Alternative treatments in reproductive medicine: much ado about nothing

‘The fact that millions of people do not master arithmetic does not prove that two times two is anything else than four’: W.F.Hermans

C.N.M.Renckens*

Department of Obstetrics and Gynaecology, Westfries Gasthuis, 1620 AR Hoorn, The Netherlands. E mail: renckens@xs4all.nl

The popularity of alternative medicine certainly also affects patients suffering from infertility. Alternative medicine started in the seventies but there have always been unorthodox practitioners, treating infertile women and men. Some historical examples will be described. The claims made for alternative medicine in the lay press have not been accompanied by similar reports in the mainstream medical journals. Practitioners and advocates of alternative medicine have used several strategies to defend their position. These were mostly of a philosophical nature, but more recently the practitioners of alternative medicine admit that the effectiveness of their therapies should be proven in randomized trials, as is considered mandatory in regular medicine. There are very few well-designed papers on the effectiveness of alternative medicine with the exception of one kind of paper that is hard for editors of medical journals to resist: seemingly impeccable papers proving absurd claims, whose mechanisms of action are, for instance, completely incomprehensible. We argue that this type of paper should be rejected for publication and indeed offer explanations for their mere existence.

Key words: acupuncture/alternative medicine/homeopathy/intercessory prayer/quackery

Introduction

‘Alternative therapy can really help couples desperate to have children’: the headline of a story by Sally Brown in The Guardian of Saturday, August 11, 2001. The reader gets educated about acupuncturists ‘removing blocks to conception’, ‘redressing subtle imbalances’ and—by placing needles along the ‘conception vessel’ meridian—preparing the womb for pregnancy. This treatment is said to result in a pregnancy rate of up to 60% amongst those consulting the quoted London-based acupuncturist. A reflexologist suggested that 13 out of 23 women she treated for infertility became pregnant. With the rather new Bowen-technique (a variant of chiropractice) ‘the endocrine system and the pelvis are addressed’, mostly resulting in pregnancy after two sessions. A hypnotherapist treats women with a subconscious fear of pregnancy.

Unorthodox infertility treatment in a historical perspective

Quacks have long tried to exploit the suffering of childless people. In the 18th century the Briton Dr James Graham (1754–1794) became very famous with his Temples of Health, in which he exclusively treated couples suffering from infertility (Jameson, 1961). In his beautiful Temple of Health, Adelphi, in Pall Mall, London, situated near the royal palace, there stood a bed worth £12 000, the Celestial Bed. The interior of the temple was decorated in an unbelievable way with many mirrors, sculptures, paintings and the newest techniques in the field of illumination. On the outside there was a colossal golden sun and a statue of the goddess Hygieia. Graham gave lectures and treated his customers with earthbaths and also performed ‘electro-therapy’. His lectures emphasized washing the body frequently. He also stated that it is necessary to ‘tune body and mind for the most cordial and perfect enjoyment of prolific life’. He was very much against double beds: ‘There is nothing more unnatural, more indecent, than man and wife continually pigging together in one and the same bed... and to sleep and snore and steam and do everything else indelicate together 365 times every year’. He advocated fresh air and was strongly opposed to masturbation and fornication. Prostitutes ‘destroyed the vigour of the genital parts, necessity tempting them to too frequent acts of venery’. In his temple the very beautiful and young Hebe Vestina, goddess of Youth and Health, assisted him. Couples desirous of progeny were allowed to sleep together in the Celestial or Magnetico-electrico bed, amidst a wide variety of colours, odoriferous and balmy spices, under a dome on which Cupid and Psyche were depicted and where an electrically lit commandment ordered: ‘be fruitful, multiply and replenish the earth’. The couples had to pay £100, but many a nobleman was said to have paid £500 to let Graham draw the curtains for a night in the bed. His customers could expect ‘superior ecstasy’ and ‘immediate conception,'
accompanied by soft music’. The successful period for Graham was from 1779–1784, after which his business went downhill. Horace Walpole is said to have regarded it as ‘the most impudent puppet show of imposition he ever saw’. Graham lost all of his properties and had to move back to near Glasgow where he died in 1794 as a poor man.

