*Supplemental Table 1:* Baseline characteristics and Quantitative Sensory Test results, as observed in patients with and without failed back surgery syndrome (FBSS) according to primary outcome defined as persistence of pain at 12 months. N total = 137.

|  |  |  |  |
| --- | --- | --- | --- |
|  | **With FBSS** |  | **Without FBSS** |
|  |  |  |  |
|  | N = 42 | N (%) or mean ± SD |  | N = 95 | N (%) or mean ± SD |
| **Socio-demographic characteristics** |  |  |  |  |  |
| Age | 42 | 61.0 ± 14.2 |  | 95 | 61.4 ± 13.6 |
| Female | 42 | 21 (50%) |  | 95 | 59 (62%) |
| Higher education | 42 | 10 (24%) |  | 95 | 22 (23%) |
| Regular work# | 42 | 14 (33%) |  | 95 | 38 (40%) |
| Married | 42 | 25 (60%) |  | 95 | 65 (68%) |
| **Psychological characteristics** |  |  |  |  |  |
| Depression (BDI-II) | 42 | 10.9 ± 5.6 |  | 95 | 11.1 ± 6.8 |
| Anxiety (STAI Trait) | 42 | 55.1 ± 6.5 |  | 92 | 53.6 ± 8.4 |
| Catastrophizing (PCS) | 38 | 19.5 ± 11.8 |  | 86 | 16.6 ± 10.4 |
| **Clinical characteristics** |  |  |  |  |  |
| Body-Mass-Index (kg/m2) | 42 | 29.4 ± 4.6 |  | 95 | 27.8 ± 4.4 |
| Smoking | 42 | 12 (29%) |  | 93 | 25 (27%) |
| Large finger ground distance (cut-off > 10cm) | 40 | 29 (73%) |  | 93 | 48 (52%) |
| Lasègue positive | 42 | 26 (62%) |  | 91 | 37 (41%) |
| Previous back surgery | 42 | 11 (26%) |  | 95 | 17 (18%) |
| Low back pain with irradiation to leg | 42 | 34 (81%) |  | 93 | 83 (89%) |
| Long pain duration (cut-off > 5 years) | 41 | 11 (27%) |  | 89 | 20 (22%) |
| Maximum pain intensity at baseline (NRS last 7 days) | 42 | 7.7 ± 1.4 |  | 95 | 7.8 ± 1.3 |
| Disability at baseline (ODI) | 42 | 42.6 ± 12.2 |  | 95 | 39 ± 12.9 |
| Intake of non-opioid analgesics | 42 | 24 (57%) |  | 95 | 37 (39%) |
| Intake of opioid analgesics | 42 | 11 (26%) |  | 93 | 13 (14%) |
| **Radiologic characteristics (classification)** |  |  |  |  |  |
| Spinal stenosis (Schizas B, C or D) | 41 | 23 (56%) |  | 92 | 50 (54%) |
| Spondylolisthesis (Meyerding I-IV) | 42 | 22 (52%) |  | 93 | 63 (68%) |
| Endplate changes (Modic 1-3) | 41 | 30 (73%) |  | 91 | 71 (78%) |
| Scoliosis (cobb angle >10°) | 39 | 3 (8%) |  | 92 | 16 (17%) |
| Severe facet joint degeneration (Weishaupt 3) | 41 | 18 (44%) |  | 94 | 48 (51%) |
| Severe or extreme disc degeneration (Pfirrmann 4 and 5) | 39 | 33 (85%) |  | 90 | 79 (88%) |
| ≥ 50% fatty degeneration muscles (Goutaillier 3 and 4)  | 41 | 3 (7%) |  | 94 | 13 (14%) |
| **Quantitative Sensory Tests** |  |  |  |  |  |
| Electrical pain detection threshold single stimulation (mA)  | 42 | 10.1 ± 6.6 |  | 95 | 9.3 ± 3.8 |
| Electrical pain detection threshold repeated stimulation (mA) | 42 | 7.0 ± 3.5 |  | 95 | 6.3 ± 2.4 |
| Pressure pain detection threshold 2nd toe(kPa) | 42 | 259 ± 113 |  | 95 | 270 ± 107 |
| Pressure pain tolerance threshold 2nd toe(kPa) | 42 | 465 ± 157 |  | 95 | 477 ± 163 |
| Pressure pain detection threshold 2nd finger(kPa) | 42 | 296 ± 150 |  | 95 | 331 ± 156 |
| Pressure pain tolerance threshold 2nd finger(kPa) | 42 | 623 ± 190 |  | 95 | 628 ± 193 |
| Pressure pain detection threshold site most pain back | 42 | 309 ± 143 |  | 95 | 347 ± 187 |
| Pressure pain tolerance threshold site most pain back | 42 | 561 ± 234 |  | 95 | 605 ± 268 |
| Heat pain detection threshold leg (cut-off < 50.5 °C) | 41 | 32 (78%) |  | 92 | 65 (71%) |
| Heat pain detection threshold site most pain back (cut-off < 50.5 °C) | 41 | 36 (88%) |  | 91 | 81 (89%) |
| Cold pain detection threshold leg (cut-off > 0.0 °C) | 40 | 18 (45%) |  | 92 | 27 (29%) |
| Cold pain detection threshold site most pain back (cut-off > 0.0 °C) | 40 | 23 (58%) |  | 93 | 43 (46%) |
| Cold pressor test: hand withdrawal time (cut-off < 120 sec) | 40 | 34 (85%) |  | 92 | 78 (85%) |
| Conditioned pain modulation: % without increase pressure pain detection threshold 2nd toe | 31 | 6 (19%) |  | 80 | 14 (18%) |
|  |  |  |  |  |  |
| # includes houseworkersBDI-ll: Beck Depression Inventory Version 2 (0: no depression to 63: maximum depression)STAI: State Trait Anxiety Index PCS: Pain Catastrophizing Scale (0: no catastrophizing to 52: maximum catastrophizing)NRS: Numerical Rating Scale (0: no pain to 10: maximum pain)ODI : Oswestry Disability Index (0: no disability to 100: maximum disability) |

