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Improvement of urge- and mixed-type incontinence after acupuncture treatment among elderly women — a pilot study

Kristina Bergström[a], Christer P.O. Carlsson[b,*], Christina Lindholm[c], Riitta Widengren[a]

[a]*Department of Geriatrics, Rosenlund Hospital, Stockholm, Sweden*
[b]*Physical Medicine Unit, Department of Rehabilitation, Lund University Hospital, Lund, Sweden*
[c]*Department of Nursing Research, Uppsala University Hospital, Uppsala, Sweden*

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Abstract

The aim of this study was to investigate if sensory stimulation in the form of manual acupuncture could influence urge- or mixed-type incontinence among elderly women who were not satisfactorily relieved by standard pharmacological and non-pharmacological treatments given at a specialised incontinence unit. The study is an open clinical follow-up study. The study included 15 elderly women who were treated with manual acupuncture 12 times. Both subjective scorings and objective measurements in the form of leakage in grams (48 h Inco-test) were used. Evaluations were performed at discharge and 1 and 3 months thereafter. Almost all outcome measurements were significantly improved even at follow-up 3 months after the last treatment. Global scorings showed that 12 of the 15 women considered themselves improved even at the follow-up 3 month after treatments were completed. The possible mechanisms of action are discussed, as is the way to perform more studies in this field.

Keywords: Acupuncture; Incontinence; Urge incontinence; Inco-test

1. Introduction

Urinary incontinence, as defined by the International Continence Society (ICS), is a condition where involuntary loss of urine is objectively demonstrable and is a social or hygienical problem (Abrams et al., 1988). Incontinence is most common among women and the prevalence increases with ageing. A compilation of different Scandinavian studies of urinary incontinence among women over 65 years of age shows prevalence to vary between 14% and 43% (Milsom et al., 1992). The kind of incontinence most pronounced determines what treatments are tried. Existing pharmacological therapy (mainly oestrogens, anticholinergics or tricyclic antidepressants) and non-pharmacological treatments (mainly pelvic floor training, bladder training, biofeedback and electrical stimulation) often fail or give rise to too many side effects (Cardozo and Kelleher, 1995; Appell, 1998; Gorton and Stanton, 1998; Nasr and Ouslander, 1998). Furthermore, it seems that it is more difficult to treat elderly women as increasing age adversely affects the outcome after conservative treatment (Susset et al., 1995).

A few studies, both controlled and non-controlled, have been published in the West concerning the ancient Chinese method of acupuncture, as a treatment of bladder dysfunction (Philip et al., 1988; Ellis et al., 1990; Kelleher et al., 1994).

The incontinence team at the Department of Gerontology at Rosenlunds Hospital in Stockholm is a specialised unit treating women over 65 years of age with urinary incontinence, mostly of urge or mixed type. As standard treatments often do not produce satisfactory subjective symptom relief for this group of patients we decided to investigate if acupuncture could be a suitable adjuvant therapy.

The aim of the present study was to investigate if acupuncture could: (a) reduce the subjective inconvenience of urgency; reduce leakage frequency; reduce voiding at nights; (b) increase the self-perceived quality of life; (c) reduce the objective leakage of urine; (d) maintain the effects long-term (3 months) after treatment is finished.

*Corresponding author. Tel.: +46-46-157-512; fax: +46-46-157-512.
E-mail address: akusyd@swipnet.se (C.P.O. Carlsson)

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2. Patients and methods

All patients who were treated by the incontinence team during the period November 1992–September 1995 and who regarded their symptoms as not satisfactorily relieved by standard treatment (bladder and pelvic-floor muscle training and drug therapy) for at least 2 months were invited to participate in the study. The physician examined all patients and decided if further investigations had to be performed before the diagnosis was confirmed. Inclusion criteria were: urge or mixed incontinence, age under 85 years, physically and mentally able to complete an Inco-test (see below). Exclusion criteria were: wheelchair-ridden patients, patients on short-term active diuretic treatment, patients with diseases which could possibly influence the urge to void frequency, e.g., urinary tract infection, urogenital tumours, cerebrovascular lesions, dementia, diabetes or Parkinson's disease. The study design is described in a flow chart (see Fig. 1). Patients were informed individually about the study both orally and with a written document. Informed consent was obtained orally. The study was performed in 1995–1997.

