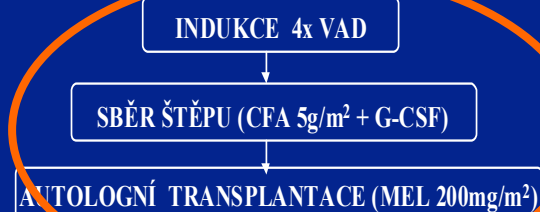


Randomized Trials of CMG

Clinical Trial 4W (1996)

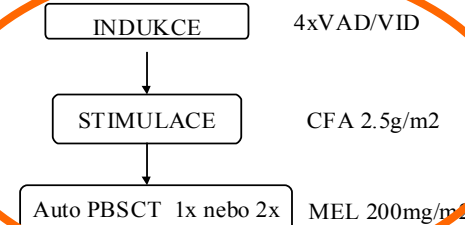


RANDOMIZACE PRO UDRŽOVACÍ

**Drop out during
INDUCTION phase
in the trial 4W was**

25%

Clinical Trial CMG 2002



**Drop out during
INDUCTION phase
in the trial CMG 02 is**

24%

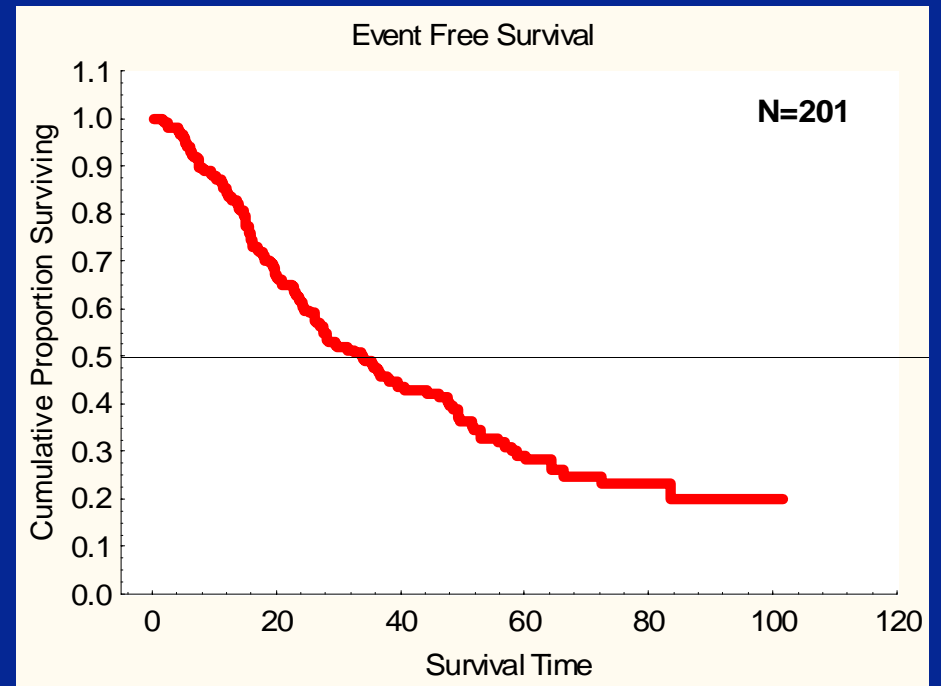
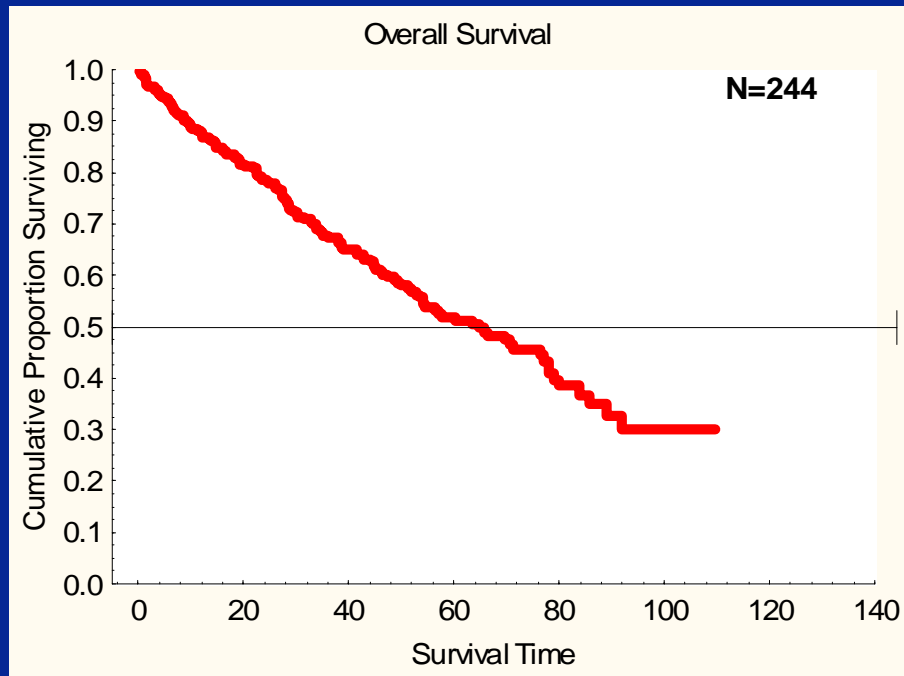
Therapeutic response after VAD4					
	4W		non-4W		
	N	%	N	%	
CR	9	4.90	1	1.60	
R	83	44.90	11	18.00	
MR	26	14.10	3	4.90	
SD	15	8.10	5	8.20	
PR	52	28.10	13	21.30	
PG	0	0.00	4	6.60	
NR	0	0.00	2	3.30	
<i>Unknown</i>	0	0.00	22	36.10	
P < 0.001					
<i>Range</i>	27-68		30-65		<0.001
Stage					
<i>I</i>	20 (10.8%)		6 (9.8%)		
<i>II</i>	36 (19.5%)		13 (21.3%)		
<i>III</i>	129 (69.7%)		41 (67.2%)		0.928
Renal failure	10 (5.4%)		14 (23.0%)		<0.001