*Supplemental Table 2:* Fully adjusted sensitivity analyses of associations between Quantitative Sensory Test and failed back surgery syndrome defined as persistence of pain at 12 months. Values are odds ratios (OR) from logistic regression models (analysis I, II and IV) or regression coefficients (Coef) from linear regression models (analysis III) with corresponding 95% confidence intervals (CI) and p-values.

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
|  | **Sensitivity Analysis I** |  | **Sensitivity Analysis II** |  | **Sensitivity Analysis III** |  | **Sensitivity Analysis IV** |
|  | OR (95% CI) | p |  | OR (95% CI) | p |  | Coef (95% CI) | p |  | OR (95% CI) | p |
| **Electrical pain (mA)** |  |  |  |  |  |  |  |  |  |  |  |
| detection threshold single stimulation a | 0.77 (0.32 to 1.83)  | 0.54 |  | 0.81 (0.35 to 1.87) | 0.62 |  | -0.22 (-1.32 to 0.88) | 0.69 |  | 0.65 (0.23 to 1.84) | 0.42 |
| detection threshold repeated stimulation a | 0.60 (0.26 to 1.40) | 0.24 |  | 0.62 (0.27 to 1.41) | 0.25 |  | -0.35 (-1.40 to 0.71) | 0.52 |  | 0.57 (0.22 to 1.53) | 0.27 |
| **Pressure pain (kPa)** |  |  |  |  |  |  |  |  |  |  |  |
| detection threshold 2nd toe a | 1.26 (0.55 to 2.91) | 0.59 |  | 1.35 (0.59 to 3.07) | 0.47 |  | 0.39 (-0.67 to 1.45) | 0.47 |  | 1.99 (0.69 to 5.69) | 0.20 |
| tolerance threshold 2nd toe a | 0.94 (0.41 to 2.18) | 0.89 |  | 0.98 (0.43 to 2.26) | 0.97 |  | -0.02 (-1.12 to 1.08) | 0.97 |  | 1.00 (0.38 to 2.64) | 1.00 |
| detection threshold 2nd finger a | 1.58 (0.68 to 3.70) | 0.29 |  | 1.75 (0.77 to 3.97) | 0.18 |  | 0.84 (-0.21 to 1.90) | 0.12 |  | 1.69 (0.68 to 4.21) | 0.26 |
| tolerance threshold 2nd finger a | 0.80 (0.32 to 2.03) | 0.64 |  | 0.83 (0.33 to 2.08) | 0.69 |  | -0.13 (-1.31 to 1.07) | 0.84 |  | 0.79 (0.27 to 2.32) | 0.66 |
| detection threshold site most pain back a | 1.06 (0.43 to 2.63) | 0.90 |  | 0.98 (0.40 to 2.37) | 0.96 |  | 0.30 (-0.86 to 1.46) | 0.61 |  | 1.00 (0.36 to 2.73) | 1.00 |
| tolerance threshold site most pain back a | 0.93 (0.36 to 2.44) | 0.89 |  | 0.94 (0.37 to 2.39) | 0.89 |  | -0.01 (-1.22 to 1.20) | 0.99 |  | 1.16 (0.41 to 3.29) | 0.78 |
| **Heat pain (cut-off < 50.5 °C)** |  |  |  |  |  |  |  |  |  |  |  |
