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ORIGINAL ARTICLE

Decrease of pregnant women's pelvic pain after acupuncture: A randomized controlled single-blind study

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Abstract

Background. The efficacy of acupuncture on low-back and/or pelvic pain in late pregnancy is reviewed in few reports. Our aim was to evaluate the effects of two different acupuncture stimulation modes on pelvic pain intensity and some emotional symptoms due to the pain condition. *Methods*. In a prospective randomized controlled single-blind study, pregnant women with pelvic pain, median gestational age 26 weeks (range 18–35), were given 10 acupuncture treatments. Needles were inserted subcutaneously over acupuncture points without further stimulation (superficial, $n=22$), or intramuscular and stimulated repeatedly until a perceived sensation of numbness, *de qi*, (deep, $n=25$). Self-reported pain intensity at rest and during daily activities was assessed on a visual analog scale. The variables pain, emotional reactions, and loss of energy were assessed according to the Nottingham Health Profile questionnaire. Changes in assessed variables were analyzed with a nonparametric statistical method allowing for analysis of systematic group changes separated from additional individual changes. *Results*. After acupuncture stimulation, significant systematic group changes towards lower levels of pain intensity at rest and in daily activities as well as in rated emotional reaction and loss of energy were seen. The results also showed additional individual changes in most variables. In this study, no differences between the effects induced by the superficial and deep acupuncture stimulation modes were observed. *Conclusion*. Acupuncture stimulation that is individually designed may be a valuable treatment to ameliorate suffering in the condition of pelvic pain in late pregnancy.

Key words: *Acupuncture, change, NHP, nonparametric statistics, pelvic pain, VAS*

Abbreviations: *VAS: Visual Analogue Scale, NHP: Nottingham Health Profile, 4P test: Posterior Pelvic Pain Provoking test, BL: bladder, KI: kidney, CV: conception vessel, SP: spleen, LR: liver, LI: large intestine, SD: standard deviation, ROC: relative operative characteristic, RP: relative position, RV: relative rank variance, CI: confidence interval*

Pain in the lower back and pelvic region is a common complaint in late pregnancy and affects approximately 50% or more of all pregnant women (1–4). The pain is likely of nociceptive origin where altered posture due to enlargement of the uterus and decreased stability of lumbar and pelvic ligaments due to hormonal changes have been proposed as probable causes. The exact etiology of the pain is, however, still unknown (5). Low-back and pelvic pain increases during pregnancy (2), during the day and by daily activities as well. Furthermore, pregnant women experiencing low-back pain have reported a reduction in their health-related quality of life (3).

The efficacy of acupuncture and other nonpharmacological interventions on back and pelvic pain in pregnant women is reviewed in few reports (6,7), concluding that both acupuncture and physical therapy might reduce the pain and that the efficacy needs to be confirmed.

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The aim of this prospective randomized study was to evaluate the effects on both group and individual levels of two alternative modes of acupuncture stimulation (superficial and deep) on perceived pelvic pain in late pregnancy, and also by taking daily activities and emotional reactions into account.

Materials and methods

Pregnant women with low-back pain and/or pelvic pain attending two different maternity health care departments were invited to participate in this study, which was approved by the ethics committee of the Uppsala University, Dnr 99269.

Women who met the inclusion criteria (Table I) gave their informed consent and were randomized to one of two alternative modes of acupuncture stimulation, superficial or deep (8–10). Sealed envelopes with labels for determination of treatment were used in randomization provided by a statistician not involved in the study. The women were physically examined with tests that were chosen for sensitivity in provoking pelvic structures (4) in order to distinguish pelvic pain from low-back pain. For ethical and practical reasons an additional control group with no treatment was not included.

Outcome assessments

Prior to treatment, for five consecutive days at home, the women were asked to rate their pain intensity at rest and during three daily activities (turning from one side to another in bed, rising from sitting to standing, walking) three times a day: in the morning (8 a.m.), in the middle of the day (2 p.m.), and in the evening (8 p.m.). The same rating procedure was performed five days after the end of treatment. The pain ratings were made on separate report sheets on horizontal visual analog scales (VAS, 0–100) with the anchors "no pain" and "worst imaginable pain".

The pain assessments on the 5th day prior to treatments and the 5th day after treatments were used as the pre- and post-treatment values, respectively. The morning and evening assessments were used for evaluation of the change in pain intensity during the day.