PRIMARY ENDPOINT ANALYSIS

Event Free Survival, Overall Survival

Basic statistical summary (percentiles of survival times)

		All patients
EFS	50%	33.9
OS	50%	64.4



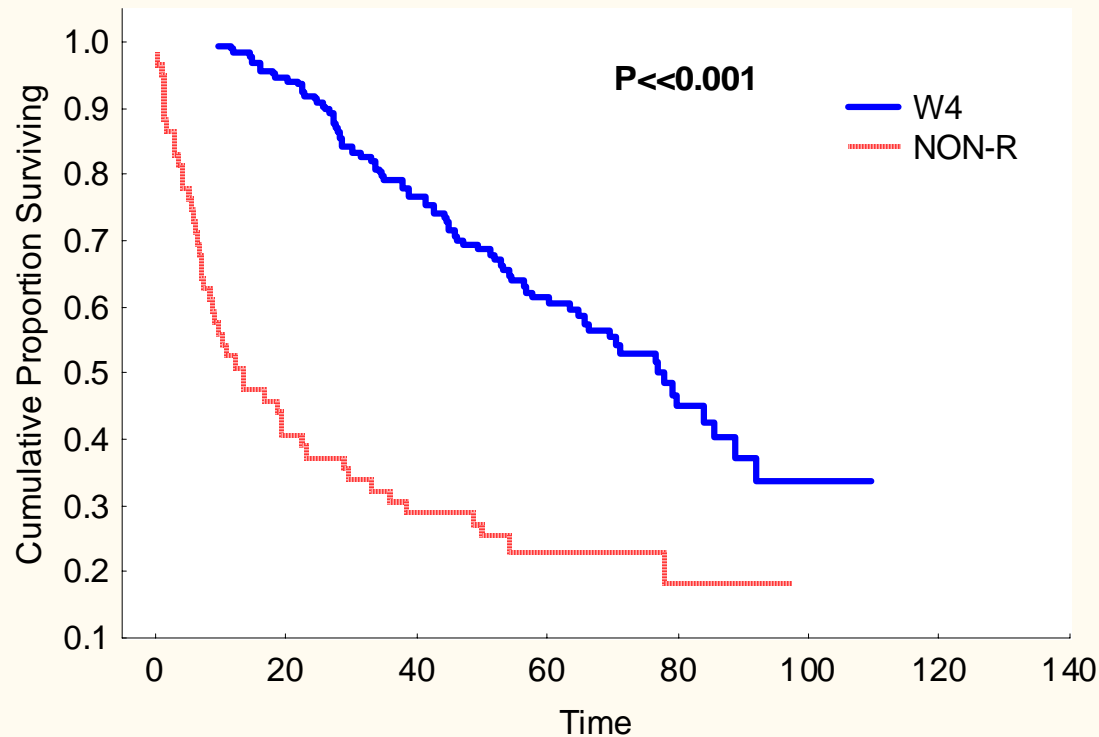
PRIMARY ENDPOINT ANALYSIS

Event Free Survival, Overall Survival

Basic statistical summary (percentiles of survival times)

