Original Article

The role of homoeopathic treatment in women suffering from post-caesarean backache: An open observational clinical trial

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Abstract

Context: An open observational trial was carried out at National Institute of Homoeopathy, India, to assess the possible effects of individualised Homoeopathy in individuals suffering from post-caesarean backache. **Aim:** The aim of the study was to find the role of homoeopathic treatment in individuals suffering from post-caesarean backache. **Methods:** Fifty subjects were enrolled. The Short-Form McGill Pain Questionnaire (SF-MPQ) and Oswestry Low Back Pain Disability Questionnaire (ODQ) were used as the outcome measures, assessed at baseline and after 3 months of treatment. Medicines prescribed followed homoeopathic principles. Non-parametric Wilcoxon signed rank test was applied to compare the dependent observations. $P < 0.05$ two-tailed was considered statistically significant. **Results:** Five subjects dropped out and 45 completed the trial. Intention-to-treat sample ($n = 50$) was analysed. There were statistically significant reductions in pain rating index percentage score (median 83.3 (IQR 66.7 to 100) vs. median 66.7 (IQR 33.3 to 71.1), $P < 0.001$); visual analogue scale score (median 7.0 (IQR 6.0 to 8.0) vs. median 6.0 (IQR 4.8 to 7.0), $P < 0.001$); present pain index score (median 3.0 (IQR 2.0 to 3.0) vs. median 2.0 (IQR 2.0 to 3.0), $P = 0.019$) and ODQ% score (median 44.0 (IQR 39.5 to 50.0) vs. median 39.0 (IQR 31.9 to 44.0), $P < 0.001$) over 3 months of treatment. *Natrum muriaticum* ($n = 11$, 22%); *Staphysagria* ($n = 8$, 16%); *Bryonia alba* and *Rhus toxicodendron* ($n = 6$ each, 12%) and *Pulsatilla nigricans* ($n = 4$, 8%) were prescribed frequently. **Conclusion:** Indicated homoeopathic medicines reduced SF-MPQ and ODQ scores. Further randomised trials are warranted with enhanced methodological rigour.

Keywords: Backache, Caesarean section, Homoeopathy, Oswestry Low Back Pain Disability Questionnaire, Short-Form McGill Pain Questionnaire

Introduction

In caesarean section, the foetuses after 28th week are delivered through abdominal route.[1] The caesarean delivery rate in the United States in 2010 was 32.8%.[2] The estimate for caesarean section rates in India is rising.[3] The WHO report suggests that a higher rate of caesarean section was associated with greater risk of maternal and perinatal mortality and morbidity.[4] Although the WHO has recommended since 1985 that the rate is not to exceed 10%–15%,[5] a study conducted by Sarkar *et al*. showed the rate to be around 32%.[6] Literature review shows homoeopathic medicines to be effective in injury to spine.[7] Low back pain also restricts mobility, interferes with normal functioning and results in lifelong pain and permanent disability.[10] Back pains after surgery may result from a multitude of causes that include posture during surgery, aggravation of an existing medical condition or needle trauma during central neuraxial blocks.[11,12] Although caesarean section is one of the most commonly performed operations, chronic pain after caesarean section has not been well studied. The prevalence of chronic pain after caesarean section is usually observed in retrospective studies and varies considerably from one study to another. Moreover, the number of studies that have examined the risk factors of chronic post-surgical pain after caesarean section is limited.[13]

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Methods

Trial design

This open-label, prospective, observational, non-controlled clinical trial of pre–post comparison design was conducted at the Outpatient Department of National Institute of Homoeopathy (NIH), Kolkata, India. The study protocol was approved by the Institutional Ethical Committee (Ref. No. 5-023/NIH/PG/Ethical Comm. 2009/Vol. III/1970 [A/S]; dated 27 March 2017) and was registered prospectively in the Clinical Trials Registry – India (Trial registration: CTRI/2017/06/008849). The trial protocol and full dissertation was submitted as a post-graduate thesis of the corresponding author to The West Bengal University of Health Sciences.

Participants

Inclusion criteria were female subjects suffering from backache over 3 months following caesarean section (2019 ICD 10 Diagnosis Code G89.28, other chronic post-procedural pain), aged between 18 and 45 years and willing to participate in the study by giving written consent. Exclusion criteria were the cases too sick for consultation, unable to read patient information sheets and not giving consent to take part, post-menopausal women, female subjects presenting with confounding variables such as backache existing before caesarean section, with immediate complications after caesarean section, diagnosed cases of unstable psychiatric illness or other systemic disease affecting quality of life, currently receiving homoeopathic treatment for chronic condition(s), pregnant and lactating women, self-reported immune-compromised state, substance abuse and/or dependence.