Furthermore, the variables pain, emotional reactions, and loss of energy according to the Swedish version of the Nottingham Health Profile (NHP) questionnaire for health-related quality of life (11) were assessed once pre- and once post-treatment. The variables are measured by agreement (yes, no) to statements concerning complaints. Pain was measured by eight statements, which means eight possible indicators of pain, and furthermore means that the level of pain ranges from 0 (no indications of pain) to 8 (all indicators of pain). Correspondingly, emotional reaction and loss of energy were assessed by 10 (0–9) and 4 (0–3) statements, respectively.

Table I. Inclusion and exclusion criteria for participation in the study

Inclusion criteria
Gestational age: 22–36 weeks
Duration of pain: ≥2 weeks
Pain intensity last week, rated on VAS, 0–100: ≥60
Increased pelvic pain by walking, turning from one side to the other in bed, or rising from sitting to standing
Physical examination confirming provoked pelvic pain:
1) in one of three tests – posterior pelvic pain provoking test (4P test), standing on one leg, Patrick's Fabere test
2) in palpating tissue over – the sacroiliac joints, the symphysis pubis, or mm. gluteus maximus/medius
Exclusion criteria
Earlier experience of acupuncture treatment
Fear of needles
Urogenital infections
Symptoms of lingering pelvic pain due to earlier pregnancy

Acupuncture stimulation

Ten acupuncture treatments each of 30 min were given twice weekly over five weeks by a registered physiotherapist, well experienced in acupuncture, with a regular clinical practice.

For each treatment session, 10 classical acupuncture points were selected for stimulation and chosen depending on the site of pain (BL 27, 28, 29, 31, 32, 54, KI 11, CV 3) in combination with more peripheral points (SP 6, LR 2, LI 4), intra- or extrasegmental related to the neurological innervations of the painful area (Table II). Usually three to four of the BL points were used and applied bilaterally.

Two types of sterilized steel acupuncture needles were used for acupuncture stimulation: 15 mm length/0.20 mm diameter (Seirin) and 30 mm length/0.30 mm diameter (Marco Polo, Schwa Medico).

During the superficial stimulation the shorter/thinner needles were inserted subcutaneously over the acupuncture points and left in place until the end of the treatment. To mimic the procedure of deep stimulation, the therapist sat down by the patient

Table II. Acupuncture points used for treatment of pelvic pain. The neurological innervation of the points is given separated to skin (S) and muscular (M) segmental innervation, except for the points KI11, CV3, and LR2 where they coincide

Points	Localization	Segmental innervation (skin, S; muscular, M)	Penetrated tissue in the deep stimulation modality
BL 27	The level of 1st sacral foramina, 1.5 cun lateral to the dorsal body midline	S: N. lumbalis (L3); M: Nn. thoracodorsalis, thoracicus, lumbalis (C6–8, Th9–12, L1–3)	Fascia thoracolumbalis, m. erector spine
BL 28	The level of 2nd sacral foramina, 1.5 cun lateral to the dorsal body midline	"	"
BL 29	The level of 3rd sacral foramina, 1.5 cun lateral to the dorsal body midline	"	"
BL 31	The level of 1st sacral foramina, between BL 27 and the dorsal body midline	"	"
BL 32	The level of 2nd sacral foramina, between BL 28 and the dorsal body midline	"	"
BL 54	The level of hiatus sacralis, 3 cun lateral to the dorsal body midline	S: N. sacralis (S1–3); M: N. gluteus inferior (L5–S2)	M. gluteus maximus
KI 11	2 cun caudal to the umbilicus, 0.5 cun lateral to the ventral body midline	Nn. thoracicus, subcostalis (Th6–12)	Vagina m. recti abdominalis, m. rectus abdominis
CV 3	In the ventral body midline, 4 cun caudal to the umbilicus	N. iliohypogastricus (L1)	Connective tissue
SP 6	3 cun proximal to the most prominent point of the medial malleolus	S: N. saphenus (L3–4); M: N. tibialis (L4–S2)	Mm. flexor digitorum longus, tibialis posterior
LR 2	Between the 1st and the 2nd metatarsal bone	N. peroneus profundus (L4–5, S1–2)	Connective tissue
LI 4	At the middle, radial side of the 2nd metacarpal bone in the highest point of m. interosseus dorsalis with the thumb adducted	S: N. radialis (C6–8); M: Nn. medianus, ulnaris (C8, Th1)	Mm. interosseus dorsalis I, lumbricalis II, adductor pollicis

BL, bladder; KI, kidney; CV, conception vessel; SP, spleen, LR, liver; LI, large intestine. 1 Cun, the Chinese body inch equaling the breadth of the distal phalanx of the thumb at its widest point

four additional times during the treatment without manipulating the needles.