2.1. Measurement methods

2.1.1. Scoring inconvenience of urgency, leakage frequency and voiding during nights

At the outset of the study, all patients estimated subjectively different aspects of urgency, leakage and frequency of voiding using a structured questionnaire. After the final acupuncture treatment and at follow-up after 1 and 3 months, the patients again subjectively estimated these different aspects of inconvenience by means of a similar questionnaire. The different aspects were as follows: (A) urge to void, type: None; light; moderate; intensive; (B) urge to void, intensity: reach toilet in time; usually reach toilet in time; seldom/never reach toilet in time; (C) leakage frequency: once a month or less; once weekly — several times every month; once daily — several times each week; several times/day; (D) number of voiding during nights and during daytime.

In the same questionnaire estimation of daily fluid intake was checked, as was the use of medication which could possibly have influenced the urge to void and leakage frequency. The patients also noted if they were constipated, had diarrhoea or had normal stools.

2.1.2. Quality of life assessment (iQoLI)

Self-perception of the quality of life was assessed with the help of a structured interview form developed by Pharmacia/UpJohn, Uppsala, Sweden. The form has been tested for validity and reliability (McKenna et al., 1997; Renck-Hooper et al., 1997). This assessment has been developed for women suffering from urge incontinence and contains questions concerning the influence of urinary incontinence on daily life. The questionnaire consists of 25 questions and the scoring can range from 0 to 75 points, where 0 is the worst possible condition and 75 means that there is no influence on daily living of the symptoms. Assessment was made at the time of the patients' first interview and again at follow-up 3 months post-treatment.

2.1.3. Overall global outcome

After the last treatment and at follow-up 1 and 3 months thereafter, the patients gave a global scoring of their overall situation with respect to incontinence, related to their condition before start of the acupuncture treatments. Using a structured questionnaire, they scored their condition as one of the following: symptom-free; much improved; slightly better; unchanged; worse.

2.1.4. Leakage in grams, Inco-test

The patients recorded their urinary habits with the help of an Inco-test (Siltberg et al., 1997). This test was performed over 48 h and consisted of measurement of the amount of leakage by weighing incontinence pads as well as recording the amount of urine passed and frequency in voiding. The baseline Inco-test was performed 1 week before the acupuncture treatments started. Before this test ''training-test'' done 1 week earlier to make the patients acquainted to the measurement methods. The Inco-test was performed in the same manner the week after completion of the acupuncture treatments and at the 1 and 3 months follow-up. The patients were requested not to alter their normal way of living during the Inco-test days.

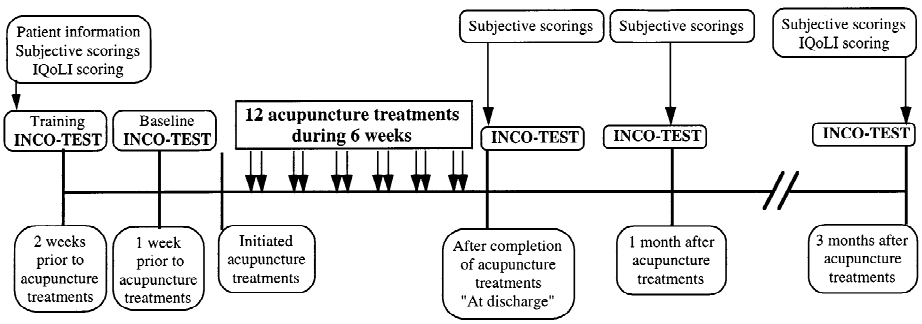

Fig. 1. Flow chart over the study design.