Intervention

Intervention was planned as the administration of indicated homoeopathic medicines in centesimal or 50 millesimal potencies and in individualised dosage, as decided appropriate to the case or condition. In centesimal potencies, each dose consisted of four cane sugar globules medicated with a single drop of the indicated medicine, preserved in 90% v/v ethanol. In 50 millesimal potencies, a single-medicated cane sugar globule of poppy seed size (no. 10) was dissolved in 50 ml distilled water with addition of 2 drops of 90% v/v ethanol, 10 doses marked on the vial, each dose of 5 ml was directed to be taken after 10 uniformly forceful downward strokes to the vial in 45 ml normal water in a clean cup, to stir well, to take 5 ml of this liquid orally and to discard rest of the liquid in the cup. Patients were instructed to take each dose orally on clean tongue with empty stomach. Duration of such therapy was 3 months. Medicines were obtained from good manufacturing practice-certified firms of India. Single individualised medicine was prescribed on each occasion taking into account presenting symptom totality, clinical history details, constitutional features, miasmatic expressions, repertorisation using RADAR® software (version 10.0.028 (ck), Archibel 2007, Belgium) when required with due consultation with Materia Medica. Subsequent prescriptions were generated as per Kent's observations and Hering's law. Participants were assessed by three homoeopaths at a time. Medicine was selected on each occasion by two homoeopaths, and in case of any differences in opinion, it was resolved by involvement of another homoeopath.

General management

All the participants were given general guidelines to remain active within the limits of pain, avoid activities which would make the pain worse (e.g., lifting heavy weights) and consider alternative positions or ways to minimise pain, rest when needed. They were advised to be present for monthly follow-ups.

Outcomes

- Primary outcome measure – Short Form McGill Pain Questionnaire (SF-MPQ).[14] The SF-MPQ, the shorter version of the MPQ, is a multidimensional valid and reliable measure of perceived chronic pain in adults. It is comprised of 15 words (first 11 sensory and last 4 affective), which are rated on an intensity scale as 0 = none, 1 = mild, 2 = moderate and 3 = severe. The SF-MPQ also includes one item for present pain intensity (PPI; 0–5) and one item for a 10-cm Visual Analogue Scale (VAS) for average pain. The total Pain Rating Index (PRI) score is obtained by summing the item scores (range 0–45). There are no established critical cut points. As for the MPQ, a higher score indicates worse pain. The SF-MPQ takes 2–5 min to complete. A mean improvement in total scores >5 on the 0–45 scale demonstrated a clinically important change. It was administered at baseline and after 3 months of treatment
- Secondary outcome measure – Oswestry Low Back Pain Disability Questionnaire (ODQ),[15] It is one of the most commonly used outcome measures for individuals with low back pain and considered to be gold standard in the assessment of patient-rated outcome. It is a valid, reliable and responsive condition-specific assessment tool that is suited for use in clinical practice. It is easy to administer and score, objectifies clients' complaints and monitors effects of therapy. For each section, the total possible score is 5, the first statement is marked = 0, the last statement is marked = 5. Total section = 10; total possible score = 50. Minimum detectable change (90% confidence) was 10% points (change of less than this may be attributable to error in the measurement). It was administered at baseline and after 3 months of treatment.[15-17]

Before this trial was initiated, the questionnaires underwent standardised translation into local vernacular Bengali after obtaining permission from the developer of the questionnaire via e-mail, which was checked for face-and-content validity, and subjected to pilot testing and thereafter formal psychometric validity and reliability testing.

Sample size

No relevant data were available on the reduction of SF-MPQ and ODQ scores by individualised homoeopathic treatment using an open observational study design over 3 months

of intervention. Thus, assuming a medium effect size (*d*) of 0.5, alpha = 0.05 and power of 90%, to detect a significant difference between two dependent means of PRI% (mean pre- and post-scores) by Wilcoxon signed rank test (matched pairs), we would have required a sample size of 47. Keeping a provision for about 5% drop-outs, the target sample was 50.

Statistical methods

The analysis was carried out with intention-to-treat approach; i.e., every included patient entered into the final analysis. Missing values were replaced by the last observation carried forward method. Data distribution was examined by histograms, Q–Q plots, Kolmogorov–Smirnov test and Shapiro–Wilk test. The baseline descriptive data (categorical and continuous) were presented in terms of absolute values, percentages, means, standard deviations, medians, and inter-quartile ranges. Non-parametric Wilcoxon signed rank tests were planned to be used as inferential statistics comparing non-normally distributed dependent observation of continuous outcomes at baseline and after 3 months. $P < 0.05$ was considered statistically significant. No interim and subgroup analyses were planned. SPSS®-IBM® version 20 (IBM Corp., IBM SPSS Statistics for Windows, Armonk, NY: USA) for Windows was used for the analysis of data.

Results

Participant flow

As per the pre-specified inclusion and exclusion criteria, 120 female subjects suffering from backache with obstetrical history of caesarean section were screened; 70 were excluded on account of various reasons; 50 met the eligibility criteria and were enrolled into the trial. Following that, baseline socio-demographic and outcome data were obtained. After 3 months of intervention, outcome data were recorded again. During the course of treatment, five dropped out; 45 completed the trial [Figure 1].

Recruitment

Starting from May 2017, follow-up of the last enrolled patient was completed by the end of August 2018.