For the deep stimulation, the longer/thicker needles were used and inserted intramuscularly into the depth according to the acupuncture manual (12). The needles were stimulated five times during the treatment sessions by manually twirling the needles 180° back and forth until the patients reported sensations of numbness, heaviness, and warmth, described as *de qi* in Chinese traditional medicine. During the treatment the patients lay on their sides and for optimal comfort were supplied with pillows.

Statistical methods

The mean value and standard deviation (SD) were calculated for age; the median and range was used to describe the other variables. The pattern of change in VAS was described by a scatter plot and the pattern of change in the discrete ordered levels of the NHP variables was described by square contingency tables. The proportions of women that rated a lower level, the same level, and a higher level in the variables after treatment were calculated. The hypothesis of no change in the paired assessments was analyzed by the Sign test with correction for continuity. A nonparametric rank-based method (13,14) was used to further evaluate possible treatment effects on group and on individual levels as well. The size of a treatment effect, change, attributed to the group is expressed by the measure of systematic change in position, RP, ranging from -1 to 1 and visualized by a relative operating characteristic (ROC) curve. A systematic change towards lower pain levels after treatment results in a negative RP value and a ROC curve deviating above the main diagonal.

Additional individual variations in change, unexplained by the systematic change, are expressed by the RV (relative rank variance), ranging from 0 to 1 (no additional individual changes to total additional individual changes) (14).

In order to obtain an overall p-value less than 5% the individual p-values were adjusted for multiple tests according to Holm (15).

The software package SYSRAN 1.0 for Matlab 6 was used to calculate the measures of RP and RV,

and corresponding 95% confidence intervals (CI). STATISTICA 6.0 was used otherwise.

Results

In total, 106 women were examined, but 36 were excluded according to the criteria for exclusion: fear of needles, spontaneous recovery, and earlier experiences of acupuncture treatment. The remaining eligible (70) women were randomized to one of the two acupuncture stimulation treatment modes, superficial or deep. Forty-seven women were included in the study as the dropout rate was 23 (Table III).

Change in pain intensity at rest

In the superficial stimulation group, the morning pain intensity was rated lower by 16 (73%) and higher by six (27%) women after treatment, RP −0.25 (95% CI, −0.54 to 0.03). In the deep stimulation group the morning pain was rated lower in 18 (72%), unchanged in two (8%), and higher in five (20%) women, RP −0.27 (95% CI, −0.49 to −0.05). The additional individual changes were high in both groups, but with very wide confidence intervals: RV 0.65 (95% CI, 0.10 to 1.00) and RV 0.40 (95% CI, 0.08 to 0.73) (Figure 1a,c,).

The patterns of change in evening pain intensity were similar. In the superficial stimulation group pain was rated lower by 15 (68%), unchanged by one, and higher by six (27%) women, RP −0.28 (95% CI, −0.49 to −0.07). In the deep stimulation mode, 18 (72%) rated lower and seven (18%) women rated higher pain levels, RP −0.31 (95% CI, −0.48 to −0.14). Individual variations were evident for both groups: RV 0.22 (95% CI, 0.00 to 0.44) and RV 0.28 (95% CI, 0.07 to 0.49), respectively (Figure 1b,d).

The overlapping confidence intervals of the measures of change in pain levels and the similar proportions of women who decreased their pain intensity after treatment in the two treatment groups (range 68–72%) indicate that, according to our study, there is not enough evidence of different treatment effects between the two stimulation modes of acupuncture. Therefore, the evaluations of change in the variables were performed for all women together ($n=47$).

The rated *morning pain levels* changed significantly after treatment towards lower pain levels, as a majority (34) of the 47 women (72%) rated lower, two (4%) unchanged, and 11 (23%) higher pain levels ($p=0.003$); the systematic change for the group was negative: RP −0.26 (95% CI, −0.43 to −0.10). Additional individual variations in VAS pain were evident: RV 0.46 (95% CI, 0.21 to 0.70).

The changes in *evening pain levels* showed a similar pattern, as 33 (70%) had lower, one unchanged, and 13 (28%) women higher pain levels after treatment ($p=0.01$): RP −0.29 (95% CI, −0.42 to −0.16). The additional individual variation was RV 0.25 (95% CI, 0.11 to 0.39).

