data from a meta-analysis of balneological clinical trials

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Methodology

- **Bibliographical inquiry**
  - References 1st screening : 983
  - Randomized trial + clinical main criterium : 48 papers
- **Quality assessment : Jaddad's score**
- **Statistical issues**
  - Association test significant $p<.05$
  - Heterogeneity test acceptable $p>.1$
  - Effect size determination $>.4$

Meta-analysis : Qualitative approach

Jadad score (randomisation, blindness, withdrawals)

Score	1	2	3	4	5
Low back pain	1	3	2		1
Osteoarthritis	1	3	4	2	1
Inflammatory arthritis	2	5	2		1
Fibromyalgia	4	3	2		
Chronic periph. arterial disease	1				1
Varicose Venous insufficiency	1	2			

Qualitative approach : Impact factor
(36 papers)(15 journals)

Impact factor	No	0-2	2-5	> 5
Low back pain	4		2	1
Osteoarthritis	5	3	1	1
Inflammatory arthritis	5	2	2	2
Fibromyalgia	2	4		
Chronic periph. arterial disease		2		
Varicose Venous insufficiency		3		

Quantitative approach (effect size)

Effect size	.4 – .8	.8 - 2	> 2
R A	Morning stiffness		Pain frequency Pat opinion Doct. opin.
A S Pso A	Pain ESR	Disabil. Morn stif Pasi	 Pat opinion
Fibro-myalgia	Press. Pain (algomet.)	Spont. Pain	FIQ N painf. pts Pain thresh.

Quantitative approach (effect size)

Effect size	.4 – .8	.8 - 2	> 2
Osteo arthritis	Grip strength QOL	Stairs down use	Womac disab. Opin doct & pat
Back Pain	Pain intensity Drugs consumpt. Anxiety Depres.	Pain palpation Patient opinion Disability Stiffness Lasegue	Muscles sensib. & contract. Doctor opinion

Rheumatoid arthritis

(6 trials, 262 patients ; 13 items tested : 5 statistically significant)

Symptom	N of papers	N of patients (SPA/control)	Effect size
Pain attacks reduction	1	28/29	2.37
Morning stiffness impr.	1	32/25	0.54
Global improvement : patient's opinion	1	32/25	2.42
Global improvement : doctor's opinion	1	32/25	2.13

Fibromyalgia

(6trials, 248 patients)(13 items tested :8 statistically significant)

Symptom	N of papers	N of patients SPA/control	Effect size
Pain intens. VAS	2	42/40	-1.68
headache	1	24/24	0.65
Pain threshold	1	20/20	3.86
PT to max painful point	1	20/20	4.01
N. Tender point	1	22/20	-2.75
6 pts pression difference	1	20/20	0.91
Pain relief	1	20/20	3.51

Knee osteo-arthritis

(8 trials, 543 patients)(18 items tested : 5 statistically significant)

Symptom	N of papers	N of patients (SPA/control)	Effect size
Stairs down use	1	31/27	1.51
QOL (AIMS2) improvement	1	91/97	0.44
Doctor's opinion	1	48/24	-4.16
Patient's opinion	1	48/24	-4.27
Womac disab.	1	48/24	- 6.3