Baseline data

Eleven variables were studied for the baseline socio-demographic features of the female subjects – age, residence, religion, duration of suffering, treatment taken, body mass index, systolic blood pressure, diastolic blood pressure, educational status, employment status and family income status [Table 1].

Numbers analysed

Outcomes from 45 female subjects were complete; therefore, all the enrolled subjects ($n = 50$) entered into the final analyses.

Data distribution

Data distribution seemed to be inconclusive from the histograms and Q-Q plots; however, the Kolmogorov–Smirnov test and the Shapiro–Wilk test revealed *P* values much less than α (=0.05), thus indicating stronger evidence against normal distribution. Thus, non-parametric Wilcoxon signed rank test was planned to be performed.

Outcomes and estimation

Statistically significant reductions were achieved on three individual components of the MPQ – the PRI% score ($P < 0.001$, Wilcoxon signed-rank test), VAS score ($P < 0.001$), PPI score ($P = 0.019$) and ODQ% score ($P < 0.001$) [Table 2]. An 11.1% point reduction in total PRI% score is considered as minimal detectable change (*vide* a mean improvement in total scores more than 5 on the 0–45 scale demonstrated a clinically important change).[14] After 3 months of treatment, minimum 11.1% score reduction was achieved in 28 subjects. A 10% point reduction in total ODQ% score is considered as minimal detectable change at 90% confidence level.[16,17] After 3 months of treatment, minimum 10% score reduction was achieved in 15 subjects.

Medicines used

Sixteen different individualised medicines were prescribed in the study – *Natrum muriaticum* ($n = 11$, 22%), *Staphysagria* ($n = 8$, 16%), *Bryonia alba* and *Rhus toxicodendron* ($n = 6$ each, 12%), *Pulsatilla nigricans* ($n = 4$, 8%), *Calcarea carbonicum* ($n = 3$, 6%), *Ruta graveolens* and *Sulphur* ($n = 2$ each, 4%), *Arnica montana*, *Causticum*, *Hypericum perforatum*, *Ignatia amara*, *Lachesis mutus*, *Medorrhinum*, *Natrum sulphuricum* and *Sepia officinalis* ($n = 1$ each, 2%). Percentages were calculated by dividing the number of prescriptions of each medicine by total number of prescriptions (i.e., 50) multiplied with 100. Indications of the prescribed medicines are given in Table 3.

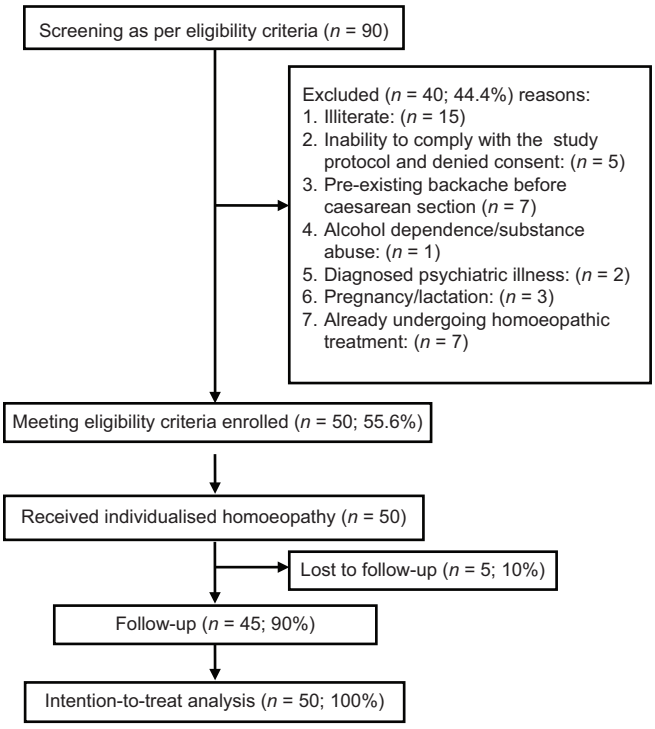

Figure 1: Study flow diagram

Adverse events

Patients were instructed to report any harms, unintended effects, serious adverse events and undue aggravations either directly in the outpatients or over phone, but not a single incidence was reported from either group.

Discussion

This open observational clinical trial found statistically significant improvement in both the outcomes after homoeopathic treatment, suggesting Homoeopathy as a promising treatment option for women suffering from backache following caesarean section and suggesting further substantiation using methodologically sound trials.