Change in pain intensity during daily activities

Table IV shows that a majority of women rated lower pain levels after treatment when "turning from one side to the other in bed" and "walking", while the opposite holds for "rising from sitting to standing". The RP values show that the change in pain levels was the same for the whole group, as

Table III. Demographic data of patients on entry to the study, dropout rate, with reasons for dropout and data of patients included in the analysis

	Mode of acupuncture	
	Superficial, *n*	Deep, *n*
Randomized to the study	35	35
Dropout	13	10
Reasons for dropout		
Noncompliant in submitting pain diaries	9	4
Spontaneously recovered, fear of needles		1
Ameliorated	1	
Increased pain		1
Fainting during treatment		1
Allergic reaction to nickel	1	
Failed to travel to the clinic		1
Psychological insufficient	1	
Delivery during the study	1	
Hospital care due to unstable blood glucose		1
Hospital care due to gastric ulcer and biliary colic		1
Included in the study and analysis	$n=22$	$n=25$
Maternal age (years), mean (SD)	29.9 (3.0)	29.0 (5.5)
Gestational age (week), median (range)	26 (18–34)	26 (19–35)
Number of pregnancies, median (range)	2 (1–4)	2 (1–4)
Debut of pain (gestational week), median (range)	19 (3–28)	20 (4–26)
Pain intensity latest week (VAS), median (range)	77 (62–98)	74 (60–90)