We skip a century and cross the ocean to meet a staunch lady, called Lydia Pinkham (Young, 1992). The 19th century also produced a famous person, active in the same field, but ending her life more happily than Graham did. Lydia Estes, born in Boston (USA) in 1817, would become very famous under her name as a married woman: Lydia Pinkham. She invented the famous Vegetable Compound, which made her the first female millionaire of the USA and the first woman to achieve enormous marketing success. Professionally trained as a teacher, she had liberal opinions from a young age and was a free-thinker, opposed to discrimination of blacks, in favour of women’s rights and their right to vote. She once proposed that priests who were in favour of the capital punishment should perform the killing themselves. Her husband was an unsuccessful broker and the family suffered financial hardship. Lydia had two hobbies: an interest in medicinal herbs and a strong aversion against the gynaecologists of her day. In her own family she used herbal mixtures, described in John King’s American Dispensary. In 1873 she decided to bring her favourite household brew to the market and she called it Pinkham’s Vegetable Compound. It was said to contain ‘unicorn root, pleurisy root, life-root, black cohosh and fenugreek seed’. It was recommended for female illnesses and became very popular after an intelligent advertising campaign in which the friendly grandmotherly face of Lydia played a key role. She wrote a book A Guide to Women, in which doctors were not very much praised. She also gave written advice to women asking her for help. The sales of her firm rose to $30 000 per month in 1881. The main indications for use of the compound were infertility, genital prolapse and urinary problems. The texts of her advertisements became very popular, as this one: ‘Elsie W. had no children, There was nothing in her blouse, So she took some Vegetable Compound. Now they milk her with the cows.’

Pinkham’s claims came under the scrutiny of the Food and Drugs Act in 1906 and strict limitations were imposed on the allowed claims. In 1930 the words on the bottles with the nostrum only mentioned that it was ‘In use over 50 years’. Lydia died in 1883, a fact that was kept secret from the public during the long time during which the letters of her fans continued to be answered by ‘10-dollar-a-week-typists’, as had been the case during her life. A journalist discovered her tomb in 1903 and published its photograph, causing a riot amongst her followers and fans. In the later years her sons tried to continue the business and started to promote the Compound as also being suitable for men with urinary complaints. This was, as one of them wrote, because in New York ‘About half of the people here are troubled with kidney complaints or think they are’.

People thinking that the considerable progress made by the medical science should have nearly eradicated the consumption of unorthodox treatment modalities at the end of the 20th century are grossly wrong. Not only do the extravagant claims in The Guardian of this summer point in that direction, but the periodical of the Dutch Patient Union for Fertility Problems—‘Freya’—which in March 1996 was exclusively devoted to alternative treatments, signalled a lot of interest in homeopathy, acupuncture, paranormal therapy, naturopathy, astrology (‘Cosmobiological fertility-regulation’) and orthodox medicine. I am not aware of any published figures on the percentage of fertility patients using alternative therapies, but it is not unreasonable to suppose that it will be substantially higher than that of the general population of which in Holland (CBS-gezondheidsenquete, 2001) and Israel (Bernstein et al., 1996) 6% visits an alternative practitioner. These percentages are usually higher in countries where chiropractors are active, as in Australia and the USA, where these figures amount to around 20% (Eisenberg et al., 1993; MacLennon et al., 1996). More women than men consult alternative practitioners, particularly so when having a chronic problem which is not always easily treated and/or explained by mainstream medicine, so we can assume that a substantial proportion of infertile women do visit alternative practitioners.

The debate about the evidence

It is a frequently quoted figure that <20% of standard Western medicine is evidence-based (Heptonstall, 1999). Why do we dare to demand sufficient scientific evidence from alternative practitioners, as we do not have it ourselves in our daily practice? This logical fallacy tu quoque (‘you did it too’) has already by itself no merit, because one can of course rightfully accuse someone of a fault that oneself makes as well. But, more relevantly, the figure is completely wrong and actually about 76% is evidence based, as recently and elegantly described (Imrie and Ramey, 2001), in a study that revealed the figure of 15–20% (see above) stems from an informal evaluation of drug prescription amongst 19 GPs’ in 1963(!) and has been endlessly repeated parrot-wise since then.

Although we can rightfully consider the above mentioned alternative therapies as useless and insufficiently based on serious research, we cannot but admit that in mainstream reproductive medicine, in the not too distant past, quite a few treatments have been given without any evidence: antefixation-operations, male infertility treated with hormones, anti-estrogens and vitamins, operative treatment of ‘subclinical’ varicoceles, endocrine therapy of endometriosis, high dose steroids for male auto-immune infertility and ‘condom-therapy, combined with timed intercourse’ for women with antisperm antibodies. Thus it is not unlikely that in the sixties the 15–20% was close to the real figure for treatment of infertile couples. Notwithstanding this sobering fact, there still remains a world of difference between the best available regular therapies at a certain time (at least based on plausible hypotheses and coherent with pathophysiological knowledge of the human body) and the alternative’s absurdities such as acupuncture (based on anatomical nonsense), homeopathy (based on the statement that ‘like cures like’ and the supposed transsubstantiation of inert substances by shaking and diluting them endlessly) and vulgar psychosomatic thinking. But strong
evidence of effectiveness for the regular therapies was frequently lacking, as we must retrospectively admit. At present, however, the situation is quite different and with induction of ovulation, artificial insemination by donors, tubal surgery in selected cases and more recently the assisted reproductive technologies, our speciality certainly seems to fit nicely in the 76% ‘evidence based’ as calculated by Imrie and Ramey for contemporary clinical practice in general.