Table 1: Baseline socio-demographic features of the female subjects (*n*=50)

Features	*n* (%)
Age (years)[§]	28.3±6.7
Residence[Δ]	
Rural:urban	33 (66):17 (34)
Religion[Δ]	
Hinduism:Islam	24 (48):26 (52)
Duration of suffering (months)[§]	63.3±55.5
Treatment taken[Δ]	
Allopathy	21 (42)
Homoeopathy	3 (6)
Allopathy + Homoeopathy	9 (18)
None	17 (34)
BMI[§]	23.3±3.8
Systolic blood pressure	109.1±11.6
Diastolic blood pressure	70.4±9.7
Educational status[Δ]	
10th standard or below	27 (54)
12th standard	13 (26)
Graduate or above	10 (20)
Employment status[Δ]	
Self-employed	18 (36)
Employed	2 (4)
Unemployed	30 (60)
Family income status[Δ]	
Low	47 (94)
Medium to high	3 (6)

[§]Continuous data presented as mean±SD; [Δ]Categorical data as absolute values (%). Low income status: Monthly household income <Rs. 10,000/-, Medium income status: Rs. 10,000-30,000/-, High status: > Rs. 30,000/-. SD: Standard deviation, BMI: Body mass index

Strengths of the study

The possible effects of homoeopathic treatment in individuals suffering from backache following caesarean section were explored using the Bengali translated version of SF-MPQ score, a multidimensional measure of perceived pain in adults with chronic pain. It helped to discriminate among different pain syndromes and evaluate the responsiveness of different symptoms to treatment. The Oswestry Disability Index was a self-administered questionnaire that required 5 min to complete and 1 min to score. Scores were associated with degree of disability, ranging from minimal to bedbound. Homoeopathic treatment was based on the principles of individualisation. Formal validity and reliability of the Bengali versions of SF-MPQ and ODQ have also been addressed before enrolment in this study but will be reported elsewhere and beyond the scope of this paper. Another important strength was the participation of qualified and experienced homoeopathic physicians schooled in and practicing individualised Homoeopathy. Our study was representative of individualised ('classical') Homoeopathy only. In a broader interpretation of the law of similar, medicines were selected for symptoms both typical of the diagnosis and outside the pre-dominating pathologies ('constitutional').

Weaknesses of the study

The potential explanatory power of a one-armed observational trial is very limited. Although the trial was adequately powered to detect significant change in the specified outcome measures over 3 months, still the sample size was inadequate to make a definite conclusion regarding the effectiveness of homoeopathic treatment in individuals suffering from backache following caesarean section. The time period for the study was of short duration. The study was open and observational in design and hence did not involve any blinding, randomisation or control. Thus, efficacy data could not be generated and the effect sizes might have been overestimated. This might be partly explained by placebo and/or regression to the mean effects that our study was not designed to control. We also could not rule out the undisclosed use of concurrent therapeutic modalities, if any. The duration of suffering was more than 5 years on average, thus indicating other confounders playing important role such as increasing age, multiple gestation, diabetes mellitus, obesity, pregnancy-related hypertension, complicated obstetric conditions (including pre-eclampsia and eclampsia), urinary tract infection and urinary tract stone (including renal stone and ureteral stone); however, our study design could not address this issue and controlled trials are warranted for the purpose.

Table 2: Changes in outcomes over 3 months; non-parametric Wilcoxon signed-rank test (*n*=50)

Outcomes	Baseline, median (IQR)	After 3 months, median (IQR)	*Z* score	*P*	Effect sizes
MPQ					
PRI %	83.3 (66.7-100)	66.7 (33.3-71.1)	−4.293	<0.001*	0.607
VAS	7.0 (6.0-8.0)	6.0 (4.8-7.0)	−4.964	<0.001*	0.702
PPI	3.0 (2.0-3.0)	2.0 (2.0-3.0)	−2.353	0.019*	0.333
ODQ % score	44.0 (39.5-50.0)	39.0 (31.9-44.0)	−4.539	<0.001*	0.642

**P*<0.05 two-tailed considered statistically significant. IQR: Interquartile range; MPQ: McGill Pain Questionnaire; PRI: Pain Rating Index; VAS: Visual Analogue Scale; PPI: Present Pain Index; ODQ: Oswestry Low Back Pain Disability Questionnaire