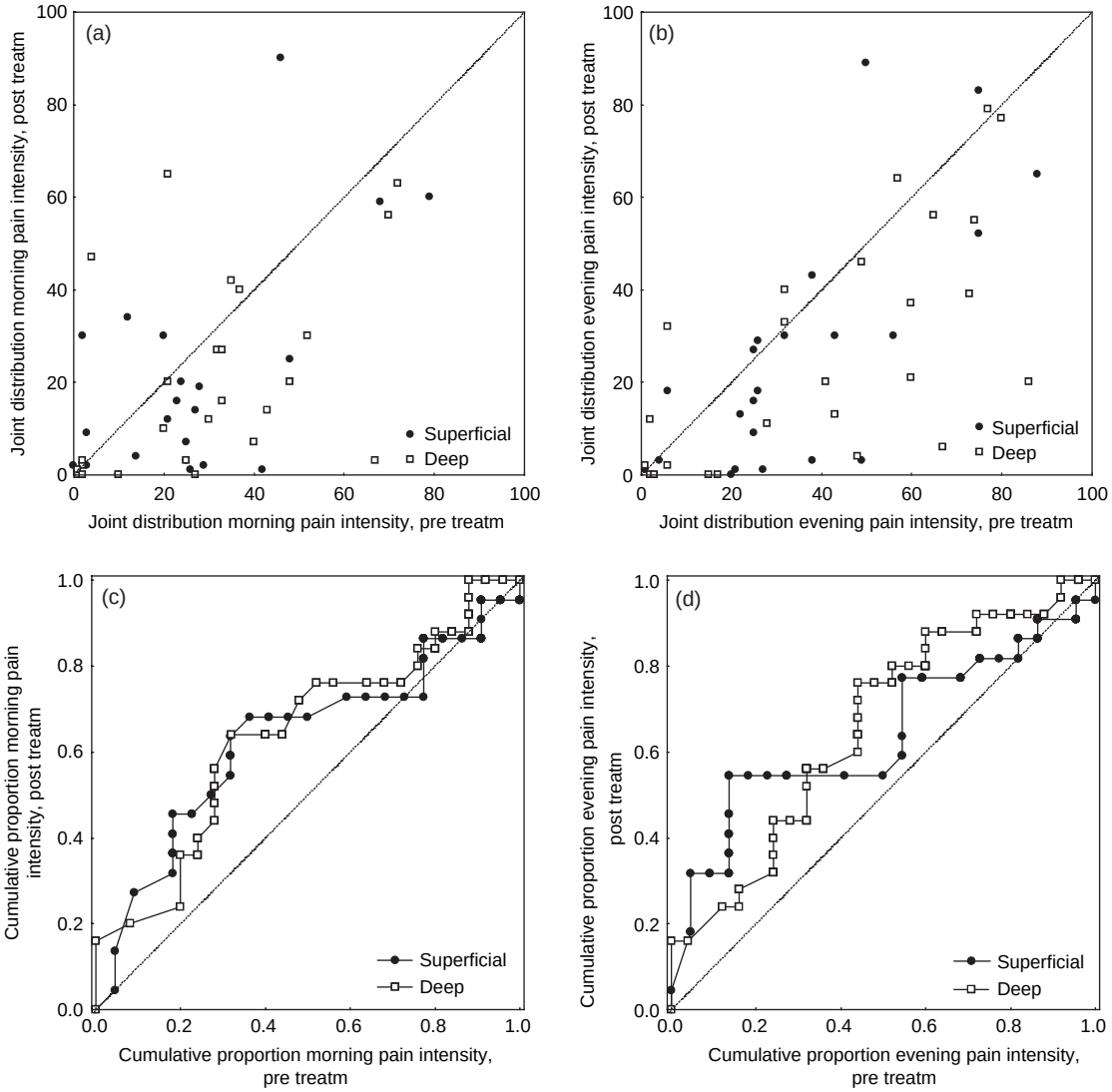

Figure 1. Changes of rated pain intensity at rest after superficial and deep acupuncture stimulation. Scatter-plots show individual variations in the morning (a) and in the evening (c). The corresponding systematic changes for the group based on cumulative proportions are shown in the ROC-curves (c, d). Acupuncture stimulation; superficial, $n=22$, and deep, $n=25$.

the 95% CI for the RP did not cover RP = 0. The individual variations in changes in pain were large according to the RV values, ranging from 0.32 to 0.55) (Table IV).

Change in variables according to the NHP

In the NHP assessments, 26 of the 47 women (55%) rated lower, eight (17%) unchanged, and 12 (26%) higher pain levels ($p=0.03$) after treatment (Figure 2a). An improvement in emotional reactions was seen in 30 women (64%), nine were unchanged (19%), and eight (17%) rated higher levels ($p=0.0007$) (Figure 2b). Regarding loss of energy, 18 women (38%) reported lower, 22 (47%) unchanged, and seven (15%) higher levels (Figure 2c). The corresponding measure of systematic changes were pain RP −0.37 (95% CI, −0.57 to −0.18), emotional reactions RP −0.38 (95% CI, −0.56 to −0.21), and loss of energy RP −0.25 (95% CI, −0.42 to −0.08) (Figure 2d). The additional individual variations were RV 0.60 (95% CI, 0.33 to 0.87), 0.28 (95% CI, 0.08 to 0.45), and 0.18 (95% CI, 0.04 to 0.33) respectively.

Discussion

In this prospective, randomized, controlled, single-blind study, the women reported significant changes in pain intensity, as well as in rated

Table IV. Change of rated pain intensity in response to acupuncture in daily activities, within the day

	Morning						Evening					
Daily activity	− (%)	~ (%)	+ (%)	*n*	*p*	RP (95%CI)	RV (95%CI)	− (%)	~ (%)	+ (%)	*n*	*p*	RP (95%CI)	RV (95%CI)
Turning to the other side in bed	31 (66)	3 (6)	13 (28)	47	0.03	−0.23 (−0.37 to −0.08)	0.32 (0.15 to 0.59)	30 (64)	2 (4)	15 (32)	47	0.04	−0.17 (−0.35 to 0.01)	0.49 (0.21 to 0.77)
Walking	36 (77)		11 (23)	47	0.004	−0.38 (−0.56 to −0.20)	0.55 (0.27 to 0.83)	33 (79)		9 (21)	42	<0.001	−0.34 (−0.51 to −0.18)	0.46 (0.21 to 0.70)
Rising from sitting to standing	9 (20)	1 (2)	35 (78)	45	<0.001	0.26 (0.14 to 0.39)	0.21 (0.06 to 0.36)	9 (22)	6 (14)	27 (64)	42	0.03	0.12 (0.05 to 0.20)	0.06 (0.01 to 0.10)

Data are shown as number (%) of pregnant women reporting decreased (−), unchanged (~), and (+) increased pain intensity levels. Evaluated treatment effects are given as the measure of systematic change (RP) and individual variation (RV). *n*, number; CI, confidence interval; adjusted *p*-value refers to analysis with Sign test.

emotional reactions and loss of energy after treatment. The observed decrease of pregnant women's pelvic pain intensity in response to acupuncture confirms results of other studies (16–19). However, the small groups in this study did not provide enough evidence to conclude any difference in effect between the two modes of acupuncture stimulations.