Arguments used to defend alternative therapies

For a long period of time, and sometimes even now, alternative practitioners have held the opinion that the super-individually adjusted approach of their patients precluded the possibility of randomized trials. This argument is, in these days of evidence-based medicine, no longer acceptable and for instance the Dutch Health Council Committee on Alternative Medicine and Scientific Research concluded that research into the effectiveness of alternative treatments is possible, as long as one is prepared to put the underlying hypotheses in a black box and just limit the exercise to properly defined patient selection and objectively checked endpoints (Health Council, 1993). The more enlightened pro-alternative authors now agree with this conclusion (Lewith et al., 2000, for example). Another trick to withstand the threatening demand of randomized trials and proper research has been the misuse of philosophers and sociologists of science. Kuhn introduced the term paradigm, being an ill-defined notion referring to a common set of presuppositions and methods on which a certain type of scientist implicitly agreed (Kuhn, 1962). Conclusions and findings of research based on another or a new paradigm were not commensurable with those from the other and could ergo not be criticised by them. Alternative practitioners said that their therapies were based on a different paradigm than orthodox medicine. Sociologists of constructivist/relativist direction state that science is a more or less incidental activity, strongly influenced by the prevailing sociocultural surrounding: ‘The point is that neither logic nor mathematics escapes the contamination of the social’, as Aronowitz put it in his Science as Power (quoted by Gross and Levitt, 1998). This way of thinking, promoted in many variations by influential authors as Feyerabend, Foucault, Derrida and Latour has had a strong impact on many American universities. It seriously undermined the scientific rigour, especially in the humanities, a problem that has been the subject of a recommendable book, Higher Superstition (Gross and Levitt, 1998). There are many examples of alternative practitioners that have used this kind of sociology of science to immunise themselves against their critics.

When alternative doctors were confronted with their lack of scientific data they not infrequently used to say that they were either too busy with their practice, that they were discriminated against by universities and funding institutions or that they were lacking sufficient knowledge of scientific research. These arguments have at present lost much of their impact, as the increasing popularity of alternative medicine has stimulated parliamentarians in several countries to choose the democratic position of ‘equal rights for all therapies’. This populist approach has led to much money now being available for studies that, by serious university-based scientists, would never be considered worthwhile. Germany has its wealthy Münchener Modell and in the USA the budget of the NIH-related National Council for Complementary and Alternative Medicine (NCCAM) is at present 20 million dollars.

Data used to defend alternative medicine

So let us now leave philosophical and sociological arguments for the time being where they are and look at published data on alternative medicine in reproductive medicine. As could be expected the number of properly conducted trials with clinically relevant outcomes is surprisingly small. A PubMed-scan, searching for ‘herbs, supplements, acupuncture, naturopathy, homeopathy, chiropractice, anthroposophical medicine, manipulative treatments and paranormal therapy’, combined with infertility and/or gynaecology revealed many reviews in journals for nurses and midwives (Beal, 1998, 2000; Veal, 1998), many papers of moderate methodological quality in alternative journals and very few in peer-reviewed journals of good standing.

The first category gives some interesting figures on the types of alternative medicine in reproductive medicine and their popularity amongst the public, and offers some insight into the worrying popularity of alternative medicine amongst nurses and midwives, as quoted by Watson (1996), stating that there is ‘a natural fit between nursing’s care and healing approach, and the integration of complementary and alternative models of science’ (Watson, 1996).

The second category uniformly reports favourable outcomes for Chinese herbs (Chen and Wen, 1995), acupuncture (Zheng, 1997), homeopathy (Bergmann et al., 2000), nutritional therapy (Sinclair, 2000) and electroacupuncture (Chen, 1997), but these conclusions are not drawn from randomized clinical trial of normal quality.

