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A Randomized Trial Investigation Of Copenhagen Achilles Tendon Rupture Treatment Algorithm (CARTA) For Individualized Treatment Of Acute Achilles Tendon Rupture.

Trauma / Foot & Ankle Trauma / Surgical Treatment

Marianne Toft[1], Maria Swennergren-Hansen[2], Jannie Dybsoe Vestergaard[1], Julie Jenlar[2], Anna Kathrine Pramming[3], Stefan Moller[4], Bjorn Slott Nedergaard[5], Louise Lau Simonsen[3], Bjarke Lovbjerg Vibjerg[5], Per Hölmich[2], Kristoffer Weisskirchner Barfod[6]

1. Viborg Regional Hospital, Viborg, Denmark
2. Copenhagen University Hospital, Hvidovre, Denmark
3. Zealand University Hospital, Koege, Denmark
4. Kolding Hospital, Kolding, Denmark
5. Odense University Hospital, Odense, Denmark
6. Copenhagen University Hospital, Bispebjerg, Hvidovre, Denmark

Keywords: Achilles Tendon, Rupture, Ultrasonography, Individualized, Surgical

Background
Acute Achilles tendon rupture is a common and debilitating injury, where full functional recovery is rare. Operative treatment reduces the risk of re-rupture in comparison to non-operative treatment at the expense of higher risk of infection and nerve damage, but the functional outcome of the two treatment strategies is less well elucidated. A novel individualized, ultrasound-based treatment algorithm (The Copenhagen Achilles tendon Rupture Treatment Algorithm, CARTA) for selection of patients to operative or non-operative treatment has been proposed by the author group. According to CARTA, patients were selected for surgery if 1) insufficient overlap of tendon stumps or 2) tendon elongation of ≥7% as measured with the ultrasonographic Copenhagen Achilles tendon Length Measure (CALM) was observed.

Objectives
The primary objective of the trial was to investigate if individualized treatment of acute Achilles tendon rupture (CARTA) was more effective than treating all patients either operatively or non-operatively per default.

Study Design & Methods
A multicenter (5 departments) three-armed randomized controlled trial was conducted on patients 18-65 years of age with a primary Achilles tendon rupture. Patients were allocated 1:1:1 to the CARTA individualized, the operative, or the non-operative treatment arms. Immobilization and rehabilitation were the same for all groups. The primary outcome was Heel-rise work test after 12 months. Secondary outcomes were the Heel-rise work test (Limb Symmetry Index) at 6 months, maximal heel rise height, Achilles tendon Total Rupture Score (ATRS), CALM, Achilles tendon resting Angle (ATRA) and complications after 12 months. Follow up (except CALM) and analysis of results were blinded.
A group sample size of n=84 was calculated for the primary outcome and primary analyses were performed as intention-to-treat. Means were compared between the three treatment groups with linear regression for the data of continues nature and Chi^2 test for dichotomous data. Adjustment for the predicted confounders of demography (gender, age, height and weight) and ATRS prior to injury was applied.

Results
970 patients were assessed for eligibility in the period May 2018 to June 2023. 101 patients were allocated to

CARTA individualized, 99 to operative, and 100 to non-operative treatment. Three patients crossed over from the CARTA to the non-operative group and one withdrew consent in the operative group. Three patients were lost for all follow-ups with even distribution between groups. There were no between group differences in baseline demographics. In the CARTA individualized group 64% received operative treatment.
There was no between group difference in the primary outcome, Heel-rise work test, after 12 months. After 6 months a statistically significant better Heel-Rise Work test was found for CARTA compared to the non-operative group. The non-operative treatment group had a statistically significantly higher rate of re-rupture and ATRA and lower ATRS at 12 months compared to the CARTA group. For the remaining secondary outcomes, ATRA, and ATRS at 6 months and CALM, and Heel-rise Max height at any time point, no statistically significant differences were found between groups.
No difference in other serious adverse events between groups was found.

Conclusions
Individualized treatment by CARTA did not prove better at Heel-rise Work Test after 12 months. Using the CARTA individualized algorithm led to a 36% reduction in operative activity with a statistically significant reduction in re-rupture rate compared to non-operative treatment and the functional outcome seems sustained.