Table 3: Indications of the prescribed medicines

Medicines used	Physical generals	Mind symptoms
Natrum muriaticum	Low back pain after C/S, < lying down, > pressure against back Tongue mapped Cracked middle lower lip Desire for extra salt Hot patient Menses scanty, dark, clotted	Mental irritability Consolation <
Staphysagria	Low back pain after C/S, < early morning on rising, > warm applications Numbness in the lower extremities Intolerance to tobacco smoke	Very sensitive as to what others say about her Keeps anger within herself and suffers there from
Bryonia alba	Low back pain after C/S, < exertion, > rest, pressure Pressure in stomach after eating Thirst large quantities at long intervals Stools hard consistency	Mental irritability, fear of death
Rhus toxicodendron	Low back pain after C/S, < wet rainy weather, > rubbing, warm applications Vesicular, itching eruptions over dorsum of both hands Intolerance to milk Chilly patient	Mental irritability, apprehensiveness
Pulsatilla nigricans	Pain along the whole length of the spine, < evening, > cold applications General sensation of chilliness<evening Thirstlessness	Emotional, weeping tendency Mild, gentle, yielding disposition
Calcarea carbonicum	Backache after C/S, < standing, > pressure Multiple swellings over scalp, right forearm, left thigh Desire for eggs, salt Palms cold, to touch; menses bright red, protracted	Apprehensiveness, fearfulness
Ruta graveolens	Aching pain over the low back, < wet weather, > lying on the back History of fall over back leading to injury over spine Bruised feeling all over the body	Anxious about her troubles Weeping tendency Memory weakening
Sulphur	Low back pain after C/S, < standing, > drawing up of lower limbs History of suppressed skin eruptions Desire for sweets, salts Dislike for bathing Burning sensation in palms, soles Offensive stool and urine	Mental irritability
Arnica montana	Low back pain after C/S, < touch, > lying down Sore, lame, bruised feeling over whole body Face and head hot, rest part cold Incontinence of urine	History of mental trauma
Causticum	Low back pain after C/S, < motion, > warmth Keloid with a raw sensation Aversion to sweets Stools hard consistency Chilly patient	Sympathetic
Hypericum perforatum	Low back pain after C/S, < touch, > pressure History of fall over coccyx Pain in the fingertips Tongue white coated at base tip clean	Melancholy mood
Ignatia amara	Low back pain after C/S in small spots, < in the morning, warmth, > change of position Intolerance to tobacco smoke	Changeable mood History of grief
Lachesis mutus	Low back pain after C/S, < rising from sitting posture, > rest Sudden starting from sleep Dysmenorrhoea, > by flow	Loquacity; sadness

Contd...

Table 3: Contd...

Medicines used	Physical generals	Mind symptoms
Medorrhinum	Low back pain after C/S, < daytime	Weak memory
	Burning sensation over extremities	Fear of darkness
	Sensation of trembling	
	Menses: Offensive, stains difficult to wash out	
Natrum sulphuricum	Low back pain after C/S, < damp weather, > pressure	Sadness
	History of head injury	Suicidal tendency
	Tongue: Thick brown coating leucorrhoea: Yellowish	
Sepia officinalis	Low back pain after C/S, < left side, > warm application	Mentally irritable
	Weakness over back	Prefers company
	Menses: Early and profuse	Indifference towards family

C/S: Caesarean section

Strength and weakness in relation to other studies

Controversies exist whether caesarean section is associated with chronic low backache or not;[18-22] however, a recent meta-analysis finds a clinically relevant incidence of chronic post-surgical pain after caesarean section ranging from 15% at 3 months to 11% at 12 months or longer that has been largely stable in recent years.[23] Recent large-scale cohort studies also support the claim[24-27] with evidence of impaired quality of life.[28] Dexamethasone local pre-treatment was found to significantly reduce the incidence of post-operative acute low back pain and the degree of pain after epidural delivery analgesia.[29] However, the Complementary and Alternative medicine (CAM) modalities remained under-researched and were examined for efficacy mostly in short-term backache following caesarean section, but not for chronic low back pain.[30] Thus, we intended to compare the treatment effect sizes of Homoeopathy with that of other CAM, physiotherapy or usual treatment, but scarcity of trials in the relevant subject area did not allow for such comparisons. A prospective, randomised, double-blind placebo-controlled clinical trial was conducted under the official title "Effect of Homeopathic Drugs *Bellis perennis*, *Staphysagria* on the Post-Operative Recovery, of Women Undergoing Cesarean Section – (An exploratory) Double Blind, Placebo Controlled Study" with 90 participants from August 2008 to April 2009 (ClinicalTrials.gov identifier: NCT00725569). It was anticipated that homoeopathic treatment proved to be both safe and effective in shortening the duration of post-operative healing, with respect to both healthcare costs and patient suffering. It is supposed to open the door for further research in the field of trauma medicine, as well as other stress-related illnesses.[31] A randomised, double-blind, placebo-controlled trial was conducted from December 2003 to May 2007 on 248 patients with a homoeopathic drug combination *Lymphdiaral basistropfen*, which was established in the treatment of oedema and swellings. It was for the first time the effectiveness and safety of the drug were investigated in the treatment of chronic low back pain. This trial showed that the homoeopathic drug combination could improve the treatment of chronic low back pain.[32] A prospective, multicentre cohort study was conducted in 2005 with 3981 patients suffering from long-term chronic diseases. According to both physician and patient assessments, the severity of complaints decreased markedly over the 24-month observation period. Younger patients and those with more severe disease appeared to benefit most from homoeopathic treatment. Amongst adults and children, an improvement in quality of life was observed. The findings indicated that homoeopathic medical therapy might play a beneficial role in the long-term care of patients with chronic diseases.[33] A placebo-controlled study was conducted on 144 women with an average age of 23.5 years, who had undergone surgical childbirth by comparably trained obstetricians. The sample was divided into a treatment group receiving an ointment of St. John's-Wort (*Hypericum perforatum*) 24-h post-operation, a placebo group who received a placebo ointment 24-h post-operation and a control group who received no treatment. Assessment was done for redness, oedema, ecchymosis, discharge, approximation scale and VAS. The study found a significant difference in the St. John's-Wort group's wound healing and scar formation, while there was little difference in wound healing and scar formation in the placebo or control group.[34]