The third category of papers gives a more mixed picture: negative results are reported of DHA-supplementation in subfertile males (Conquer et al., 2000) and another paper on herbs used in our speciality concludes that no remedies can be recommended because of a ‘surprising lack of adequate clinical trials’ (Pinn, 2001). Slightly more positive are two papers on acupuncture treatment of extreme oligozoospermia. These papers, published by the Institute of Chinese Medicine in Tel Aviv, conclude that acupuncture ‘may be useful’ in these patients (Siterman et al., 1997, 2000). A paper from Scotland reported improvement of some sperm parameters after supplementation with selenium and the vitamins A, C and E in a group of infertile men with a low selenium status (Scott et al., 1996). One paper reported a possible explanation for the supposed positive effects of the Chinese herb Hochu-ekki-to on unexplained male infertility (Amano et al., 1996). In Human Reproduction we found two papers, both from Gothenburg, on electroacupuncture (EA). In 1996 a report claimed to have found a positive effect of eight treatments of EA over 4 weeks on the blood flow of the uterine arteries in GnRHa down-regulated women (Stener-Victorin et al., 1996). There has been no serious follow up of this result. The same Swedish group reported that EA as anaesthesia during...
oocyte aspiration compared favourably with alfentanil (Stener-Victorin et al., 1999). This effect can be explained as a result of simple counter irritation (Mendelson, 1977), reinforced by the strong placebo effect of exotic and ‘new’ therapies in general. One wonders if this way of killing the pain of oocyte retrieval still persists in Gothenburg.

So far, so good. Until this moment conventional doctors do not have much to worry about: the onus probandi (burden of proof) lies with the practitioners of alternative medicine and the available evidence does not present much reason to feel that someone neglecting alternative medicine is withholding potentially useful ways of treatment from his patients. Nor is there any reason to fear that the widely accepted biomedical model of our speciality is under serious threat. But this comfortable position is not completely unchallenged. The strongest attack arises when incomprehensible absurdities of alternative medicine are proven in impeccable trials. This has actually happened before in general medicine and very recently also in the field of reproductive medicine. Submission of this type of paper poses a most serious testing of the intellectual stature of the editors of our medical journals. This problem of—as I will call them—‘seemingly impeccable papers proving absurd claims’ arose for the first time when a Scottish homeopath reported favourable results of extremely diluted (and for that matter far under the Avogadro-threshold of molecular presence) pollen (‘C 30’) in patients with hayfever. Its publication in The Lancet (Reilly et al., 1986) prompted Petr Skrabanek to his ‘Demarcation of the absurd’, (Skrabanek, 1986) later on enlarged and published under the title ‘Scepticism, irrationalism and pseudoscience’ (Skrabanek, 2000). He argued in these classical and very erudite papers that complete ‘open-mindedness’ and the readiness to examine even absurd claims is to be called ‘irrational scepticism’ and results from the inability to accept the existence of the absurd: one’s mind stays so open that the brains fall out! Rational scepticism, as he calls his philosophy, combines a dogmatic refusal to accept absurdities and a tentative belief in facts. He quotes Hume, who stated that ‘it is the business of history to distinguish between the miraculous and the marvellous; to reject the first ... and to doubt the second’. Skrabanek closes with remarking: ‘The worst that can happen by following this pragmatic strategy of rational scepticism is that the baby of truth will be thrown out with the absurd bathwater’. This analogy, however, is grossly misleading. First, the ‘bath’ is not a bath but a vast ocean of nonsense. Second, it is not one imaginary Gargantuan baby we should worry about but rather the fate of thousands upon thousands of our fellow-men, who, swallowing gallons of water and blindly thrashing in this absurd ocean, are near drowning.

