothesis

Does early clot removal for proximal DVT speed symptom relief, preserve valves, prevent PTS?

Objectives of Study Design

- Results reflect actual use of PCDT in U.S. practice — get the accurate answer!
  - good, flexible practice
- Results credible to PCDT proponents and skeptics — “best fair test of PCDT”
- Structural design promotes rigor, integrity, & balance
- Rigorously evaluate PTS, QOL, and safety; limited for secondary issues

Study Population

- Symptomatic proximal DVT involving the iliac, common femoral, and/or femoral vein
  - stratify randomization by thrombus extent
  - actual: 60% with “iliofemoral” DVT
- EXCLUDE patients with:
  - Higher bleeding risk, CNS lesions
  - Acute limb threat or massive PE
  - Symptom duration > 2 weeks
  - Same-leg PTS or DVT < 2 yrs
  - Active cancer

Technique A – Trellis
- 1mg TPA/3cm Thrombus min 4mg
- 25mg first session, 35mg total (max)
- Therapeutic UFH or LMWH

Technique B – AngioJet
- 1mg TPA/3cm Thrombus min 4mg
- 25mg first session, 35mg total (max)
- Therapeutic UFH or LMWH

Technique C – CDT - ‘Drip & Ship’
- ≤0.01mg/kg/hr (max 1mg/hr for 24h)
- 35mg total (max)
- LMWH or sub-tx UFH (6-12u/kg/hr, max 1000u/hr)

December 16, 2014
FULLY ENROLLED
Early 2017
RESULTS

ATTRACT Trial NIH sponsored trial

Acute Venous Thrombosis: Thrombus Removal with Adjunctive Catheter-directed Thrombolysis

Aim: Determine if the initial adjunctive use of Pharmacomechanical Catheter-Directed Thrombolysis (PCDT) in symptomatic patients with acute proximal DVT reduces the occurrence of Post-Thrombotic Syndrome (PTS) over 24 months follow-up

Miami Cardiac & Vascular Institute

ATTRACT STUDY SCHEMA

STUDY ENROLLMENT
Patient with proximal DVT meets eligibility criteria and provides informed consent

PRE-RANDOMIZATION PROCEDURES
Initiation of AC (LMWH or UFH) and completion of baseline assessments

RANDOMIZATION (1:1 Ratio)
CONTROL ARM SUBJECTS
Complete 5 days heparin therapy (LMWH or UFH) and immediately bridge to warfarin (INR 2.0 – 3.0)

PCDT ARM SUBJECTS
Complete 5 days heparin therapy (LMWH or UFH) concurrent with performance of PCDT procedure, then bridge to warfarin (INR 2.0 – 3.0)

LONG-TERM TREATMENT - ALL SUBJECTS
Long-term (> 3 months) warfarin therapy and daily use of graduated elastic compression stockings (initiated 10 days post-randomization)

FOLLOW-UP VISITS – ALL SUBJECTS
Early (10 days & 30 days post-randomization)
Late (6, 12, 18, & 24 months post-randomization)
In conclusion, ATTRACT will be the first U.S. multicenter RCT to determine the long term clinical impact of endovascular thrombolysis in proximal DVT. This study will greatly aid patients, physicians, payors, and policy-makers who face decisions on the use of catheter-based DVT therapy.