| detection threshold leg b | 1.01 (0.39 to 2.61) | 0.98 |  | 1.22 (0.46 to 3.24) | 0.70 |  | 0.31 (-0.91 to 1.53) | 0.61 |  | 0.82 (0.28 to 2.44) | 0.72 |
| detection threshold site most pain back b | 0.72 (0.19 to 2.64) | 0.62 |  | 0.71 (0.19 to 2.57) | 0.60 |  | -0.30 (-1.96 to 1.37) | 0.73 |  | 0.60 (0.13 to 2.78) | 0.51 |
| **Cold pain (cut-off > 0.0 °C)** |  |  |  |  |  |  |  |  |  |  |  |
| detection threshold leg b | 1.61 (0.65 to 3.95) | 0.30 |  | 1.78 (0.73 to 4.34) | 0.21 |  | 1.23 (0.09 to 2.38) | 0.04 |  | 1.41 (0.51 to 3.89) | 0.51 |
| detection threshold site most pain back b | 1.09 (0.45 to 2.60) | 0.85 |  | 1.12 (0.47 to 2.69) | 0.79 |  | -0.11 (-1.22 to 0.99) | 0.84 |  | 1.28 (0.48 to 3.45) | 0.62 |
| **Cold pressor test (cut-off < 120 sec)** |  |  |  |  |  |  |  |  |  |  |  |
| hand withdrawal time b | 0.61 (0.19 to 2.01) | 0.42 |  | 0.87 (0.28 to 2.72) | 0.82 |  | -0.23 (-1.67 to 1.21) | 0.75 |  | 0.83 (0.22 to 3.08) | 0.78 |
| **Conditioned pain modulation (CPM)** |  |  |  |  |  |  |  |  |  |  |  |
| % without increase of pressure pain detection threshold 2nd toe b | 1.15 (0.32 to 4.13) | 0.83 |  | 1.23 (0.35 to 4.37) | 0.74 |  | 0.28 (-1.32 to 1.87) | 0.73 |  | 1.18 (0.27 to 5.13) | 0.83 |
| all analyses adjusted for type of surgery, number of segments operated, gender, catastrophizing, Body-Mass-Index, Lasègue sign, finger ground distance, disability at baseline, intake of non-opioid analgesics, intake of opioid analgesics**Sensitivity analysis I:** Logistic regression analysis after multiple imputation including acute post-surgical pain as co-variate; (N=141).**Sensitivity analysis II:** Logistic regression analysis of patients with complete outcome data at both follow-up; (N=137).**Sensitivity analysis III**: Multivariable linear regression analysis after multiple imputation; (N=141)Sensitivity analysis IV: Logistic regression analysis after multiple imputation of patients not previously operated (N=113)OR > 1.0 and Coef >0.0 means more pathological values of QST are associated with increased risk for failed back surgery syndrome (i.e. low thresholds after pressure, electrical and heat stimulation, high thresholds after cold stimulation, short hand withdrawal time and impaired CPM)a OR or Coef per two standard deviation decrease of QSTb quantitative sensory tests with missing data |