2.2. Acupuncture treatment

Acupuncture treatments were performed twice weekly. The first three patients were treated with acupuncture eight times; the remainders were treated 12 times. Disposable needles were used. Patients lay prone on a treatment couch or sat on a comfortable massage chair. During the first treatment, only four needles were inserted. The number of needles was gradually increased to 14. Needles were inserted, bilaterally, in the following acupuncture points: three sacral and one lumbar (between L2 and L3) paravertebrally, two in the lower legs and one near the elbow. These points are named, according to WHO proposal (World Health Organisation, 1991): BL31, BL32, BL33, BL23, SP6, KI3 and LI11. As to why these points were selected, see Section 4. The needles were stimulated (rotated, drawn slightly up and down) until the patient experienced the de-qi feeling, i.e., a characteristic feeling of numbness, soreness or slight pain that spreads around a correctly located acupuncture needle. The needles remained in place for 25 min and were stimulated twice during each treatment to regain the de-qi feeling. The physiotherapists who performed the treatments had been trained in acupuncture more than 2 years before this study was undertaken. After this, they had been performing about 10 acupuncture treatments every week for different kinds of pain problems. Before this study was started, they also underwent special training (two different courses) in the use of acupuncture against incontinence.

2.3. Statistical method and ethical aspects

All the data from the study were saved in an SPSS database and the statistical analyses were performed from the SPSS 8.0 (for Windows 95) software. The non-parametric test Wilcoxon signed ranks test was used for comparison of results from 1 week prior to acupuncture with those obtained at discharge, and at follow-up 1 and 3 months after the last treatment.

For comparisons between responders and non-responders concerning age, duration of incontinence and some scorings Student's *t*-test was used to see if there seemed to be any major differences between these subgroups.

The Local Ethical Committee, Huddinge Hospital in Sweden, approved the study.

3. Results

Twenty-five patients were asked to participate in the study and 15 patients agreed and 10 declined. Their reasons were as follows: knee surgery ($n=1$), move to another part of the country ($n=1$), infirmity/other disease ($n=5$), long stay abroad ($n=1$), preferred other treatment ($n=1$), refused due to negative experience of acupuncture ($n=1$). Four patients were diagnosed as having urge incontinence and the remainder as having mixed incontinence. The average age in the group was 76.4 years (66–82 years). The average duration of incontinence was 3.7 years (1–11 years).

All women had performed pelvic floor training (2–104 months, median 10 months). Thirteen of the 15 women had performed bladder training (2–24 months, median 10 months). Twelve of the patients were taking oestrogen and four anticolinergics against their incontinence. No change of this medication occurred in any patient during the whole study period, including the three months of follow-up. All the 15 women completed the whole study including the follow-up at 3 months after treatments. In the database there were four missing values for the leakage in grams (Inco-test). One patient's baseline value was missing. For this patient we used the value from the ''training-test'' as her baseline value. The other three missing values were on three different occasions of follow-up for three different patients.

3.1. Measurement methods

3.1.1. Scoring inconvenience of urgency, leakage and frequency of voiding

There were significant improvements in both the urge to void, ''type'' and ''intensity'' at discharge and the two follow-ups. Before treatments none of the patients reached the toilet in time. This number had increased to six at discharge and at 1 month follow-up. At 3 months follow-up, four reached the toilet in time. There were also significant improvements in the leakage frequency from baseline to discharge and both follow-ups (see Fig. 2), as well as from discharge to the follow-up after 1 month. At 3 months follow-up, there was a tendency for the improvement to decline, but this was not significant. Before start of treatment, six patients had either diarrhoea or were obstipated. This number was reduced to two patients directly at the last treatment and one patient after 1 month; these

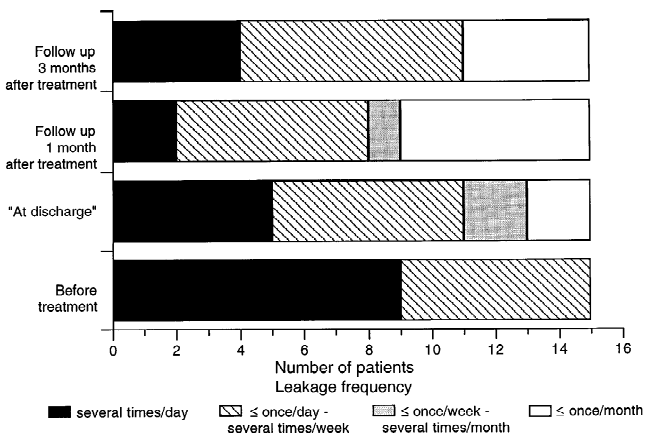

Fig. 2. Number of patients with different scorings of leakage frequency before treatment and at follow-up times indicated in the figure.