Unanswered questions and future research

The role of homoeopathic treatment on the radiological changes including bony and soft tissue changes could not be studied. The assessment for the same can be done in future. The trial would have been methodologically better if randomisation and blinding techniques could have been included. Role of few medicines such as *Bellis perennis* and *Kalium carbonicum* in post-traumatic backache which is mentioned in available Homoeopathic literature could not be assessed in the present trial. Further investigations can be undertaken to study the efficacy or effectiveness of the above-stated medicines in the management of post-traumatic complications, especially in backache following caesarean section. A comparative study can be carried out to assess whether treatment results vary with individualised medicines or with specific medicines for a clinical condition. Further studies can be carried out to assess the magnitude of back pain in primary and repeat caesarean section as well as on the type of anaesthetic technique used during deliveries so that necessary treatment protocol can be framed accordingly. In an observational study of 64 healthy, singleton, new-born infants (33 boys) born at term, cord blood was sampled after elective caesarean section and vaginal

delivery. The study concluded that there was increasing evidence for epigenetic changes with caesarean section, suggesting that it might not be just the mother and infant who were affected by surgical deliveries, but there might be transgenerational effects.[35] It can be deduced from the above facts that there is ample scope for doing further methodical research in Homoeopathy in the management of post-caesarean complications.

Conclusion

In this open-label, prospective, observational, clinical trial of pre–post comparison design conducted on 50 female subjects suffering from post-caesarean backache revealed statistically significant improvement in both SF-MPQ and ODQ scores after 3 months of individualised homoeopathic treatment. Further explorations by adequately powered randomised trials and independent replications are warranted.

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Conflicts of interest

None declared.

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पोस्ट–सिज़ेरियन पीठ दर्द से पीड़ित महिलाओं में होम्योपैथिक उपचार की भूमिकाः एक खुला अवलोकन नैदानिक परीक्षण

संदर्भः सीजेरियन पीठ के दर्द से पीड़ित महिलाओं में व्यक्तिगत होम्योपैथी के संभावित प्रभावों का आकलन करने के लिए राष्ट्रीय होम्योपैथी संस्थान, भारत में एक खुला अवलोकन परीक्षण किया गया।

उद्देश्यः पोस्ट सिजेरियन पीठ दर्द से पीड़ित महिलाओं में होम्योपैथिक उपचार की भूमिका।

सामग्री और विधिः इस अध्ययन के लिए पचास महिलाओं को नामांकित किया गया। आधारभूत उपायों में शॉर्ट–फॉर्म मैकगिल दर्द प्रश्नावली (एसएफ–एमपीक्यू: पीआरआई, वीएएस और पीपीआई सहित) और ओस्वेस्ट्री लो बैक पेन डिसएबिलिटी प्रश्नावली (ओडीक्यू) शामिल थे, जिनका मूल्यांकन बेसलाइन और 3 महीने के बाद किया गया। औषधियों को होम्योपैथिक सिद्धांतों के अनुसार निर्धारित किया गया। पी <0.05 टू–टेल्ड को सांख्यिकीय रूप से महत्वपूर्ण माना गया।

परिणामः पांच महिलाओं ने परीक्षण को बीच में ही छोड दिया तथा 45 ने परीक्षण को पूरा किया। इंटेंशन टू ट्रिट सैम्पल (एन=50) का विश्लेषण किया गया। उपचार के 3 महीनो के उपरांत दर्द रेटिंग इंडेक्स प्रतिशत स्कोर (मिडियन 83.3 (आईक्यूआर 66.7 से 100) बनाम मिडियन 66.7 (आईक्यूआर 33.3 से 71.1), पी < 0.001); विजुअल एनालॉग स्केल स्कोर (मिडियन 7.0 (आईक्यूआर 6.0 से 8.0) बनाम मिडियन 6.0 (आईक्यूआर 4.8 से 7.0), पी=< 0.001); वर्तमान दर्द सूचकांक स्कोर (मिडियन 3.0 (आईक्यूआर 2.0 से 3.0) बनाम मिडियन 2.0 (आईक्यूआर 2.0 से 3.0), पी=0.010) और ओडीक्यू प्रतिशत स्कोर (मिडियन 44.0 (आईक्यूआर 31.9 से 44.0), पी < 0.001) में सांख्यिकीय रूप से महत्वपूर्ण कटौती हुई। नैट्रम म्यूरिएटिकम (एन=11, 22 प्रतिशत); स्टैफिसैग्रिया (एन=8, 16 प्रतिशत); ब्रायेनिया अल्बा और रस टॉक्स (एन=6, 12 प्रतिशत प्रत्येक) तथा पल्सेटिला नाइग्रिकेन्स (एन=4, 8 प्रतिशत) अक्सर दी गयी औषधियां थी।

निष्कर्षः निर्दिष्ट होम्योपैथिक औषधियों ने एसएफ–एमपीक्यू और ओडीक्यू स्कोर को कम कर दिया। आगे यादृच्छिक परीक्षण विधिवत प्रयासों के साथ आवश्यक हैं।

Le rôle d'un traitement homéopathique chez les personnes souffrant de maux de dos suite à une césarienne : un essai clinique observationnel ouvert

Contexte: Le taux croissant des césariennes a eu des conséquences négatives sur la santé maternelle et néonatale. Un essai observationnel ouvert a été réalisé à l'Institut national de l'Homéopathie en Inde pour évaluer les effets possibles de l'homéopathie personnalisée chez les personnes souffrant de maux de dos suite à une césarienne.