		All patients
4W	50%	77.1
non-4W	50%	12.8

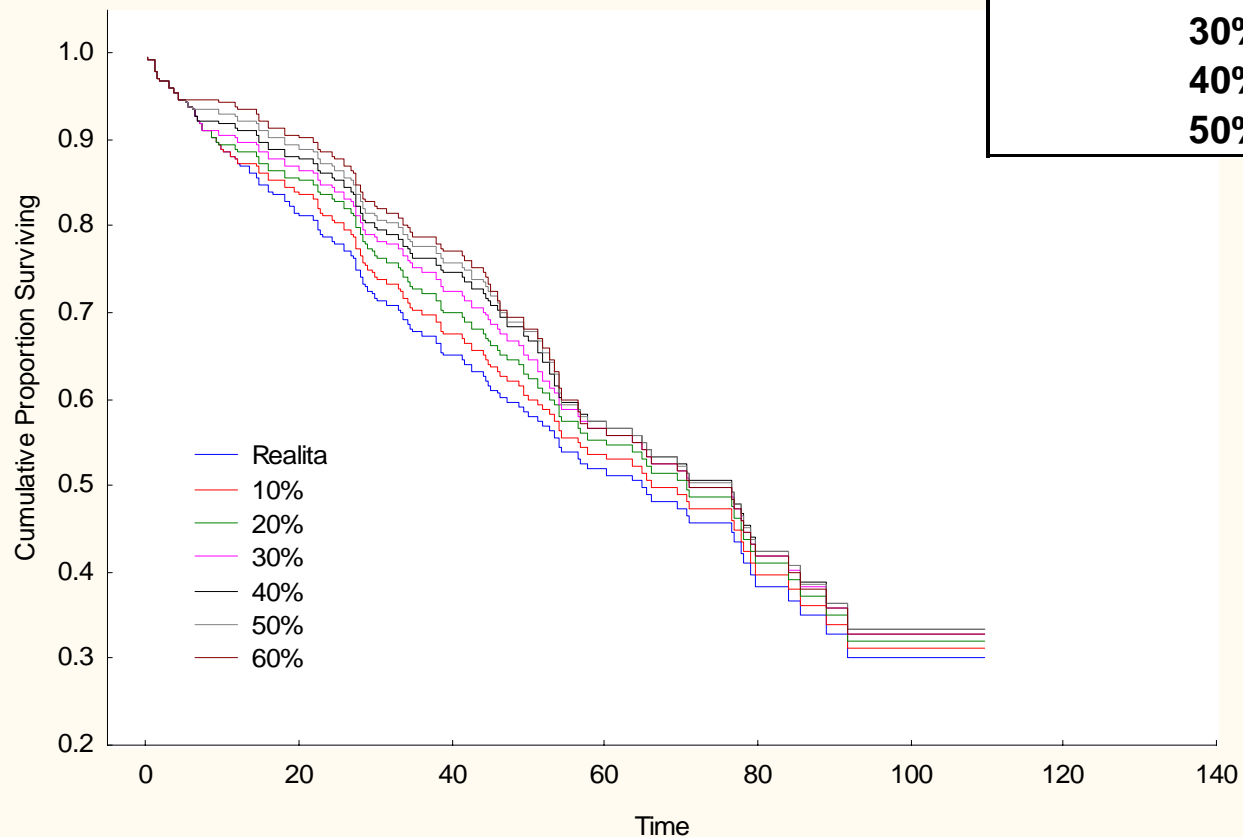
Overall Survival



Improvement of Overall Survival

Percentage of pts shifted to "transplant group"	Median OS [months]	P-value
0%	64.4	--
10%	66.2	0.648
20%	70	0.363
30%	71.1	0.199
40%	73.4	0.115
50%	73.3	0.084

Overall Survival



**Based on these data and statistic model applied
we confirmed:**

Reduction of droptout from

24% to 12% (50%)

**will improve median of overall survival
for whole analysed group**

of 9 months

Modification of the key parts of the all strategy