Table 1
The *p*-values for the differences on the variables from baseline scorings to ''discharge'' and follow-ups after 1 month and after 3 months. Wilcoxon signed ranks test

Variable	'At Discharge'	After 1 month	After 3 months
Urge, type	0.008	0.003	0.009
Urge, intensity	0.020	0.011	0.034
Leakage	0.040	0.006	0.027
Diarrhea/obstipation	0.046	0.025	0.180

changes are also significant. In Table 1, all the exact *p*-values for the above changes are given. The mean frequency of voiding at nights was significantly reduced at discharge and at the follow-ups including the one after 3 months (from 1.57 to 0.97, $p=0.004$–0.009). The mean frequency of voiding at daytime did not show any significant changes. The mean daily fluid intake did not change significantly during the whole study time.

3.1.2. Quality of life assessment

Self-estimated quality of life (IQoLI) improved significantly from baseline to 3 months after the treatment series. The median increased from 41 to 55, $p=0.001$.

3.1.3. Overall global outcome

The results of the subjective scorings of global outcome are summarised in Fig. 3. Eight of the 15 women (53%) subjectively scored as ''much improved'' at follow-up after 3 months.

3.1.4. Leakage in grams, Inco-test

The reduction of leakage was found to be significant from baseline to the follow-ups after 1 and 3 months. See Fig. 4 and Table 2 where the results are summarised.

3.2. Responders–non-responders

We compared the group of patients scoring themselves as ''symptom free'' or ''much improved'' (responders, $n=7$) with the group scoring as ''unchanged'' or ''worse'' (non-responders, $n=5$) one month after the treatments to see if there was any major differences between them.

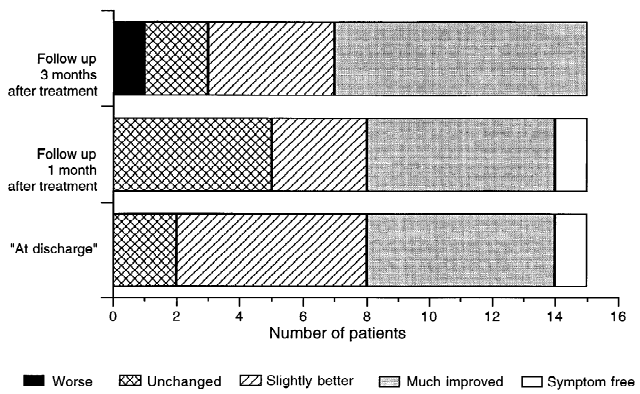

Fig. 3. Number of patients with different scorings of overall global outcome at follow-up times indicated in the figure.

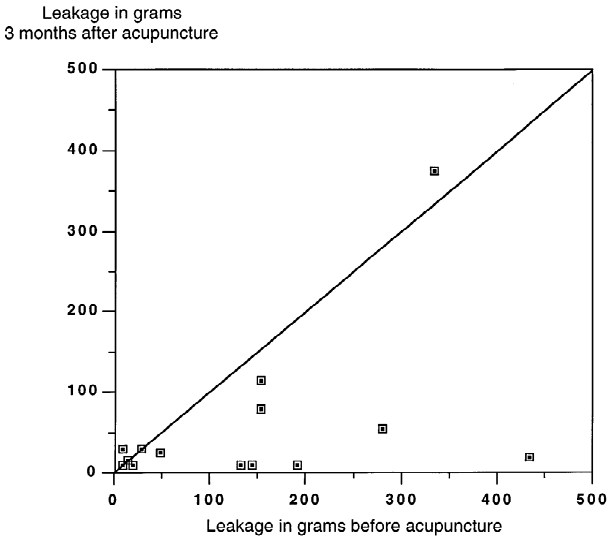

Fig. 4. 48-h Inco-tests. Leakage in grams in the individual patients. The *x*-axis gives the baseline values and on the *y*-axis the leakage at the 3 months follow-up are indicated. This means that all patients ''under the line'' are those who reduce their leakage ($n=14$ as there was one missing value for one patient).