Objectif: Étudier le rôle d'un traitement homéopathique chez les individus souffrant de maux de dos suite à une césarienne.

Matériel et méthodes: Cinquante patientes ont été inscrites pour cette étude. Les résultats ont été mesurés à l'aide d'une version abrégée du Questionnaire McGill sur la Douleur (QMD: y compris le PRI (Indice de notation de la douleur- IND), la VAS (Échelle visuelle analogique - EVA) et la PPI (Intensité de la douleur actuelle-IDA) et du Questionnaire Oswestry sur l'invalidité causée par les douleurs lombaires (QOID) au début de l'étude et au bout de 3 mois. Les médicaments ont été prescrits selon les principes homéopathiques. Une $P < 0,05$ bilatérale a été considérée comme significative statistiquement.

Résultats: Des baisses statistiquement significatives du pourcentage de l'indice de notation de la douleur (IND%) ont été observées [77,4 ± 18,9 contre 59,2 ± 24,2 ; une réduction moyenne de 18,2, Intervalle de confiance 95% de 10,9-25,5, $P < 0,001$] ; du score de l'échelle visuelle analogique (EVA) [7,1 ± 1,4 contre 5,7 ± 1,7 ; une réduction moyenne de 1,4, Intervalle de confiance 95% de 1,0-1,7, $P < 0,001$] ; du score d'intensité de la douleur actuelle (IDA) [2,8 ± 0,9 contre 2,4 ± 1,0 ; une réduction moyenne de 0,4, Intervalle de confiance 95% de 0,1-0,7, $P = 0,012$], et du pourcentage du score du Questionnaire Oswestry sur l'invalidité (QOID) [45,3 ± 10,8 contre 39,2 ± 11,3 ; une réduction moyenne de 6,2, Intervalle de confiance 95% de 3,9-8,5, $P < 0,001$] après trois mois de traitement. Natrum muriaticum ($n = 11$; 22%), Staphysagria ($n = 8$; 16%), Bryonia alba et Rhus toxicodendron ($n = 6$ pour les deux; 12%), et Pulsatilla nigricans ($n = 4$; 8%) ont été fréquemment prescrits.

Conclusion: Les médicaments homéopathiques mentionnés ont réduit les scores du QMD et QOID. Des essais randomisés de plus grande ampleur et dotés d'une rigueur méthodologique renforcée sont encore nécessaires.

Papel del tratamiento homeopático en personas con dolor de espalda poscesárea. Ensayoclínicoobservacionalabierto

Contexto: Las cifras crecientes de cesáreas han dado lugar a un impacto negativo en la salud de la madre y del neonato. En el Instituto Nacional de Homeopático, India, se efectuó un ensayo observacional abierto para evaluar los posibles efectos de la homeopatía individualizada en personas con dolor de espalda poscesárea.

Objetivo: Estudiar el papel del tratamiento homeopático en personas con dolor de espalda poscesárea.

Material ymétodos: En este estudio, se incluyeron 50 personas.Los parámetros fueron la versión corta del cuestionario de dolor de McGill (*Short-FormMcGillPainQuestionnaire*;SF-MPQ; que incluye PRI[*Pain Rating Index*], VAS[*Visual AnalogScale*]yPPI[*PresentPainIndex*]) y el cuestionario de incapacidad por dolor de espalda de Oswestry (OswestryLow Back *PainDisabilityQuestionnaire*;ODQ), que se evaluaron al principio y tras 3 meses. Los medicamentos se prescribieron conforme a los principios homeopáticos. La significación estadística se estableció en una P<0,05 bilateral.

Resultados: Se observaron reducciones estadísticamente significativas en la puntuación del PRI porcentual [77,4 ± 18,9 frente a 59,2 ± 24,2; reducción media 18,2, IC del 95% 10,9-25,5, $P < 0,001$], en la puntuación de la VAS [7,1 ± 1,4 frente a 5,7 ± 1,7; reducción media 1,4, IC del 95% 1,0-1,7, $P < 0,001$], en la puntuación del PPI [2,8 ± 0,9 frente a 2,4 ± 1,0; reducción media 0,4, IC del 95% 0,1-0,7, $P = 0,012$] y en la puntuación del ODQ porcentual [45,3 ± 10,8 frente a 39,2 ± 11,3; reducción media 6,2, IC del 95% 3,9-8,5, $P < 0,001$] durante 3 meses de tratamiento. *Natriummuriaticum* ($n = 11$; 22%), *Staphysagria* ($n = 8$; 16%), *BryoniaalbayRhustoxicodendron* ($n = 6$, cada uno; 12%) y *Pulsatillanigricans* ($n = 4$; 8%) fueron administrados con frecuencia.