*Supplemental Table 3:* Fully adjusted secondary analyses of associations between Quantitative Sensory Test and failed back surgery syndrome at 6 months according to different outcome definitions. Values are odds ratios (OR) with corresponding 95% confidence intervals (CI) and p-values from logistic regression models after multiple imputation, N total =141.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  |  |  |  |  |  |
|  | **Persistence of pain**  |  | **Persistence of disability**  |  | **Persistence of** **pain or disability**  |
|  | OR (95% CI) | p-value |  | OR (95% CI) | p-value |  | OR (95% CI) | p-value |
| **Electrical pain (mA)** |  |  |  |  |  |  |  |  |
| detection threshold single stimulation a  | 1.33 (0.60 to 3.00) | 0.48 |  | 0.76 (0.34 to 1.72) | 0.52 |  | 1.09 (0.50 to 2.37) | 0.83 |
| detection threshold repeated stimulation a | 0.97 (0.45 to 2.11) | 0.95 |  | 0.75 (0.34 to 1.65) | 0.48 |  | 0.85 (0.40 to 1.80) | 0.68 |
| **Pressure pain (kPa)** |  |  |  |  |  |  |  |  |
| detection threshold 2nd toe a  | 0.86 (0.39 to 1.91) | 0.72 |  | 0.92 (0.42 to 2.03) | 0.84 |  | 1.05 (0.49 to 2.24) | 0.90 |
| tolerance threshold 2nd toe a  | 1.05 (0.47 to 2.37) | 0.90 |  | 0.76 (0.34 to 1.69) | 0.50 |  | 1.15 (0.53 to 2.52) | 0.72 |
| detection threshold 2nd finger a | 0.96 (0.43 to 2.16) | 0.93 |  | 1.15 (0.52 to 2.56) | 0.72 |  | 1.32 (0.61 to 2.86) | 0.48 |
| tolerance threshold 2nd finger a  | 0.72 (0.29 to 1.80) | 0.48 |  | 1.06 (0.43 to 2.63) | 0.90 |  | 1.14 (0.49 to 2.69) | 0.76 |
| detection threshold site most pain back a | 1.48 (0.62 to 3.54) | 0.38 |  | 1.50 (0.63 to 3.57) | 0.36 |  | 1.45 (0.63 to 3.35) | 0.38 |
| tolerance threshold site most pain back a | 2.58 (0.95 to 6.98) | 0.06 |  | 1.94 (0.74 to 5.10) | 0.18 |  | 2.18 (0.87 to 5.49) | 0.10 |
| **Heat pain (cut-off < 50.5 °C)** |  |  |  |  |  |  |  |  |
| detection threshold leg b | 1.04 (0.41 to 2.63) | 0.93 |  | 0.41 (0.16 to 1.05) | 0.06 |  | 0.60 (0.25 to 1.44) | 0.25 |
| detection threshold site most pain back b | 1.31 (0.33 to 5.19) | 0.70 |  | 0.79 (0.21 to 2.94) | 0.73 |  | 0.91 (0.27 to 3.11) | 0.89 |
| **Cold pain (cut-off > 0.0 °C)** |  |  |  |  |  |  |  |  |
| detection threshold leg b | 1.09 (0.44 to 2.69) | 0.85 |  | 0.80 (0.32 to 2.03) | 0.64 |  | 0.90 (0.38 to 2.14) | 0.82 |
| detection threshold site most pain back b | 0.58 (0.24 to 1.37) | 0.21 |  | 0.72 (0.30 to 1.71) | 0.45 |  | 0.53 (0.23 to 1.22) | 0.14 |
| **Cold pressor test (cut-off < 120 sec)** |  |  |  |  |  |  |  |  |
| hand withdrawal time b | 1.70 (0.51 to 5.65) | 0.39 |  | 1.70 (0.49 to 5.90) | 0.40 |  | 2.83 (0.86 to 9.35) | 0.09 |
| **Conditioned pain modulation (CPM)** |  |  |  |  |  |  |  |  |
| % without increase of pressure pain detection threshold 2nd toe b | 1.39 (0.41 to 4.75) | 0.60 |  | 1.82 (0.55 to 6.02) | 0.32 |  | 1.60 (0.51 to 5.06) | 0.42 |
| adjusted for type of surgery, number of segments operated, gender, catastrophizing, BMI, lasègue sign, finger ground distance, disability at baseline, intake of non-opioid analgesics, intake of opioid analgesicsOR>1.0 means more pathological values of QST are associated with increased risk for failed back surgery syndrome (i.e. low thresholds after pressure, electrical and heat stimulation, high thresholds after cold stimulation, short hand withdrawal time and impaired CPM)a OR per two standard deviation decreaseb quantitative sensory tests with missing data |

*Supplemental Text 1:* Detailed description of the assessment methods of Quantitative Sensory Tests.