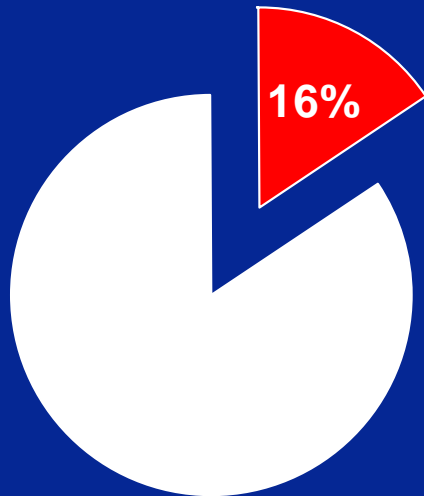
Focus on INDUCTION PART of the protocol

TROMBEMBOLISM (VDT and LE)

BASIC CHARACTERISTICS OF PATIENTS

Number of patients analysed:	N=191
Number of patients with TEN:	N=30
<i>Embolism:</i>	<i>N=4</i>
<i>DVT:</i>	<i>N=22</i>
<i>Embolism+DVT:</i>	<i>N=2</i>
<i>Unknown:</i>	<i>N=2</i>
Number of patients with LMWH:	N=70

Percentage of patients with
TEN (N=191)

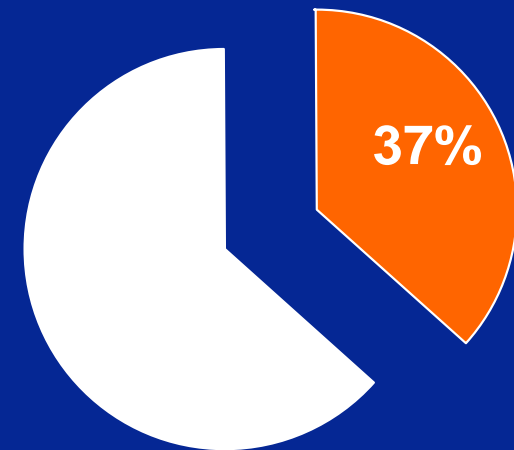


Patients with TEN

Patients without

TEN

Percentage of patients with
LMWH (N=191)