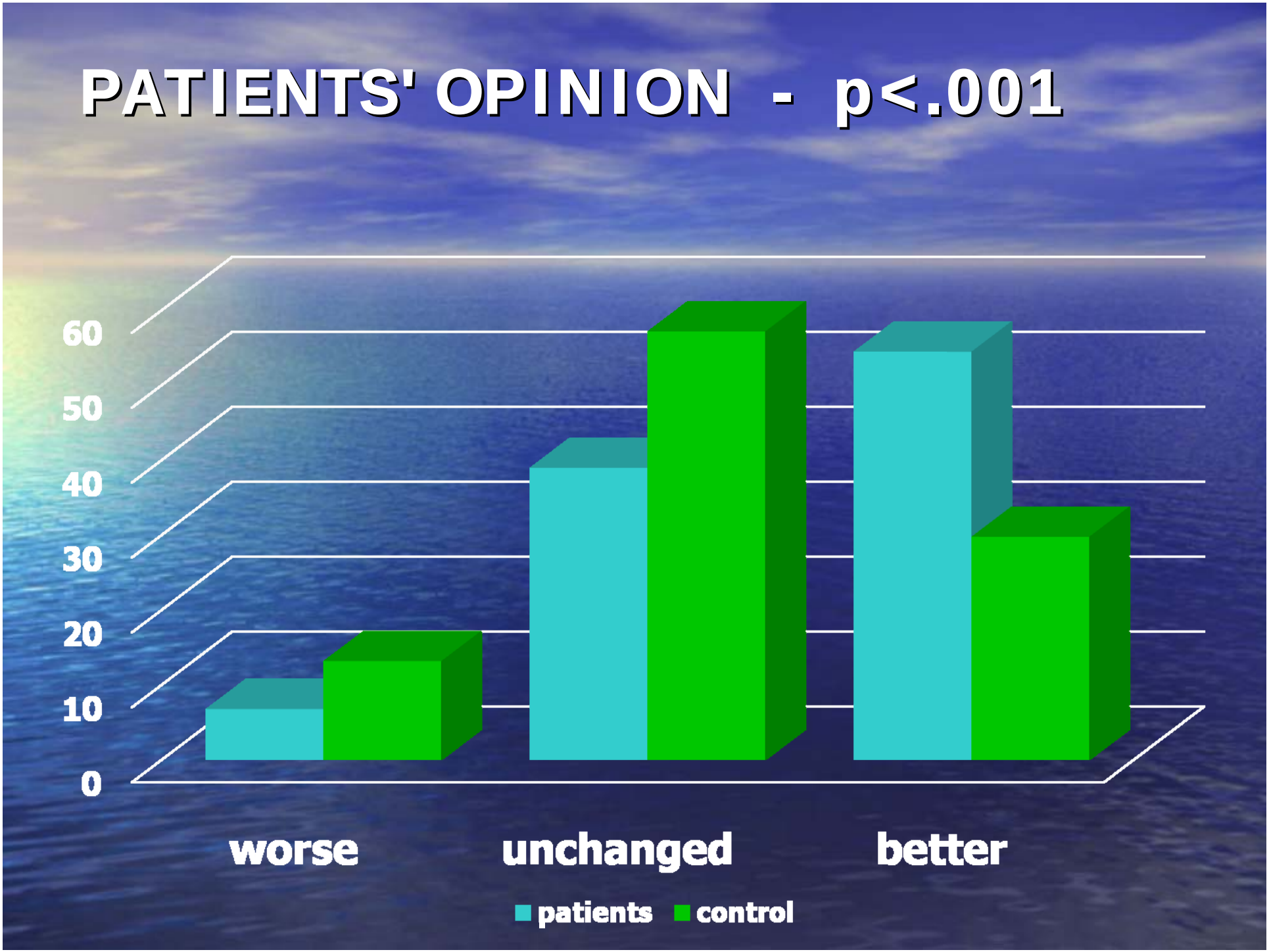
Thermarthrose : aRCT thermal treatment of knee osteoarthritis

- Examined patients : 630, non eligible : 168
- Accepted for publication in Ann Rheum Dis

	THERMAL TREATMENT	CONTROL GROUP	TOTAL
RANDOMISED	232	230	462
REFUSAL, GROUP CHANGE	28	23	51
6 MONTHS ITT	195	187	382
9 MONTHS ITT	175	174	349


Minimum Clinically Important Improvement (p<.005)

