Author's response to reviews

Title: Treatment of pelvic girdle pain with acupuncture: adverse effects during pregnancy and delivery.

Authors:

Helen Elden (helen.elden@vgregion.se)
Hans-Christian Ostgaard (hans-christian.ostgaard@vgregion.se)
Monika Fagevik-Olsen (monika.fagevik-olsen@vgregion.se)
Lars Ladfors (lars.ladfors@vgregion.se)
Henrik Hagberg (henrik.hagberg@obgyn.gu.se)

Version: 2 Date: 22 January 2008

Author's response to reviews:

Gothenburg, 22 th January 2008

Hereby the manuscript entitled ¿Treatment of pelvic girdle pain with acupuncture: adverse effects during pregnancy and delivery¿ is submitted to be considered for publication as a fulltext article in BMC Complementary and Alternative Medicine.

There are studies that have shown promising results for acupuncture for the management of pelvic girdle pain and/or lumbar back pain in pregnant women. However, the use of acupuncture for pelvic girdle pain in pregnant women is sparse as there are too few studies of insufficient size to draw firm conclusions about the influences of acupuncture on the pregnancy and the neonates. This is the first large clinical trial of acupuncture administered, with stimulation that may be considered strong, for pelvic girdle pain to report on pregnancy outcome. We used 17 needles, stimulated them to de qi 3 times during 30 minutes and acupuncture points that have been stated by others to be avoided during pregnancy (Colon 4, Bladder 31 and 33) were used. Moreover, 50% of the patients started the treatment already during the second trimester of pregnancy. In addition, this is the first study that has assured viability and wellbeing of the fetus during and after acupuncture with analysis of CTG: s readings.

Data were collected of adverse effects, minor adverse events and the women¿s opinions of the different treatments. Influence of acupuncture on the fetus was measured with cardiotocografi (CTG) before-during and after 43 acupuncture sessions in 43 women. A standardised computerized method to analyze the CTG reading numerically (Oxford 8000) was used. Data of analgesia and oxytocin argumentation during labour, duration of labour, frequency of preterm birth, operative delivery, Apgar score, cord-blood gas/ acid base balance, birth weight and other infant outcomes were also recorded.

This study adds support to the view that acupuncture even with strong stimulation does not lead to serious adverse events on the on the pregnant
women, the delivery or the fetus/neonate. We think that the study result has important clinical implications in eliminating fear of serious adverse effects when treating pregnant women with acupuncture. Even if more studies are required to confirm our results, this is the most comprehensive data reported so far.

The manuscript is enclosed in an electronic version including 7 tables in Microsoft Word and 1 figure in power-point.

This study was conducted in 2000-02 and it was not registered in a trial registry as it was not the policy to register clinical trials in 2000. Also, according to the Statement by the International Committee of Medical Journals Editors this policy applies to any clinical trial starting enrollement after July 1, 2005.

On behalf of the authors
Yours Sincerely
Helen Elden

Address for correspondence and reprint requests: Helen Elden, Perinatal Center, Department of Obstetrics and Gynecology. Institute for Clinical Sciences, Sahlgrenska University Hospital/East, University of Gothenburg, SE-416 85 Sweden. Office: +46 31 343 58 99. FAX: +46 31 25 83 74. Mail: helen.elden@vgregion.se