Patients with LMWH

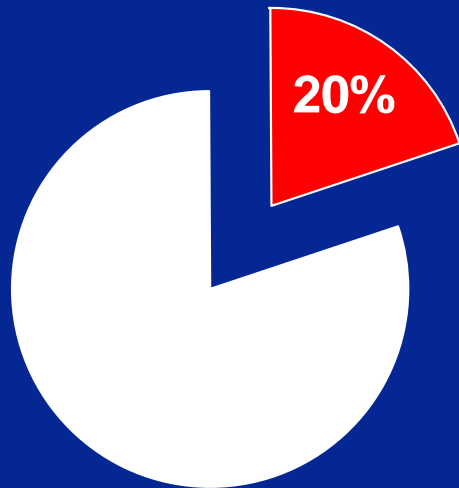
Patients without

LMWH

FREQUENCY OF TEN ACCORDING TO USEAGE OF LMWH

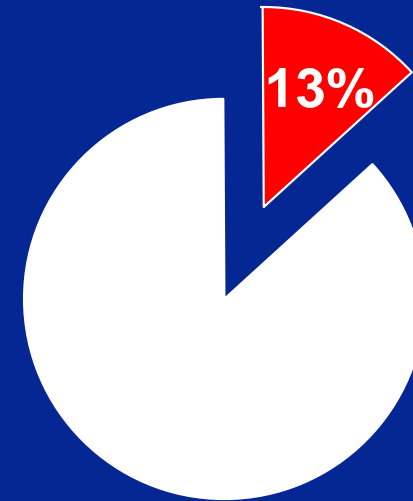
PATIENTS WITH LMWH
(N=70)

Percentage of patients with
TEN



**PATIENTS WITHOUT
LMWH (N=121)**

Percentage of patients with
TEN



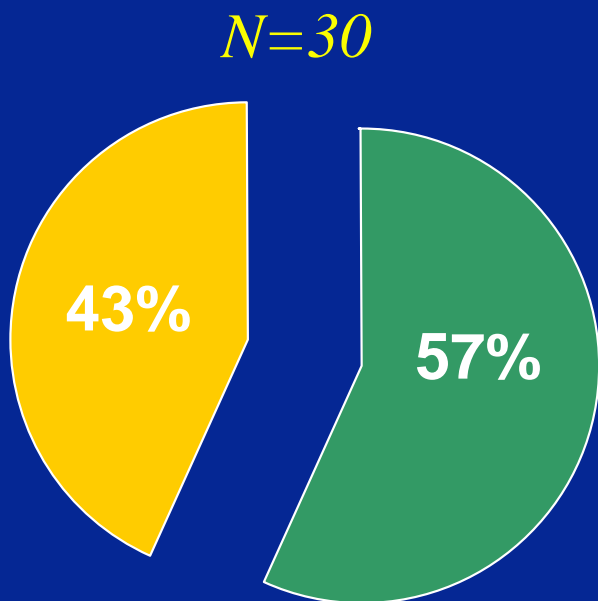
$p=0.223$

Patients with TEN

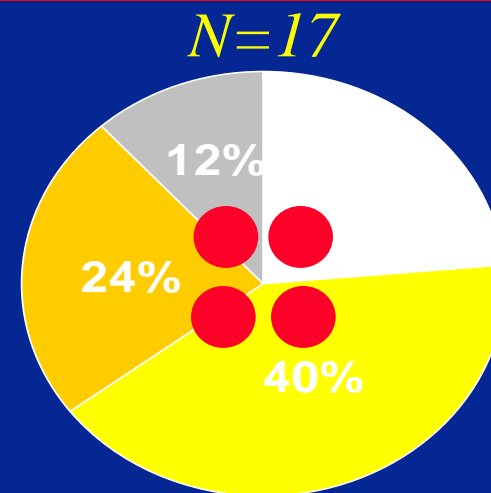
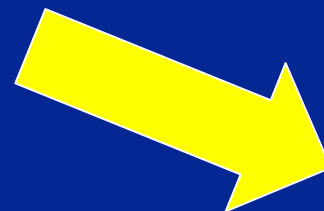
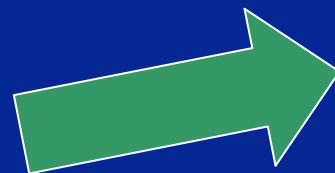
Patients without
TEN

The difference in frequency of TEN between groups of patients with and without LMWH is not statistically significant.