No connection could be identified between the results of acupuncture treatment and age, duration of incontinence, number of voiding at nights, initial scoring of quality of life test, number of months with training or amount of leakage at baseline (Student's *t*-test).

3.3. Adverse effects of acupuncture

No side effects or complications of the acupuncture treatments were reported or observed.

4. Discussion

In this study we have documented significant improvements for older women with urge- or mixed-type urine incontinence after a series of manual acupuncture treatments and at follow-up 1 and 3 months thereafter. The improvements were registered in almost all our outcome measurements. Of course, as this was a non-controlled study, there are possibilities of placebo effects and of spontaneous variation in symptoms that can influence our results. Our study group was a group of very old women (average age 76.4 years) with symptoms for a considerable time (average duration of incontinence was 3.7 years). All of them had tried the other treatments given at this specialised unit (training and pharmacological treatments) without getting sufficiently improved. Acupuncture is a form of somatic sensory stimulation. Other forms of stimulation techniques, invasive procedures such as intravesical or nerve root stimulation as well as transcutaneous

Table 2
Objective leakage according to 48 h Inco-test in gram (median, mean, range) at different times indicated in the table. *p*-values according to Wilcoxon signed ranks test

Inco-test (leakage)	Baseline value	''At discharge''	1 month follow-up	3 months follow-up
Median (g)	123	11	5.0	12.5
Mean (g)	121	69	33	46
Range (g)	0–425	0–445	0–175	0–365
p-values for differences from baseline		0.153	0.028	0.018

electrical nerve stimulation (TENS), have already been tried against a variety of voiding disorders (Appell, 1998; Hasan and Neal, 1998). TENS applied over the suprapubic area, over the sacral dermatomes or over quadriceps and hamstring muscles has shown some positive effects (Nakamura et al., 1986; Fall and Lindström, 1994). The success rate for different kinds of electrical stimulation (''neuromodulation'') against urinary incontinence varies from 45% to 91%. All studies seem to agree that about 1/3 of all patients will get good long-term results and a review reports that 20% of the patients became dry and 37% were significantly improved (Appell, 1998). In our study 8/15 patients (53%) scored as ''much improved'' even 3 months after the treatment series. In different placebo-controlled studies, the effect of placebo (percentage of patients describing themselves as ''good'' or ''very good'' after treatments) is between 8% and 27% (Yamanishi et al., 1997; Burgio et al., 1998; Hasan and Neal, 1998). The increase in IQoLI in this study was (in mean values) from 39.4 at baseline to 50.8, 3 months after the treatments. In the study, when examining the psychometric properties of IQoLI, a placebo-controlled study with anticholinergics was performed. In that study IQoLI improved from 53.6 to 59.4 after 3 months with the drug (Renck-Hooper et al., 1997). That improvement was considered highly significant ($p<0.0001$), while the placebo group only improved from 57.9 to 59.0 (n.s). The improvements, in our study, seemed to be best 1 month after completion of the treatments and many positive effects remained even after 3 months. All the different circumstances ahead make us believe that it is unlikely that spontaneous remissions and placebo effects are the main reasons for our results. We even mean that when such a group of patients as the one in this study has the positive results seen here, then the treatment is clinically useful whether or not some of the effects later can be shown to have a placebo origin (Götzsche, 1994).

This study confirms the results of other studies in the field (Philip et al., 1988; Ellis et al., 1990; Kelleher et al., 1994) even if those studies did not have this rather homogenous study group (both diagnostically and by age). Kelleher et al. (1994) demonstrated in a randomised, controlled study that superficial acupuncture was as effective as anticholinergic therapy in the management of irritative bladder symptom. However, the frequency of side effects was much higher in the group treated with anticholinergics. The 39 patients in the study had not tried any other treatment before participation in the study. There was a very wide spreading of age (18–75 years) and there were no clear diagnoses indicated.