The non-zero RV values demonstrated individual variations in the changes of pain and the emotional variables. This indicates that individually tailored interventions with acupuncture in the treatment of pregnant women's pelvic pain are recommended and further studies could be performed with the use of a naturalistic protocol. Such a naturalistic protocol has been advocated when carrying out any acupuncture studies (9).

In this study no difference in effects between the superficial and deep acupuncture stimulations was found between the two groups of previously acupuncture-inexperienced women. However this does not mean that the physiological effects must be the same. It has been claimed that the responses are unspecific. On the other hand, the responses to superficial needling could be seen as specific for the treatment itself and not as inert placebo interventions. The observed decreased pain intensity, emotional reactions, and loss of energy may reflect an interaction between the perceived pain intensity and the emotional state. Also the interaction between the patient and therapist could certainly account for part of the present results. The present findings showing that even superficial stimulation may exert inhibitory effects on pain are supported by previous studies (20,21).

Limitations of the study

The limited number of subjects in this study, and the possibility that some of the women would have obtained greater relief by an increased number of treatments, calls for precautions in generalization of the present results. We did not include an untreated control group because of the risk of interaction bias and the lack of blindness.

Conclusion

Acupuncture relieves pregnant women's pelvic pain intensity and emotional variables and could be regarded as a clinically relevant treatment strategy. The individual variations call for individually based interventions for optimal results.

(a)

Nr of indicators of pain variables, post treatment	Nr of indicators of pain variables, pre treatment: 0	1	2	3	4	5	6	7	8	Tot	CP
8								1	1	2	1.00
7				1		1	3	2		7	0.96
6				1		1	2	3		7	0.81
5			1		1	3		3	1	9	0.66
4							1		1	2	0.47
3		1	1			3	5		1	11	0.43
2							1	1	2	4	0.19
1		1				2				3	0.11
0							1	1		2	0.04
Tot	0	2	2	2	1	10	13	11	6	47	
CP	0	0.04	0.09	0.13	0.15	0.38	0.64	0.87	1.00		

(b)

Nr of indicators of emotional reaction variables, post treatment	Nr of indicators of emotional reaction variables, pre treatment: 0	1	2	3	4	5	6	7	8	9	Tot	CP
9											0	1.00
8											0	1.00
7											0	1.00
6											0	1.00
5	1					1	1	1			4	1.00
4			1	2	1	1		1			6	0.91
3			2	1	1			1			5	0.79
2				1	1	2	1				5	0.68
1	2	2	4		2	4	1				15	0.57
0	4		5	1	2						12	0.26
Tot	7	2	12	5	7	8	3	3	0	0	47	
CP	0.15	0.19	0.45	0.55	0.70	0.87	0.94	1.00	1.00	1.00		

(c)

Nr of indicators of loss of energy variables, post treatment	Nr of indicators of loss of energy variables, pre treatment: 0	1	2	3	Tot	CP
3			4	12	16	1.00
2	1	2	5	5	13	0.66
1		2	2	5	9	0.38
0	3	1	2	3	9	0.19
TP	4	5	13	25	47	
CP	0.09	0.19	0.47	1.00		

(d)

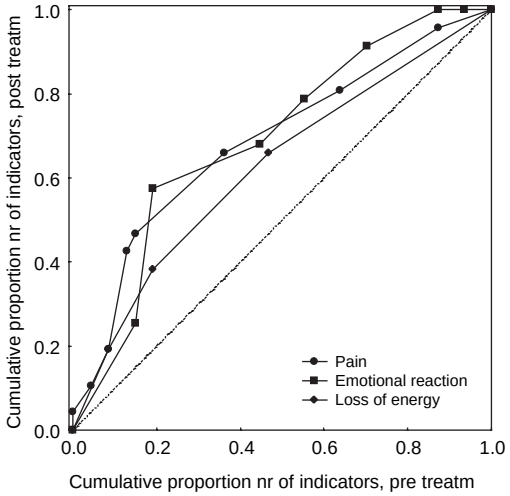

Figure 2. Responses in the NHP variables pain, emotional reaction and loss of energy after acupuncture. Contingency tables show the individual variation in number of indicators in rated pain (a), emotional reaction (b) and loss of energy (c). Tot = total frequency. CP = cumulative proportion. The corresponding systematic changes for the three variables based on cumulative proportions are shown in the ROC curve (d), $n = 47$.

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