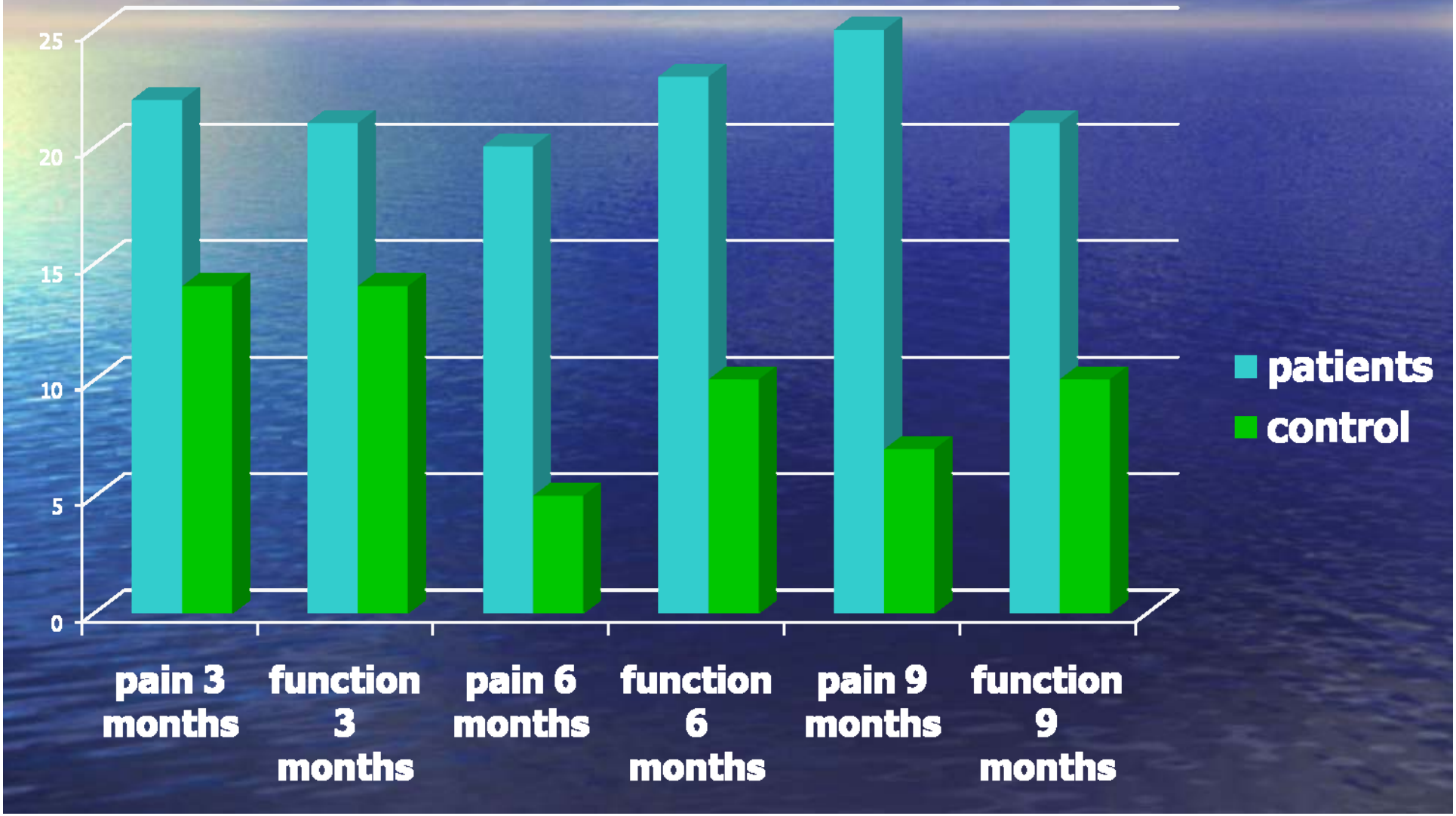
PATIENTS' OPINION - p<.001



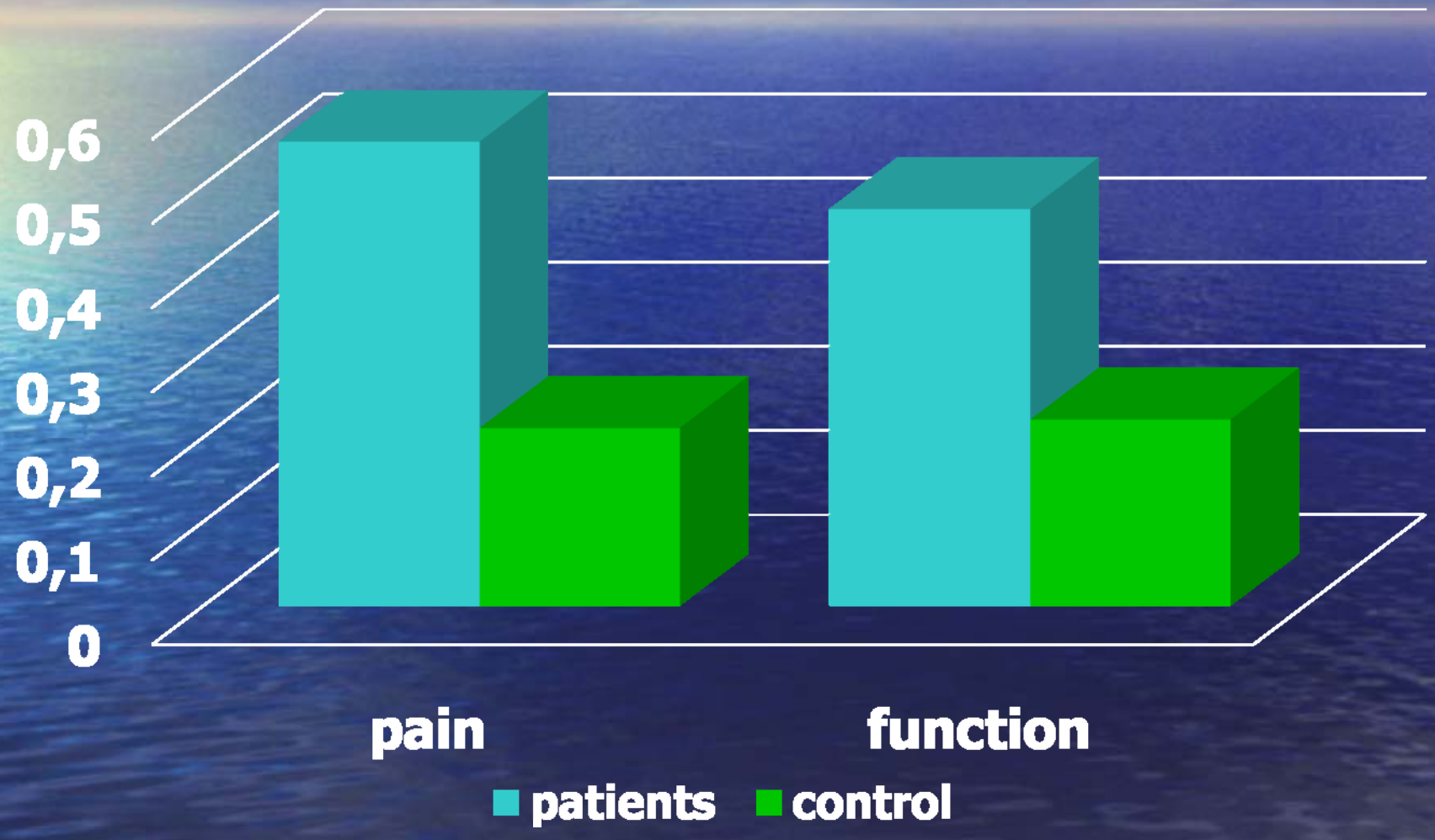
DOCTOR's OPINION - p<.001

% Improvement of Pain and Function

p<.003 Vas pain, p<.001 Womac



Effect size of the improvement



Effect sizes of the different treatments

TREATMENT	EFFECT SIZE
Chondroitin (unbiased studies)	0.03
Education	0.06
Massages	0.10
Weight reduction	0.13
Acetaminophen	0.21
Diacerein	0.22
NSAID (unbiased studies)	0.23
Muscular Streghtening Exercises	0.32
Hyaluronic Acid	0.32
SPA Therapy (litterature)	0.46
SPA Therapy (Thermarthrose)	0.55

Chronic Low Back Pain

(7 trials, 829 patients ; 40 items tested, 25 statistically significant)

Symptom	N of papers	N of patients SPA/control	Effect size
VAS (mm)	6	397/311	- 0.80
Analgesic drugs' intake	3	190/145	-0.47
Pain duration (hours)	3	236/208	-1.02
Fingertip floor distance (cms)	4	266/228	-0.58

Conclusion

- Many trials, an appreciable number of patients enlisted
- Lack of conclusive trials and of well achieved trials
- Many items statistically tested and significant but very limited number of papers and patients for most of the items : level of evidence II or silver
- A need for well achieved and conclusive trials (some tested items can be useful)