Ellis et al. (1990) showed, in a randomised placebo-controlled single-blind study, that the frequency of voiding at night was reduced after acupuncture among elderly in two geriatric hospitals. Twenty patients, three males and 17 females, were included in the study. Their ages varied from 65 to 96 years. Mock TENS (TENS apparatus with no electrical output) was used as a placebo control (Lewith and Vincent, 1995). The study period was 2 weeks and during that period the patients received 10 treatments. There was no follow-up at all.

Philip et al. (1988), successfully used acupuncture to treat patients with idiopathic bladder instability. In their open non-controlled study, they claimed significant symptomatic improvement of 10 out of 13 patients (77%) in the subgroup with diurnal symptoms.

The choice of acupuncture points in this study was in accordance with the earlier-performed studies in this area (above) and some were selected according to usual textbooks in the field (e.g., Stux and Pomeranz, 1988). The acupuncture points BL31, BL32 and BL33 are located just above the sacral foramina 1, 2 and 3, and thus over the nerve roots S1, S2 and S3. The acupuncture points on the legs, KI3 and SP6, have innervation from L5–S2. The point BL23 is situated in the lumbar area, and the deep innervation there is from the primary dorsal ramus from Th11. The efferent, as well as the afferent innervation of the bladder, is Th11–L2 (sympathetic) and S2–4 (parasympathetic). The innervations of the muscles in the area (e.g., the sphincters) are also coming from S2–4 (Chai and Steers, 1997). Many of the points were thus chosen because we wanted the segmental innervation of the bladder and the acupuncture points to correspond because of probable mechanisms of actions, see below. This study provided important information as to the most suitable number of acupuncture treatments. At the start of the study, eight treatments were planned, but our first three patients did not experience improvement until the seventh or eighth time and the programme was therefore extended to 12 treatments. This study did not address the question whether electroacupuncture might be even better than manual acupuncture, it did not also address the question whether it would be wise to do some sparse follow-up treatments in order to get even more prolonged improvements. For more reliable results, it had been desirable if

patients had performed Inco-tests more frequently but this was not possible in practice due to the advanced age in this group.

4.1. Mechanisms of action for acupuncture

The mechanisms of action for acupuncture have been studied extensively, especially when trying to explain the pain-relieving effects. Human studies indicate that the release of neuropeptides (mostly endorphines) is critical for the pain-relieving effect (Mayer et al., 1977; Sjölund et al., 1977; Sjölund and Eriksson, 1979; Clement-Jones et al., 1980; Kiser et al., 1983). Experimental studies in animals have further indicated that there are several mechanisms behind acupuncture analgesia (Han and Terenius, 1982; Bossut et al., 1991; Chen and Han, 1992). The ideas that acupuncture partially works through the endorphinergic system now have a solid biological ground (Price and Mayer, 1995). Besides, physiologically there are similarities between the physiology of muscle training and acupuncture and there are proposals that acupuncture can be regarded as an artificial way of muscle training (Andersson and Lundeberg, 1995). There is also reasonable evidence, from controlled clinical trials, that acupuncture has a clinically relevant pain-relieving effect on certain forms of chronic nociceptive pain (Helms, 1987; Vincent, 1989; Deluze et al., 1992; Ernst and White, 1998).