We used bipolar surface Ag/AgCl-electrodes for electrical stimulation and placed them distal to the lateral malleolus, which corresponds to the innervation area of the sural nerve. We used a computer-controlled constant current stimulator (NCS System, Evidence 3102 evo, Neurosoft, Russia) and a single increasing intensity staircase to assess pain detection and reflex threshold 1,2. The current intensity was increased from 1 mA in steps of 1 mA until the electrical stimulus was perceived as painful and until a nociceptive withdrawal reflex (NWR) of the biceps femoris with an amplitude higher than 20µV for at least 10ms in the 50 to 150ms post-estimation interval was elicited (NWR threshold) 2-5. Single electrical stimulation consisted of a train-of-five 1-ms square-wave impulse of an overall duration of 25 ms, which the patients perceived as a single stimulus. Temporal summation occurs when repetition of a stimulus is associated with an increase in pain perception 6. To elicit temporal summation, we repeated the train-of-five stimulus five times with a frequency of 2 Hz at a constant intensity and again assessed pain detection threshold 6.

We assessed pressure pain detection and tolerance thresholds using an electronic pressure algometer with a 1 cm2 surface probe (Somedic, Hörby, Sweden) 7. We performed the pressure tests at the center of the pulp of the 2nd toe, the 2nd finger and the site of most pain at the back. Pressure was increased from 0 at a rate of 30 kPa/s to a maximum of 1000 kPa. We defined pain detection threshold as the point at which the pressure sensation turned into pain and pain tolerance threshold as the point at which the subject felt the pain as intolerable. The participants had to press a button when reaching these points and the algometer displayed the corresponding pressure intensity. Whenever a participant did not press the button below 1000 kPa, we considered this value as threshold.

We measured pain detection threshold to dynamic heat and cold stimulation with a thermode of a 30 x 30 mm surface (TSA-ll, Medoc, Ramat Yishai, Israel) 8. We performed the tests at the lateral aspect of the leg (midway between the knee and the lateral malleolus) and at the site of most pain at the back. The temperature of the thermode was changed at a rate of 0.5 ºC/sec from 30 ºC to a maximum of 50.5 ºC and to a minimum of 0.0 °C until the stimulus was perceived as painful and the participants pressed a button. Threshold values were truncated in case participants did not report pain at the maximum of 50.5°C or the minimum of 0.0°C, respectively, and these values were considered as thresholds.

We assessed the response to a tonic cold painful stimulus with the cold pressor test. The hand was immersed in ice saturated water (1.5± 1°C) for a duration of two minutes. The device consisted of a container separated into an outer and an inner part by a mesh screen. The mesh screen prevented direct contact between the ice (placed in the outer part) and the hand of the subject (placed in the inner part). We recorded the hand withdrawal time at which the participants considered pain as intolerable. Whenever a participant did not perceive the stimulus as intolerable below two minutes, we considered this value as threshold.

We assessed CPM using the cold pressor test as conditioning noxious stimulus and pressure pain detection threshold at the 2nd toe as test stimulus 9-13. Thus, after two minutes of hand immersion in the ice water, we reassessed pressure pain detection threshold. Patients who had intolerable pain before two minutes elapsed could briefly retract their hand from the cold water and re-immersed it until two minutes were reached. We considered an increase in pressure pain detection threshold at the 2nd toe after hand immersion as measure of CPM indicating efficient endogenous pain inhibitory processes.

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*Supplemental Text 2*: Detailed description of radiologic assessment of degenerative changes of the lumbar spine.

We assessed the degree of spinal stenosis according to Schizas ranging from A (normal) to D (extreme stenosis) 1 and compared patients with and without spinal stenosis (Schizas B, C, D vs Schizas A). We used the classification of Meyerding to measure the degree of spondylolisthesis ranging from 0 (normal) to IV (76% - 100% listhesis) 2 and compared patients with and without spondylolisthesis (Meyerding I-IV vs Meyerding 0). Changes of the endplates were scored using the Modic classification from 0 (normal) to 3 (sclerotic endplates) 3 and we compared patients with endplate changes to patients with normal endplate (Modic 1-3 vs Modic 0). We defined the presence of scoliosis as cobb angle > 10° 4,5. We used the classification of Weishaupt to characterize the degree of facet joint degeneration ranging from 0 (normal) to 3 (severe facet joint degeneration) 6 and compared patients with and without severe facet joint degeneration (Weishaupt 3 vs Weishaupt 0-2). Disc degeneration was classified according to the grading system proposed by Pfirrmann with 1 (normal) to 5 (extreme degeneration) 7 and we compared patients with and without severe or extreme disc degeneration (Pfirrmann 4 and 5 vs Pfirrmann 1-3). We measured fatty degeneration of paraspinal muscles according to the scoring system by Goutailler with 0 (normal) to 4 (>50% fat) 8 and compared patients with at least 50% fat to patients with less than 50% fat (Goutailler 3 and 4 vs Goutailler 0, 1 and 2).

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