In spite of Skrabaneks passionate plea against taking absurd claims seriously, several ‘seemingly impeccable papers proving absurd claims’ have been accepted by respected scientific journals: the homeopathic treatment of hay fever in The Lancet (Reilly et al., 1986); biological effects in vitro of sub-Avogadro diluted homeopathic serum in Nature (Davenas et al., 1988); favourable effects of prayer on coronary care patients in South Med. J. (Byrd, 1988); favourable conclusions for homeopathy after meta-analysis of controlled trials in The Lancet (Linde et al., 1997); and moxibustion/acupuncture helping to correct breech presentations in JAMA (Cardini and Weixin, 1998). Apparently this type of publication is not always rejected by the editors of mainstream scientific journals. Several factors seem to be involved in the production of this kind of paper. The least one can say of these ‘seemingly impeccable papers proving absurd claims’ is that the published results usually are not confirmed in independent repetition of the experiment (Reilly et al., 1986) and are sometimes clearly contradicted by repetition by other researchers. The results by Harris et al. (1999) could not confirm Byrd, although Harris himself discovered a minute positive effect (Harris et al., 1999) and those of Davenas et al. (1988) were contradicted by Ovelgonne et al. (1992) (Davenas et al., 1988; Ovelgonne et al., 1992). Discovery of clear-cut fraud as reported by Benveniste’s group (Davenas et al., 1988) gave rise to much publicity (Maddox et al., 1988). The paper by Linde et al. (1997) originated from a richly funded alternative centre: the Münchener Modell-Center for Complementary Medicine Research in München, Germany (Linde et al., 1997). It was strongly criticised by Vandenbroucke in The Lancet itself (Vandenbroucke, 1997). He mentioned the fact that randomized trials with external funding (Davidson, 1986) were more likely to produce positive outcomes. In Linde’s meta-analysis he presumed the role of small distortions, small mistakes, exclusions, subgroup-analyses and accepted the authors emphasis that publication bias was unlikely. He did not mention the possibility of fraud. I would also like to point to a handicap of many meta-analysts, namely their lack of familiarity with the clinical issue and therefore running the risk that statistical precision prevails above clinical validity. For example: when two placebos are compared in 100 randomized trials, in five of those trials a P < 0.05 will be reached by accident. In these days of EBM the clinical epidemiologist is held in high esteem and one does not need to agree with the famous Rutherford quote (‘If your experiment needs statistics to make a conclusion you must have done a better experiment than in cases where statistical analysis was superfluous’) in order to see that sometimes statistical analysis leads to incomprehensible or even absurd conclusions. In those cases there is only one choice left: reject the outcome or sacrifice the present physicochemical paradigm of medical science.

Very recently a ‘seemingly impeccable paper proving absurd claims’ was published in a serious and (hitherto?) respected journal in the field of reproductive medicine: Does prayer influence the success of in vitro fertilization-embryo transfer? (Cha et al., 2001) In a well-designed trial they demonstrated a statistically significant positive effect of intercessory prayer on the outcome of in-vitro fertilization-embryo transfer. In the ‘prayer-group’ 50% of the patients became pregnant and in the control group 26%. The groups were reasonably comparable, although there was a tendency towards younger patients in the prayer group and there was a substantial number of patients excluded for unclear reasons. This paper, that drew a lot of attention in the lay press, was written by the chairman of the Cha Hospital in Seoul, Dr Cha, by an attorney with a diploma in parapsychology, Dr Wirth (whose firm Wirth and Wirth Esq. could not be traced by journalists in Pennsylvania) and
Dr Lobo, a professor in obstetrics who is an expert on matters of the menopause. Dr Cha calls himself an ‘associate research scientist’ and was the first president of the Korean Pochon Cha University, the first in Korea to incorporate alternative medicine in the curriculum. He organised a big symposium on alternative medicine in 1999. His hospital, that also accommodates an IVF centre, financed the trial. Daniel P.Wirth is neither theologian nor IVF specialist. He earlier published papers on Therapeutic Touch, qigongtherapy and spiritual healing. In 1993 he wrote ‘The effect of noncontact therapeutic touch on the healing rate of full thickness dermal wounds’ in Subtle Energies, vol. 1, no. 1, pp. 1–20. When the philosopher Dale Beyerstein tried to learn more about the design of that trial he first experienced many difficulties in locating Wirth and afterwards was threatened by Wirth with legal steps if he insisted in his endeavour to challenge Wirth’s data. The New Yorker Dr Lobo stated to be very surprised by the findings himself but refers further questions to Wirth. Fraud is difficult to extract from an apparently impeccable paper, but everyone is invited to draw one’s own conclusions about the trustworthiness of the authors. We do not believe anything of the story and are very much opposed to publishing this kind of absurdity in serious journals.

Conclusions

Considering the fact that there are still many unresolved problems in reproductive medicine we are quite unhappy to conclude that the contribution of alternative medicine to our field can best be summarized as ‘much ado about nothing’. It is even more regrettable that it is unlikely that praying can mobilize supernatural forces to improve the still not perfect IVF-practice of our days, because more exciting and far-reaching data could otherwise be obtained. What to think of a comparative trial praying to the Christian God, to the Jewish Yahweh, to Allah, to Buddha and to Hare Krishna? Would not mankind be saved from much debate, war and disunity if such a trial produced an equally unequivocal result as was obtained in the trial of Cha and colleagues?

For the the daily practice, we have only one piece of advice: doctors who want to stick to rational medicine and therefore reject alternative medicine, can best commence—if they want to ‘combine the best of two worlds’ and impress their patients—with imitating the British general practitioner Liam Farrell. He wrote in the British Medical Journal debate on ‘integrated medicine’: ‘I am a strong believer in integrated medicine. After every consultation I give my patients a teddy bear to cuddle and play them a tune on the banjo.’ (Farrell, 2001).

References


Alternative treatments in reproductive medicine