Besides pure pain-relieving effects, acupuncture also seems to affect the autonomous nervous system in different ways. There has been shown (both in humans and animals) that peripheral circulation is increased by either acupuncture or TENS. This has been shown in ischemic skin flaps (Lundeberg et al., 1988; Jansen et al., 1989), in the parotid gland (Blom et al., 1993), in connection with Raynaud's syndrome (Appiah et al., 1997) and in the uterine artery in infertile women (Stener-Viktorin et al., 1996). There are also studies showing that electroacupuncture reduces blood pressure through central sympathetic inhibition, probably mediated by increased levels of β-endorphin in the cerebrospinal fluid (Andersson and Lundeberg, 1995). As oestrogens seem to be important for many of the tissues in the area of interest, it might be interesting to note that there is a study that has shown significant improvement of climacteric vasomotor symptoms (sweating and flushes) up to 3 months after a series of electroacupuncture treatments (Wyon et al., 1995). Increase of the central β-endorphin level by electroacupuncture is thought to be the basic mechanism for these effects. Acupuncture also seems to influence the gastrointestinal system. In a study, it was shown that electrical stimulation to the sciatic nerve (in order to mimic electroacupuncture) decreased the rate of choleraic fluid secretion in the small bowel. The effects were not seen when the autonomous nerves to the intestines were interrupted (Cassuto et al., 1982). Somatovisceral reflexes do occur in different systems and have, in detail, been reviewed in (Sato et al., 1997). Sato (and his research group) has shown that, in anaesthetised animals, somatic afferent stimulation particularly on the perineal area induces changes in bladder function and sphincter activity, both excitatory and inhibitory, as a consequence of reflex changes in the parasympathetic efferent activity (Sato et al., 1975). These responses are strongly segmentally organised. Periurethral EMG showed excitation when acupuncture-like stimulation was done rostrally on the body or on the hind limbs. A reduction of this EMG was seen when the dorsal or ventral sacrococcygeal muscles were stimulated (Morrison et al., 1995). As a summary of all the experiments, the authors write: ''all of the somatically induced bladder and sphincter muscle reflex responses appear to be applicable to clinical use for modulation or therapy of micturition, by stimulating the skin and muscle or joints whose afferents enter the spinal cord at the sacral segments'' (Sato et al., 1997). The pontine micturition center in under tonic inhibition from enkephalins. Enkephalins injected intracerebroventricularly have been shown to increase the threshold for micturition. Naloxone (μ-receptor-blocking agent) has been shown to reduce the volume when the micturition reflex occurs (Chai and Steers, 1997). Thus, endorphins seem to have an effect to increase the storage capacity of the bladder.

Thus, acupuncture might work through different physiological mechanisms to have effects on the bladder. Central β-endorphins are increased by acupuncture and thus, the pontine micturition center might be inhibited and increase bladder storage. Somatovesicular reflexes described by Sato et al. (above) might explain different segmental effects of sensory simulation. Improved circulation might appear in the area by means of the different mechanisms described above. This could be an important factor as locally, the continence depends mainly on detrusor control and urethral closure function (Bernstein, 1997). If the vascularisation is impaired, then the continence mechanisms probably does not work well (Levin et al., 1996; Ulmsten, 1997). It is also to be notified that there were a significant number of women who regulated their stools — also that factor can be helpful for the results.

4.2. Forthcoming studies

Two major questions should be answered by future research: (1) how to get the best clinical effect and (2) which are the mechanisms behind the effects. The first step is to see how to get the clinically best results of acupuncture. Which points should be stimulated? Is electroacupuncture better than manual acupuncture? What number of treatment is best? Is it better to have some follow-up treatments? These and other questions should be answered in order to get the most proper ''dose'' of acupuncture. After this it is time for single-blind placebo-controlled studies with independent observer, in order to get answers about different possible mechanisms of action.

It is of no use making such complicated studies with half-doses of drugs — and the same holds for acupuncture studies. A special note is that it is unwise to use superficial acupuncture as placebo as this seems to give rise to physiological changes (Sato et al., 1975; Kelleher et al., 1994; Wyon et al., 1995). The best way to use placebos here is probably to use mock TENS (Lewith and Vincent, 1995).

5. Conclusion

We have documented significant improvements in a group of older women with urge- or mixed-type urine incontinence after a series of manual acupuncture treatments and at follow-up 1 and 3 months thereafter. Acupuncture did not deteriorate the condition and did not produce any adverse effects. In the clinical setting, there seems to be rather positive effects of manual acupuncture regardless of the mechanisms for this. We consider the results of this study so encouraging that more clinical studies should be performed, both open (in order to get the most correct ''dose'' of acupuncture against this condition) and single-blinded placebo-controlled in order to examine the mechanisms behind the effects.

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