



RANDOMISED CLINICAL TRIAL

Surgery Versus Continued Conservative Treatment for Neurogenic Thoracic Outlet Syndrome: the First Randomised Clinical Trial (STOPNTOS Trial)[★]

Jens Goeteyn ^a, Niels Pesser ^a, Saskia Houterman ^b, Marc R.H.M. van Sambeek ^{a,c}, Bart F.L. van Nuenen ^d, Joep A.W. Teijink ^{a,e,*}

WHAT THIS PAPER ADDS

There have always been doubts over whether surgery for neurogenic thoracic outlet syndrome (NTOS) is useful. In this first randomised clinical trial, the effects of surgery were compared with continued conservative treatment for patients with NTOS. A clear benefit was found for surgery over continued conservative treatment. These results offer perspective for patients with NTOS that has not improved after conservative treatment. A multicentre randomised controlled trial should be the next step to validate these results.

^a Department of Vascular Surgery, Catharina Hospital, Eindhoven, The Netherlands

^b Department of Education and Research, Catharina Hospital, The Netherlands

^c Department of Biomedical Technology, University of Technology Eindhoven, Eindhoven, The Netherlands

^d Department of Neurology, Catharina Hospital, Eindhoven, The Netherlands

e CAPHRI School for Public Health and Primary Care, Faculty of Health, Medicine and Life Sciences, Maastricht University, The Netherlands

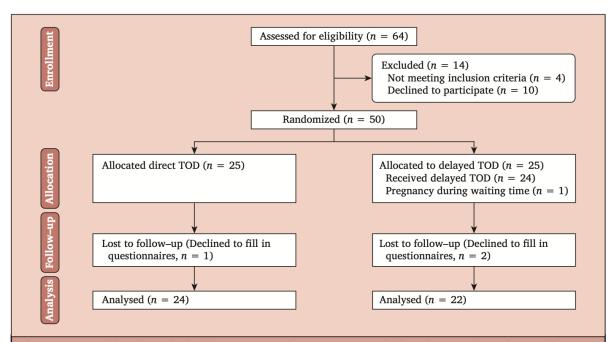


Figure 1. Consolidated Standards of Reporting Trials (CONSORT) study flow diagram of enrolment, allocation, follow up, and analyses of the patients with neurogenic thoracic outlet syndrome allocated to direct or delayed thoracic outlet decompression (TOD).

Validatie van het NTOS zorgpad





At 3 months after randomization there was a statistically significant difference between both TA-TOD group and conservative treatment group for the DASH, CBSQ and TOS Disability Scale scores. (p<0.001).

At twelve months after randomization, no statistically significant difference was found. (p=0.42 for DASH, p=0.25 for CBSQ and p=0.33 for TOS Disability Scale. No statistically significant differences were found for quality of life (PCS and MCS).





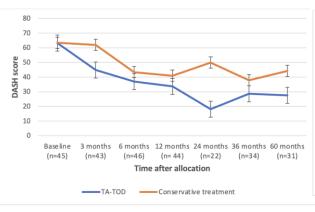


Complications	Direct TOD surgery group, n=24 (%)	Conservative treatment group, n=23 (%)
Autonomic dysregulation of the hand	0 (0.0%)	1 (4.3%)
Pulmonary embolism	1 (4.2%)	0 (0.0%)
Wound/skin infection	1 (4.2%)	2 (8.7%)
Horner's syndrome	1 (4.2%)	1 (4.3%)
N. ICB2 neuropathy	5 (20.8%)	1 (4.3%)
Hematoma	1 (4.2%)	0 (0.0%)
Frozen shoulder	1 (4.2%)	1 (4.3%)
Temporary phrenic nerve neuropathy	1 (4.2%)	0 (0.0%)
Temporary thoracic longus nerve neuropathy	1 (4.2%)	0 (0.0%)
Recurrent complaints	3 (12.5%)	3 (13.3%)
Redo surgery performed	3 (12.5%)	3 (13.3%)