Conclusión: Los medicamentos indicados educen las puntuaciones SF-MPQ y ODQ. Se precisanmásensayosaleatorizados con mayor rigor metodológico.

Die Rolle der homöopathischen Behandlung bei Rückenschmerzennach einer Sectio: Eine offene klinische Beobachtungsstudie

Hintergrund: Steigende Kaiserschnittraten haben die Gesundheit von Müttern und Neugeborenen negativ beeinflusst. Am "National Institute of Homoeopathy", Indien, wurde eine offene Beobachtungsstudie durchgeführt, um mögliche Auswirkungen einer individualisierten homöopathischen Behandlungvon Rückenschmerzen nach einer Sectiozu untersuchen.

Ziel: Untersuchung zur Rolle der homöopathischen Behandlung beiRückenschmerzen nach einer Sectio.

Material und Methoden: Indiese Studie wurden 50 Probandinnenaufgenommen. Die Ergebnissewurden am Studienbeginn und nach drei Monaten unter Verwendung des McGill-Schmerzfragebogensin Kurzform(SF-MPQ: einschließlich PRI, VAS und PPI) und des Oswestry-Fragebogenszu den Beschwerden des unteren Rückens (ODQ) ermittelt. Arzneimittel wurden nach homöopathischen Prinzipien verordnet. Zweiseitige P <0,05 wurden als statistisch signifikant angesehen.

Ergebnisse: Die prozentuale Abnahme des Schmerzbewertungsindex (PRI%) war statistisch signifikant [77,4 ± 18,9 vs. 59,2 ± 24,2; mittlere Reduktion 18,2, 95% Cl 10,9-25,5, P <0,001]; VAS-Score (Visual Analog Scale) [7,1 ± 1,4 vs. 5,7 ± 1,7; mittlere Reduktion 1,4, 95% Cl 1,0-1,7, $P < 0,001$]; aufgetretener Schmerzindex (PPI) Score [2,8 ± 0,9 vs. 2,4 ± 1,0; mittlere Reduktion 0,4, 95% CI 0,1-0,7, $P = 0,012$] und ODQ% Score [45,3 ± 10,8 vs. 39,2 ± 11,3; mittlere Reduktion 6,2, 95% CI 3,9-8,5, $P < 0,001$] über dreiBehandlungsmonate. Natrium muriaticum ($n = 11$; 22%), Staphysagria ($n = 8$; 16%), Bryonia albaund Rhus toxicodendron (jeweils $n = 6$; 12%) und Pulsatilla nigricans ($n = 4$; 8%) wurden häufig verordnet.

Schlussfolgerung: Die angegebenen homöopathischen Arzneimittel reduzierten die SF-MPQ- und ODQ-Werte. Weitere randomisierte Studien sind wegen einerhöheren methodischenGenauigkeit gerechtfertigt.

The role of homoeopathic treatment in individuals suffering from post-caesarean backache: An open observational clinical trial

順勢療法治療在剖腹手術後背痛患者中的作用：一項非盲觀察性臨床試驗

背景：剖腹手術率上升對產婦和新生兒健康造成了負面的影響。在印度國家順勢療法研究所進行了一項非盲觀察性試驗，以評估個人化順勢療法對患有剖腹手術後背痛患者的可能作用。

目的：研究順勢療法治療剖腹手術後患者的作用。

材料和方法：50名受試者參加了這項研究。結果測量指標為簡化McGill 疼痛問卷（SF-MPQ：包括PRI、VAS和PPI）和歐氏下背痛失能量問卷（ODQ），在基線與3個月後進行評估。藥物是根據順勢療法原則處方的。以$P < 0.05$雙尾為具有統計顯著性。

結果：治療3個月後，疼痛分級指數百分比（PRI%）評分【77.4±18.9 vs.59.2±24.2；平均值下降18.2，95%CI10.9-25.5，$P < 0.001$】；視覺類比量表（VAS）评分【7.1±1.4 vs.5.7±1.7；平均值下降1.4，95%CI 1.0-1.7，$P < 0.001$】；疼痛指數（PPI）評分【2.8±0.9 vs.2.4±1.0；平均值下降0.4，95%CI 0.1-0.7，$P = 0.012$】和ODQ%評分【45.3±10.8 vs.39.2±11.3；平均值下降6.2，95%CI3.9-8.5，$P < 0.001$】均有統計顯著性下降。經常處方氯化鈉（n=11；22%）、飛燕草（n=8；16%）、瀉根和毒葛（每組n=6；12%）和白頭翁（n=4；8%）。

結論：表明順勢療法藥物降低了SF-MPQ和ODQ評分。進一步的隨機試驗必須提高方法的嚴謹性。