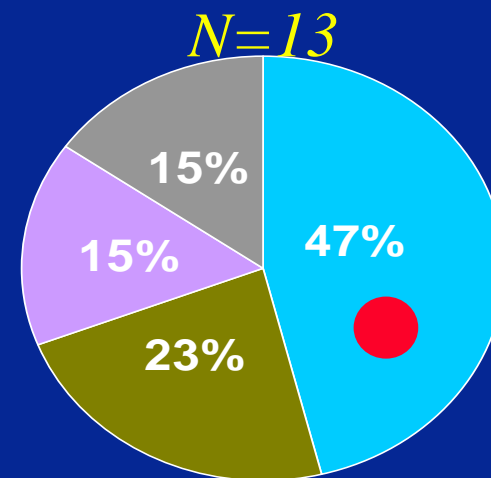
FREQUENCY OF TEN DURING TREATMENT: All cases



During induction
After induction

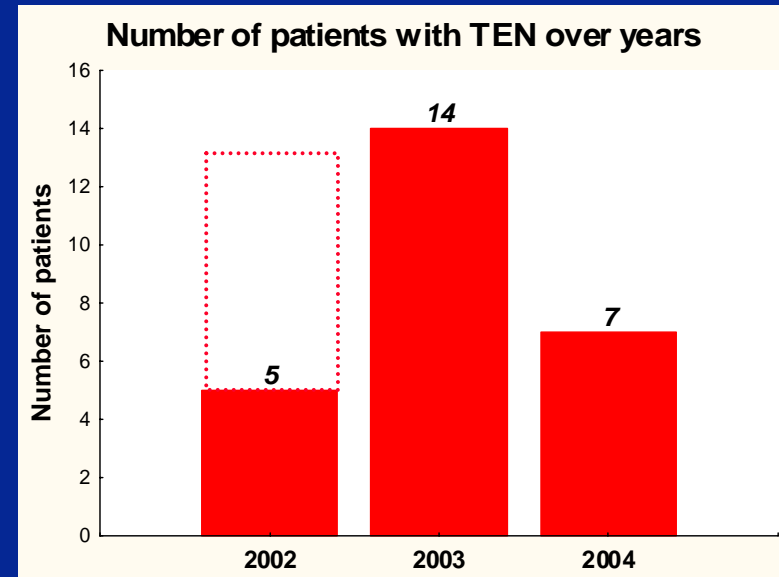
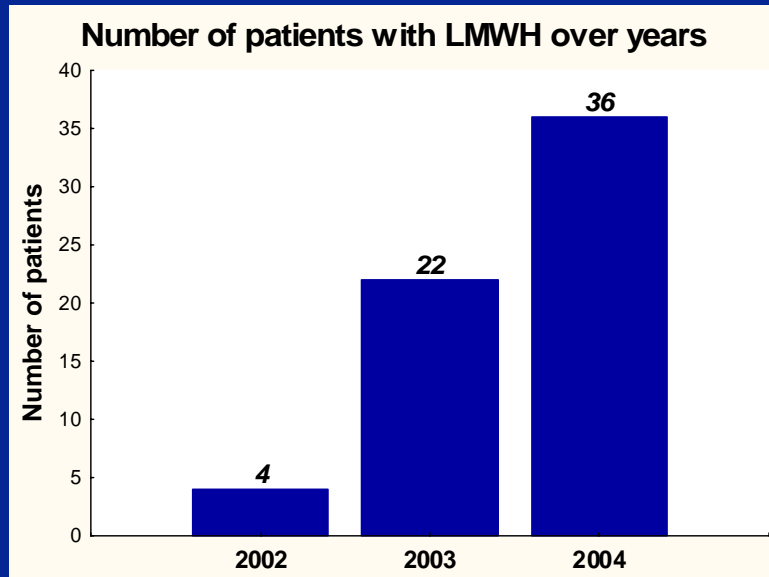


I
II
IV
Unknown



Before stimulation after
Stimulation
Transplantation
Between transplantation
and randomization

FREQUENCY OF TEN AND USAGE OF LMWH OVER TIME



As is shown in figures, the number of patients with LMWH has increased over years and the number of TENs decreased in 2004.