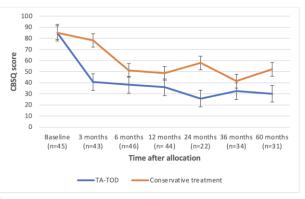
STOPNTOS: 5 jaarsresultaten



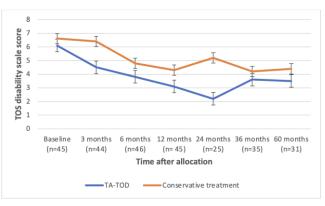
DASH Scores



CBSQ score



TOS Disability Scale Score





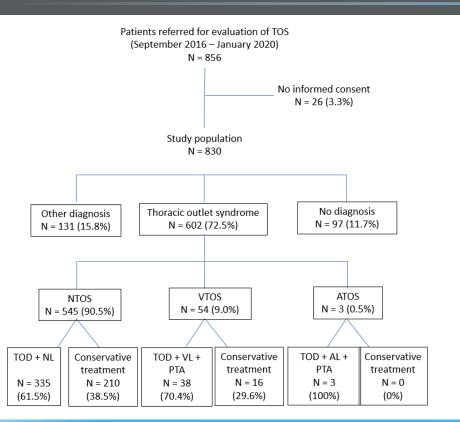


Figure 2: Schematic flow diagram for a prospective observational cohort for patient referred for thoracic outlet syndrome (TOS). (NTOS = Neurogenic thoracic outlet syndrome; VTOS = Venous thoracic outlet syndrome, ATOS = Arterial thoracic outlet syndrome; TOD = Thoracic Outlet Decompression; NL = Neurolysis; VL = Venolysis, AL = Arteriolysis; PTA = percutaneous Transluminal Angioplasty)



Table 2: Alternative diagnoses in patients referred for suspected TOS. We could not confirm the diagnosis of any form of TOS in 228 referred patients.

Other diagnoses	N	Percentage
No diagnosis	97	11.7%
Radicular syndrome	33	3.9%
Carpal Tunnel syndrome	17	2.0%
Muscoloskeletal shoulder problem	67	7.8%
Cubital tunnel syndrome	11	1.3%
Muscoloskeletal elbow problem	3	0.4%



FUNCTIONAL OUTCOME					
	BASELINE	3 MONTHS	<u>6 MONTHS</u>	12 MONTHS	24 MONTHS
NTOS					
Number of patients					
Conservative treatment	(n=233)	(n=159)	(n=180)	(n=148)	(n=47)
Surgical treatment	(n=263)	/	/	/	/
TOS Disability scale					
Conservative treatment	5.61 (±2.29)				
Surgical treatment	6.32 (±2.11)	4.42 (±2.36)	3.98 (± 2.67)	3.27 (±2.57)	3.26 (±2.61)
CBSQ Score					
Conservative treatment	66.25 (±26.46)				
Surgical treatment	72.91 (±24.27)	39.36 (±27.70)	37.85 (±28.55)	35.47 (±28.67)	38.67 (±30.43)
DASH score					
Conservative treatment	45.30 (±17.60)				
Surgical treatment	50.73 (±17.43)	39.76 (±21.93)	34.26 (±26.08)	34.30 (±24.74)	31.01 (±22.83)



Redo surgery for neurogenic thoracic outlet syndrome is useful

Jens Goeteyn, MD,^a Lieke Van Der Sanden, BA,^a Niels Pesser, MD,^a Saskia Houterman, MD,^b Marc R. H. M. van Sambeek, PhD, MD,^{a,c} Bart F. L. van Nuenen, MD,^d and Joep A. W. Teijink, MD, PhD,^{a,e} Eindhoven and Maastricht, The Netherlands



Table II. Functional outcome scores during follow-up

	Befo	re SC-REDO-TOD	6 months after SC-REDO- TOD		p.	12 MONTHS AFTER SC- REDO-TOD		
Functional outcome	Median 2	5th – 75th percentile	Median	25th-75th percentile	value	Median	25th-75th percentile	<i>P</i> -value
CBSQ score	75.63	67.69-83.57	44.66	34.87-54.45	<.001	55.63	37.69-93.57	0.66
DASH score	59.26	53.44-65.08	40.16	31.98-48.33	<.001	43.26	29.44-49.08	0.014
TOS disability scale	6.82	6.19-7.45	4.13	3.30-4.95	<.001	4.02	3.19-4.65	<.001

CBSQ, Cervical Brachial Score Questionnaire; DASH, Disability of the Arm, Shoulder, and Hand; SC-REDO-TOD, redo thoracic outlet decompression surgery through the supraclavicular approach; TOS, Thoracic Outlet Syndrome.

Median and 25th-75th quartiles are mentioned.

P values comparing results before and after are mentioned at each time interval (Wilcoxon signed ranks test).

Lange to





Table III. Overview of bony anomalies and remnants of the first rib after trans-axillary thoracic outlet decompression (*TA-TOD*)

	TA-TOD in our center, No.	n = 29, %	TA-TOD in other hospitals, No.	n = 14, %		
First rib remnant						
Posterior less than 2 cm	0	0.00	1	7.14		
Posterior more than 2 cm	0	0.00	8	57.14		
Anterior less than 2 cm	0	0.00	1	7.14		
Anterior more than 2 cm	0	0.00	3	21.43		
The results are separated between our hospital and referrals from other hospitals.						

Vragen?





NEUROGENIC THORACIC OUTLET SYNDROME: TOWARDS EVIDENCE-BASED MEDICINE

JENS GOETEYN